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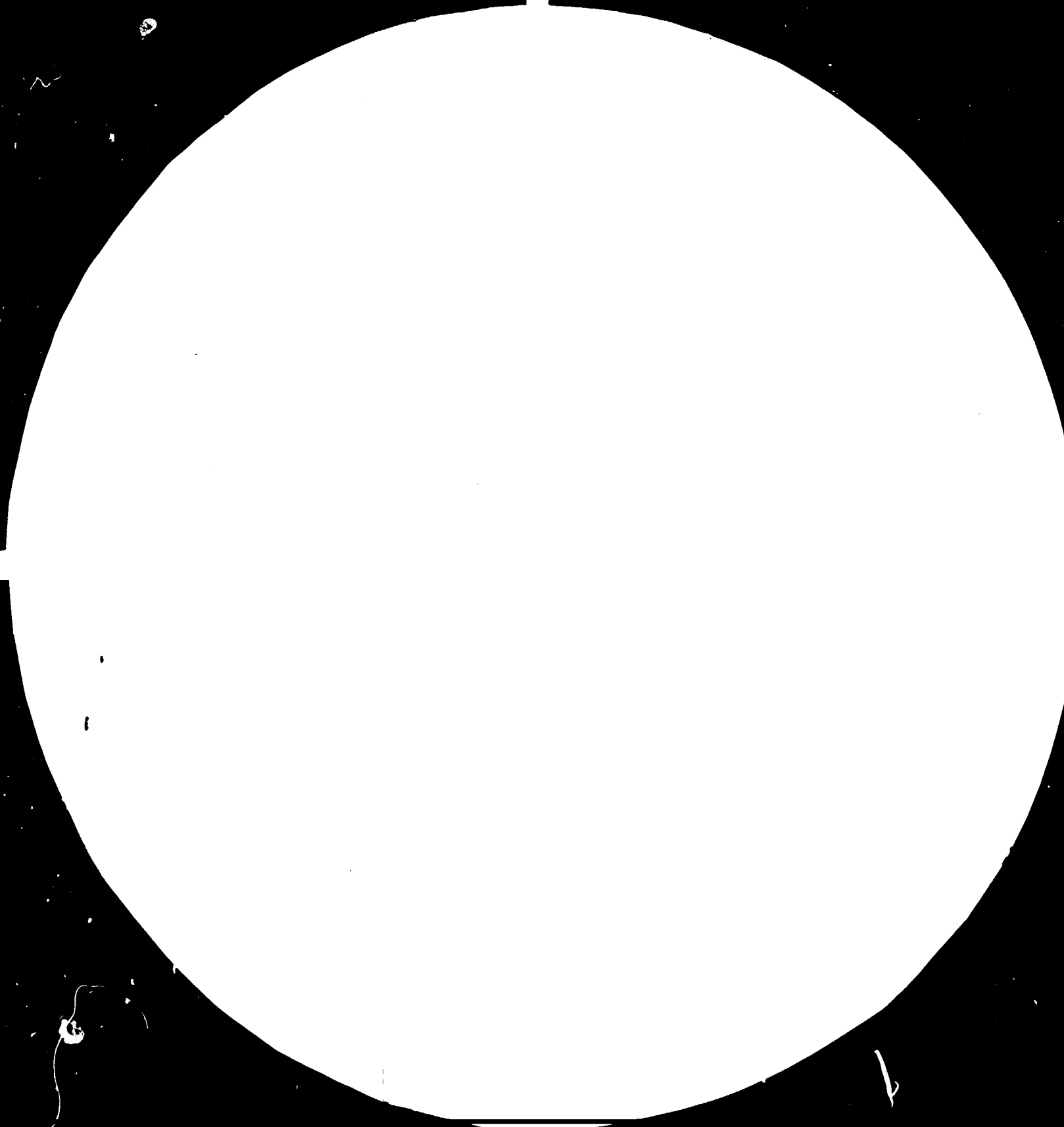
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Pharmaceutical Industry

Budapest, Hungary, 21-25 November 1983

ITEMS WHICH COULD BE INCLUDED IN CONTRACTUAL
ARRANGEMENTS FOR THE SETTING UP OF A PLANT FOR
THE PRODUCTION OF BULK DRUGS (OR INTERMEDIATES)
INCLUDED IN UNIDO ILLUSTRATIVE LIST**

Prepared by
the UNIDO secretariat

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FOREWORD

This document is the final version recommended as a result of a review by the Ad-hoc Panel of Experts ^{*/} in their advice to the UNIDO Secretariat in accordance with the recommendations of the Second Consultation on the Pharmaceutical Industry (21-25 November 1983, Budapest, Hungary). This Third Meeting of the Ad-hoc Panel was held in Vienna, 22-24 April 1985, and following experts participated in it:

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^{*/} The Second Meeting of the Ad-hoc Panel was convened in Vienna 25-29 April 1983 and discussed the draft of this document before it was presented to the Second Consultation meeting. The Ad-hoc Panel consisted of the following experts:

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Preface

In accordance with the recommendation No. 2 of the First Consultation on the Pharmaceutical Industry held in Lisbon (December 1980), UNIDO has been requested to prepare documents on the various contractual conditions, and variations thereof including background notes, related to contractual arrangements for the transfer of technology in the pharmaceutical industry.

The Morocco Round Table on the Pharmaceutical Industry (December 1981) recommended to concentrate, in the first stage of work, on licensing agreements for the manufacture of bulk drugs and intermediates.

This document has been prepared in line with the recommendations referred to. It is intended to provide guidance for the negotiation and drafting of engineering contracts for setting up a plant for the production of bulk drugs and/or intermediates or for the addition or adaptation of a plant in operation when new products or new technologies are introduced. In this context, contract means an agreement freely entered into by parties in accordance with the specific circumstances of each case and the applicable national laws and regulations.

As conceived, this document assumes the following division of responsibilities:

- a) The Licensor is responsible for the provision of basic design and process know-how, and for process commissioning, in accordance with the terms and conditions for license agreements laid down in Unido document ID/WG.393/1.
- b) The Contractor has overall responsibility for the physical installation of the plant, including in particular:
 - provision of detailed engineering;
 - assistance in procurement of equipment;
 - supervision of construction;
 - mechanical commissioning;
 - accountability for sub-contractors
- c) The Purchaser is responsible for the management and overall coordination of the work and also undertakes:
 - purchasing and storage functions;
 - site services;
 - civil works;
 - accountability for subcontractors;

- d) The Vendors supply and warrant the specified equipment.
- e) The Subcontractors are accountable to the Contractor or the Purchaser, depending upon the party that appoints them;
- f) The Consultant Engineer appointed by the Purchaser, advises the latter and reviews all the work on his behalf, particularly as regards to detailed engineering procurement of equipment and supervision of construction.

Since the work is divided among various parties, a close coordination assumes utmost importance. This type of contract requires a full involvement of the purchaser in the work, and places several important obligations on him, the due compliance of which is essential for the efficient and timely implementation of the project. The involvement of purchaser's personnel during the construction and erection ensures their familiarity with the plant being established and facilitates the creation of skills for its later operation and maintenance.

Purpose, scope and content of this document

This document includes items which could be incorporated in contractual arrangements, while negotiating transfer of technology for the construction of a plant for the manufacture of those bulk drugs and intermediates included in the UNIDO illustrative list. It is primarily addressed to parties negotiating such arrangements, and in particular to enterprises in developing countries which are able and willing to increase the range of bulk drugs (or intermediates) locally produced.

In the preparation of this document a number of general principles have been taken into account, as described in previous UNIDO documents, and recommended at the Morocco Meeting.^{*/}

(a) The transfer of technology should contribute to the identification and solution of economic and social problems related to the production and use of pharmaceuticals in developing countries, with an aim at substantially improving, at adequate costs and quality, the availability of essential drugs in developing countries;

^{*/} See in particular "Background paper for discussion on the relevant issues to be taken into account when negotiating transfer of technology agreements and the various terms, conditions and variations thereof that could be included in contractual agreements: possible scope, structure and content", PC.19.17 Oct.1981.

(b) The parties to a transfer of technology agreement should be responsive to the health, drug, industrial and other relevant policies of the receiving country, including import substitution, development of technical skills, promotion of local innovations, etc.;

(c) Licensing agreements should contain fair and reasonable terms and conditions to both parties, including payments, and be no less favourable for the recipient than the terms and conditions usually applied by the supplier or other reliable sources for similar technologies under similar circumstances;

(d) The agreement should, in particular:

- (i) Ensure the absorption of technology transferred by local personnel;
- (ii) Allow the use, as far as possible, of locally available materials and services;
- (iii) Facilitate and, in any case, do not restrict the adaptation and further development of technology received;
- (iv) Include adequate guarantees for the performance of the parties' obligations;
- (v) Provide full information on the characteristics of the technology and drugs to be manufactured, especially in respect of possible hazards and side effects;
- (vi) Not contain unjustified restraint on the recipient's use of the technology.

The document deals with the main items to be negotiated when concluding agreements of the type referred to. When appropriate, it includes:

- (i) Elements to be taken into account in the negotiation and drafting of the clauses;
- (ii) Technical aspects, and particularly difficulties that may be faced at the negotiating phase and implementation of the agreement;
- (iii) Concrete examples, wherever possible, relating to fermentation, synthesis and extraction processes;
- (iv) Recommendations as how to deal with the particular issues;
- (v) Possible clauses and variations thereof.

It should be noted here that the illustrative clauses provided in this document are presented as examples that could be used to achieve transfer of technology. These clauses should not be construed as being exhaustive or covering all possible situations that can arise in transfer of technology.

The alternatives included are those deemed more important or appropriate in view of the principles and objectives that preside the document's preparation. The importance and appropriateness of possible solutions have been assessed on the basis of four main criteria:

- (i) The likely acceptability of proposed solutions for both contracting parties;
- (ii) The compatibility of proposed solutions with existing regulations and positions on the matter, as described - for a number of issues - in an earlier UNIDO document ^{*/};
- (iii) The practices which are generally accepted in international licensing and trade, particularly in developing countries;
- (iv) The recommendations and suggestions of available clauses, contracts, or guidelines, as listed in document UNIDO/PC.19, Annex I. ^{**/}

Since the recommendations made in this document are addressed to parties located in any country, the formulations proposed here are not referred to any particular national legislation. This does not mean, however, to support the idea of a contract "without law", i.e. which is self-sufficient for solving all aspects of the relationship between the parties.

Obviously, national approaches and solutions to a number of aspects considered, vary considerably between the common law and the continental law systems, or even from country to country. To the extent possible, the document attempts to suggest formulations which conform to the general principles referred to above, and at the same time, are compatible with the main current regulation trends at the international and national level, particularly in developing countries.

^{*/} See "Preparation of Guidelines. Background paper", ID/WG.331/3, 23 September, 1980.

^{**/} This document is under revision.

1. Recitals

The inclusion of recitals or a preamble in transfer of technology agreements has become a quite common practice, even in cases where the applicable law does not confer such statements a particular juridical effect.

Recitals usually contain references to the business background of the parties, their desire in connection with the agreement and a statement as to the source of know-how to be used. In case of divergency between the recitals and the substantive provisions of the contract, the latter prevail.

Illustrative clauses */

1. Recitals

This Contract, made and entered into this day ofby and between:.....a corporation organized and existing under the laws of.....having its head office at..... (hereinafter referred to as "the Contractor"), and..... a corporation organized and existing under the laws of..... having its head office at.....(hereinafter referred to as "the Purchaser").

WITNESSETH

1. Whereas the Contractor has experience in the construction of plants for the production of drugs (intermediates).
2. Whereas the Purchaser desires to establish a Plant for the production of.....(the Products) in.....(country).**/
3. Whereas the Contractor acknowledges that the Purchaser has executed a process licensing agreement with.....for the production of.....(the Products), and that the engineering work to be carried out by the Contract must be executed in the context of said agreement.

NOW, THEREFORE, the parties hereto agree as follows:

*/ See page 5, para. 1

**/ For an example of a plant to be established from the gross root level, see Annex I.

2. Definitions

For purposes of clarity and avoidance of repetition, the agreement may contain a provision defining some of the main terms and expression employed in various clauses, such as "Purchaser", ^{*/} "Contractor", "Contract", "Civil works", etc.

^{*/} The "Purchaser" is the same person or firm named as "Licensee" in document ID/WG.385/1/Rev.1.

Illustrative clauses */

2. Definitions

The following expressions will have in this agreement the meaning assigned in this article.

1. "Purchaser" shall mean the party named as such in this Contract or his successors or permitted assigns.
2. "Contractor" shall mean the party named as such in this Contract or his successors or permitted assigns.
3. "Contract" shall mean this Contract (together with the Annexes) entered into between the Purchaser and the Contractor for the execution of the work howsoever made, together with all of the documents to which reference has been made in the Contract documents, including such amendments and/or changes (properly made from time to time by mutual agreement between the parties) to the documents constituting this Contract.
4. "Civil Works" shall mean all the buildings, roads, foundations, structures, and any other work requiring civil and public health engineering.
5. "Effective Date of the Contract" shall mean the date on which the Contract comes into force in accordance with Article 22.
6. "Equipment" shall mean the equipment, machinery, instruments, commissioning equipment and spares, and other major items required for incorporation in the Plant as specified in Annex..... and in respect of which the Contractor has provided procurement services.
7. "Plant" shall mean a plant for the production of.....(drugs or intermediates), to be constructed at.....and in respect of which the Contractor's services are provided.
8. "Products" shall mean.....(drugs or intermediates).
9. "Vendor" shall mean the person or persons from whom the supply of any equipment is obtained by the Purchaser.
10. "Raw materials" shall mean the materials necessary for the production of the Products.
11. "Site" shall mean the land upon which the Plant is to be constructed as specified in Annex.....

*/ See p. 5 para. 1

12. "Battery limits" shall be defined to mean the overall limits which include the facilities embodying the Plant as detailed in Annex */
13. "Mechanical Completion" shall mean the time when the physical construction and erection of the Plant has been completed, and a first batch of the product has been successfully produced at the Plant.
14. "Licensor" shall mean the party named as such in the licensing agreement entered into by the Purchaser and the Licensor on
15. "Sub-contractor" shall mean the person or firm to whom any part of the work or services or the execution of any part of the Contract is subcontracted.
16. "Consultant Engineer" shall mean the person(s) or firm(s) appointed by the Purchaser to review all work on the Purchaser's behalf and give such advice and instructions as may be necessary for the purpose of this Contract.
17. "Project Manager" shall mean the person appointed by the Purchaser and the Contractor with authority for the co-ordination and monitoring of the work on behalf of the Purchaser and Contractor, respectively.
18. "Valid" for the purposes of article... ("Effective date of Contract") shall mean the legal status of the Contract after its formal execution (signing).

*/ See Annex V

3. Division of work and responsibilities

The scope of the type of contract dealt with in this document, and the consequent distribution of responsibilities among the various parties involved may follow a wide variety of patterns, according, inter alia, to the Purchaser's experience and the design and engineering capabilities locally available.

In countries having little experience in the field, the Contractor may take the full responsibility of detailed engineering, procurement, construction, erection and commissioning. In such cases, the Purchaser would normally appoint consultants to monitor the project implementation.

Whenever in the Purchaser's country there is some experience in the chemical industry, and a certain degree of design and engineering capability is also available, the management, procurement and co-ordination functions are normally assumed by the Purchaser, while civil, mechanical and electrical works are carried out by the Sub-contractors. The detailed engineering, supervision of construction, erection and commissioning are performed by the Contractor. This document, and particularly the illustrative clauses contained therein has been prepared taking a situation as the one described in this paragraph into account.

In cases where the Purchaser already operates a chemical unit, in addition to the responsibilities mentioned above, he may take over part of the Contractor's and Sub-contractors' tasks, depending upon the capabilities and manpower available to him.

A plant for bulk drugs and/or intermediates is, in general, planned to manufacture a number of products, for which process know-how and basic design may be supplied by different licensors. The yields of the processes depend upon the types of reactors and, in some cases, upon the types of stirrers used. Even a single drug production scheme may involve large numbers of unit processes and operations, and each individual process reactor requires a complex piping net work consisting of pipes for liquid raw materials, utilities, solvents, effluents and pipes for the product outlets. Acidic, alkaline and neutral effluents, floor washing, sewage and return water are transported through underground piping network. Due to the corrosive nature of many

chemicals, a special type of flooring and painting on walls and pipes are needed. Further, the hazardous and explosive nature of many chemicals, requires special techniques for handling and storage. To avoid pollution problems, outlet gases and effluents call for special treatments too.

All the factors mentioned ask for an integrated approach and, hence, the Contractor working in this industry should cover all engineering disciplines, including chemical, civil, mechanical and electrical.

It is also customary that the representatives of the Contractor and the Purchaser visit and study the Licensor's production unit before commencing the design work. It is advisable that the services of a senior expert of the Licensor be available from the initial stages, for consultation and guidance. */

The Purchaser should, when negotiating this type of agreement, have a full appreciation of its own capability to undertake different functions and manage the project, and evaluate the cost implications emerging from the attribution of additional tasks to the Contractor.

It is of crucial importance for the efficient implementation of the project that the responsibilities of both parties be clearly assigned in the Contract. This will avoid delays and complicated disputes. There might be cases where during the execution of the Contract, it becomes necessary to undertake a work which has not been specifically provided for therein. A provision may be included to cover this hypothesis, stipulating that such a work would be incorporated in the Contract against payment, if appropriate, in accordance with the provisions relating to remuneration.

*/ For the Licensor's obligations, see document ID/WG. 393/1.

Illustrative clauses */

Division of work and responsibilities

3.1 In accordance with the terms and conditions provided for in this Contract, the division of work and responsibility shall be as follows:

3.1.1. The Purchaser shall be responsible for:

- a) The establishment of the design basis of the Plant. **/ The Contractor shall however review such design and suggest all changes the Contractor will deem appropriate. If such changes are approved by the Purchaser and entail modifications as to the terms agreed upon in this Contract, the parties will modify the Contract in accordance with Article 11;
- b) Procurement, transportation, receipt, storage and security of the equipment at Site;
- c) Obtaining and developing the Site, including, construction of roads, transport and communication facilities, zoning and other permits;
- d) Testing the soil characteristics;
- e) Construction and erection of works;
- f) Mechanical testing, commissioning and start up of the Plant;
- g) Obtaining the basic engineering for the Plant and all know-how for the production of the Products. ***/
- h) Supply of necessary documentation regarding basic engineering and process know-how received from the Licensor and required by the Contractor for the execution of this Contract.

3.1.2. The Contractor shall be responsible for:

- a) Preparation of the detailed engineering for the Plant;
- b) Supervision of the construction, erection and mechanical completion tests until performance guarantee fulfilment;
- c) Establishment of a list of would-be Vendors of Equipment and Sub-contractors;
- d) Assistance to the Purchaser in pre-qualifying Vendors for Equipment;
- e) Inspection of Equipment during fabrication and providing certificates of inspection;
- f) Inspection and certification of works;
- g) Mechanical commissioning of the plant.

*/ See p. 5, para. 1

**/ See Annex II and III.

***/ Ibidem.

3.2 In the event that any activity or work, of the type necessary for the successful execution of this Contract is not particularly mentioned in the scope of work above or in the specifications, drawings, or any of the Annexes of this Contract, but becomes necessary to ensure the successful operation of the Plant according to the specifications laid down in the Contract and the intent thereof, such activity or work shall also become part of this Contract as if the same had been originally included in the scope of work to be undertaken by each party in such an eventuality. Payments due, if any, will be governed by the provisions of Article 9.

4. Co-ordination of work

One of the main features of the contractual modality considered here is that the Purchaser must undertake a significant task of co-ordination for the execution of the project. Such a co-ordination is essential for the proper and timely execution of the work involved, and therefore is of utmost importance for both parties.

It is advisable to state in the Contract detailed provisions establishing the means to be used for ensuring the co-ordination between the parties. Such means may include:

a) Appointment of a Project Manager

Each party may appoint a "project manager" who would act on behalf of the same in order to monitor and co-ordinate the works.

b) Meetings between the parties

The parties should meet, through their respective project managers or other authorized representatives, as many times as deemed necessary for the execution of the project. The Contract should establish, in this regard, a schedule as well as the possibility of calling extraordinary meetings for that purpose, and the procedures to be followed as regards the agreements reached during discussions.

It may be useful to establish in the Contract a first meeting ("kick-off" meeting) short after the Contract becomes in force, in order to discuss the preliminary and most immediate matters (such as location of the Plant and off-sites, list of Vendors, design criteria ^{*/}). Another "design conference" may be held a few months later; aspects such as detailed in-Plant lay out, complete schedule and other issues may be dealt with in such a meeting.

Further meetings at the site may be useful to consider contingencies that may emerge during the project implementation, to compute and adjust, wherever necessary, payments due to the Contractor, and to revise- eventually expand or contract - the scope of the work agreed upon. In fact, daily inspection and weekly co-ordination meetings among the representatives of the Purchaser, Licensor, Contractor and Sub-contractors is often a routine to review the progress of work and for solving and settling various technical and co-ordination problems.

^{*/} See Annex IV.

c) Contractor's office at the site

In order to ensure a fluid communication between the parties and the proper performance of the Contractor's obligations, the Purchaser should provide appropriate facilities, in order for the Contractor to establish an office at the site.

d) Access by the Purchaser to the Contractor's work

The Purchaser may require access to the Contractor's work for two different reasons:

- (i) to monitor the work being done, and to establish its adequacy in view of the terms and conditions agreed upon. For this purpose, the Contractor should permit the review - by Purchaser's personnel - of work completed.
- (ii) to strengthen the technical capabilities of Purchaser's personnel, by allowing them to be present during the preparation of the detailed engineering of the plant. This is an important element for fostering the development of local skills in the field.

In both cases referred to in the preceding paragraph, the parties should agree on the number of engineers and other conditions related to the Purchaser's access to the Contractor's work. The costs of travel and subsistence will normally be at the Purchaser's charge. The access by the latter should be reasonable in scope and time, so as to avoid unnecessary or detrimental interference with the Contractor's work.

e) Appointment of a consultant engineer

Finally, the Purchaser should be recognized the right (which he may exercise or not) to appoint as his representative, a consulting engineer (or design office). Such an appointment would not alter the relations between the Purchaser, the Contractor and other participants in the Project, but would help the Purchaser to organize and supervise the work. Complex problems of responsibility may, however, arise out between the Purchaser and the consulting engineer, in case defects or omissions are identified in the plant. ^{*/}

^{*/} According with the FIDIC International General Rules for Agreement Between Client and Consulting Engineer and other conditions suggested by national associations of consulting engineers, the consulting engineer would only be responsible for the consequences of their proven mistakes and up to the amount of their fee or an amount reasonably proportionate to it. See also United Nations, Manual on the use of consultants in developing countries, UN sales no. 72-XX-P-10.

Illustrative clauses */

4. Co-ordination of work

4.1. The Purchaser and the Contractor each shall appoint a Project Manager, who shall co-ordinate and monitor the work under this Contract on behalf of the Purchaser and Contractor, respectively, within the scope of the authority entrusted to each of them.

4.2. The Purchaser and the Contractor through their designated representatives will meet periodically according to a pre-determined schedule and when necessary to examine the progress of work and mutually agree to expedite the work and resolve outstanding issues.

4.3. All notices, instructions and decisions on meetings shall be given in writing. Minutes of meetings shall be recorded and circulated for confirmation and necessary action. Minutes of meetings between Contractor's and Purchaser's representatives held at Site, or in the offices of Purchaser or Contractor shall after recording and confirmation have the same effect as notices in writing.

4.4. Whenever any approvals are required from the Purchaser under the provisions of this Contract, such approvals or reasons for withholding such approvals shall be conveyed to the Contractor within () days of receipt, unless otherwise provided in this Contract. If no reply is received from the Purchaser within the period specified, such items submitted for approval shall be deemed to be approved.

4.5. Within.... days from the Effective Date of the Contract a meeting shall be held in between the Contractor and the Purchaser to discuss all matters of common interest, including but not restricted to the finalization of co-ordination procedure, list of Vendors, and design criteria. The matters related to the concept of location of the Plant and Off-Sites within the Site shall be finalized at such a meeting.

4.6. Within.... months from the Effective Date of the Contract, a meeting shall be held at the Purchaser's offices at (town) between the Contractor and the Purchaser to discuss work completed up to that time. The detailed in-Plant layout, design sizes of the Off-Sites, time schedule, project cost and production cost optimization, and other items of common interest shall also be discussed. The Contractor shall take into account in his design any changes suggested by the Purchaser, which are acceptable

*/ See p. 5, para. 1

technically to the Contractor; and the Contractor shall advise the Purchaser of any changes in the contract price and/or time schedule, arising from such changes.

4.7. The Contractor shall open an office at Site, for which an agreed amount of space shall be provided by the Purchaser. This office shall be managed within the jurisdiction of the Project Manager of the Contractor, who shall be responsible for all liaison with the Project Manager of the Purchaser. This office shall be opened in due time for checking the progress of Civil Works and before any of the Equipment arrives at Site. For the purpose of co-ordination, the Contractor's Project Manager at Site shall liaise with Senior Site Representatives of the Purchaser. The Purchaser and Contractor shall agree at the time of the meeting contemplated under Article 4.6, the quantum of services and office personnel which shall be provided by the Purchaser at his cost, for the office of the Contractor at Site.

4.8. The Purchaser shall have the right to review completed work of the Contractor in the Contractor's offices, so as to monitor the progress and status of the work. Such review will be reasonable both in scope and time so as not to unduly interfere with the Contractor's work.

4.9. The Purchaser, if he so desires, shall have the right to assign up to a maximum of engineers to the design offices of the Contractor at (....) to be present during the detailed design of the Plant. The Contractor shall make available all technical documentation, as defined in Annex */ of the detailed design of the Plant to the engineers of the Purchaser. All costs in connection with the travel and stay of his engineers shall be borne by the Purchaser.

4.10. The Purchaser shall have the right to appoint from time to time a consultant engineer as his representative with the specified authority to participate in the meetings referred to above in this Article, and to review all work on the Purchaser's behalf and give such instructions and grant such approvals as may be necessary for the purposes of this Contract.

*/ See Annex VI, page 114

5. Information supplied to the Contractor

In order to carry out his obligations, the Contractor needs to be informed by the Purchaser on all the pertinent aspects relating to the design basis of the Plant, the suitability of the site and the applicable regulations in force.

The lack of timely and sufficient information might be a reason for justifying a later failure to comply with the Contract; the Purchaser should therefore carefully perform his obligation to inform the Contractor. However, it is likely that purchasers in developing countries lack the necessary experience so as to adequately collect and transmit all the information required by the Contractor. It is then advisable to impose on the latter the obligation to review whatever he receives from the Purchaser, and to obtain any other additional data he considers necessary to carry out the work, including from the Licensor.

As mentioned before, in an engineering contract as the one considered in this document, a Licensor supplies the know-how and basic design and engineering. The Contractor should request through the Purchaser all the information from the Licensor pertaining to basic engineering and process know-how required by him to fulfil his obligations. All the corresponding documentation should be passed on to the Contractor, who is bound to undertake his work in the context of Licensor's instructions. The Contractor would be subject to the same confidentiality obligations as agreed upon between the Purchaser and the Licensor. The various documents to be supplied to the Contractor are listed in Annex II, III, IV and V.

The same obligation as regards to confidentiality would also apply in connection with the Consultant Engineer appointed by the Purchaser.

Illustrative clauses*/

5. Information supplied to the Contractor

5.1. The Purchaser shall within following the Effective Date of the Contract, provide the Contractor with information pertaining to the suitability of the Site, the design basis of the Plant and the applicable law, rules and regulations in force in (Purchaser's country) that are available to the Purchaser and pertinent for the execution of the Contract. The Contractor shall review all such information, and obtain such other information as he may consider necessary to carry out his work under the Contract, particularly those bearing on availability of water and power for construction purposes, approach roads, physical condition of Site, uncertainty of weather and ground conditions. It shall be the responsibility of the Contractor in any event to obtain all information required for him to carry out his obligations under the Contract.

5.2. The Purchaser shall, within following the Effective Date of the Contract, make available to the Contractor all basic process and engineering data received by the Purchaser from the Licensor, as necessary for the carrying out by the Contractor of all his obligations under this Contract.

5.3. The Contractor shall be subject to the same confidentiality obligations as the Purchaser had agreed upon under the respective licensing agreement with the Licensor.

5.4. The Contractor shall not use or divulge any technical data or information given by the Purchaser or his representatives, except for the purposes strictly connected with the Contract.

5.5 The Consultant Engineer shall be subject to the same confidentiality obligations as the Purchaser had agreed upon under the respective licensing agreement with the Licensor. **/

5.6 The Consultant Engineer shall not use or divulge any technical data or information given by the Purchaser or his representatives except for the purposes strictly connected with the contract.

*/ See page 5, para. 1

**/ See ID/WG.393/1 - P. 61

6. Detailed engineering

The supply of the detailed engineering of the plant is the main obligation of the Contractor. Provisions on this issue should refer to the scope of the work, the standards to be taken into account for its preparation, and the form, place and time of delivery.

(a) Scope of work

When a new production block has to be designed and constructed, it is necessary to define the battery limits: to facilitate the piping connections of the utilities, solvents etc. indicating information on elevation of the collecting points above and underground. Annex V defines battery limits, utilities and offsite facilities needed in the case of a new plant.

In addition to the production block, the Contractor has to design various utilities facilities. In the case of antibiotic plants - compressed air, its filtration and sterilisation is a very important factor for the success of the fermentation. Air in this case is a raw material, similarly, it may be required to set up a hydrogen gas unit as well as liquid nitrogen facilities. Boiler house for the generation of various types of steam; refrigeration for chilled water, brine, etc. are other utility services which are to be designed and installed. Besides, an effluent treatment and disposal unit including treatment units for various harmful gases let out from the processes are to be designed. In a case where the process know-how

and basic engineering is supplied for different products by different Licensors, the Purchaser shall obligate the Licensors to co-operate with the Contractor in order to enable him to co-ordinate and integrate these data while designing the utilities requirements and setting up the installations.

Based upon the data mentioned above to be supplied by the Purchaser and the Licensor, the Contractor prepares various detail designing documents (see Annex VI). These are required further for the preparation of tender documents for the purchase of equipments as well as for calling bids for civil, mechanical and electrical works, instruments etc. to be executed by subcontractors.

It should also be noted that in the drug industry the processes and operations are different at various stages requiring quite large numbers of chemicals having different properties. A careful study is required for piping layout. As an example, it may be mentioned that any acid pipe should not be located on the top of other pipes in the stockade or near hazardous chemicals. In the event of leakage of acid, other pipes may get damaged, thus escalating the hazard. Secondly, for an antibiotic plant, the compressed air network requires special attention. The pressure drop for the remotest fermenter should be considered during designing. Thirdly, the cost of stockades, pipes insulation and pressure drop should be taken into account for piping engineering.

(b) Standards

The contract should specify the standards the Contractor would be bound to apply for the preparation of the detailed engineering. For instance, it may refer to the latest and best standards known to the Contractor, to the standards in the Purchaser's country, or to both of them.

Additionally, the Contractor should properly take safety rules normal to industry practice and those applicable in the Purchaser's country into account.

(c) Delivery

Provisions should be established as to the language (preferably the Purchaser's country language) and number of copies of the documentation.

The delivery may take place by airway or maritime shipment, or be effected directly to the Purchaser's personnel at a designated place. It should be noted that the choice of the place may have tax implications, according to the legislation in force in some countries.

The time for delivery should be dealt with as a part of the general time schedule (see point 10 below), in view of the timing and requirements of the various steps of the project implementation.

(d) Approvals

It should be recalled that the type of relationship considered in this document supposes the participation of a third party as Licensor, which would supply the know-how and basic engineering for the plant. The work of the Contractor should, hence, be undertaken in the framework and in accordance with the Licensor's specifications and instructions, as transmitted by the Purchaser to the Contractor. In order to ensure such a consistency, the Contract will normally require the Licensor's approval of the detailed engineering prepared by the Contractor. Such an approval should be provided for, in turn, in the agreement entered into between the Licensor and the Purchaser, as a specific obligation of the Licensor.

Illustrative clauses^{*/}

6. Detailed engineering

6.1 The Contractor will undertake the detailed engineering of the Plant, in accordance with the technical information and basic design data laid down by the Licensor, as transmitted to the Contractor by the Purchaser, and according to the latest and best design standards in line with the results of feasibility studies and good engineering practices known to the Contractor at the time of design, and particularly to the standards and codes in force in (Purchaser's country), as laid down in...

The Contractor shall also take into account all safety rules/ regulations normal to industry-practice, and safety regulations prescribed in (Purchaser's country), as stated in

6.2 All the documentation prepared by the Contractor shall be in (language) and shall include but not be limited to the following items:

.....
.....

6.3 (Alternative a: The documentation shall be despatched to the Purchaser by bill on a freight pre-paid basis and the Purchaser shall acknowledge each despatch within days following its receipt.)

(Alternative b: The documentation shall be delivered to the authorized representative of the Purchaser in (country).)

6.4 The documentation shall be supplied in copies.

6.5 The Purchaser shall submit the documentation prepared in pursuance to this Article to the Licensor, for the review and approval of the Licensor in accordance with the licensing agreement entered into with the Purchaser on

^{*/} See page 5, para. 1

7. Supervisory services

An essential part of the agreement, as conceived in this document, is the provision by the Contractor of supervisory services for procurement, construction, erection, pre-commissioning and testing of the plant to be established. The drafting of clauses on this issue generally requires the consideration of the following aspects: */

a) Scope of services

The supervision of construction and erection services will normally cover the following activities:

- (i) To schedule the site work;
- (ii) To inspect the quality of work;
- (iii) To measure and report the progress;
- (iv) To expedite the contract;
- (v) To ensure timely erection of various equipment;
- (vi) To inspect the tests;
- (vii) To check and approve the work performed;
- (viii) To cause sub-contractors to carry out tests, to check mechanical fitness and tightness of the plant. These tests are limited to water tests;
- (ix) To assist in the performance of guarantee trials.

b) Category and qualifications of supervisory personnel

The Contract should establish the category of the personnel to be sent by the Contractor, in accordance with the type of work to be executed.

It is in the interest of both parties to make sure that the personnel deputed to the site is qualified and competent for the tasks assigned. The Contractor should provide the Purchaser a reasonable time before the personnel is sent, with complete information on their qualifications and experience, and the Purchaser should have the right to ask for the replacement of a proposed person when he is not satisfied with the latter during his work.

c) Category and qualifications of personnel carrying out the project

Good engineering practices require that the work-men like welders, electricians, masons, plumbers, sheet-metal workers, instrument mechanics etc. possess proper experience and qualifications to install the plant in the record time and to avoid trouble during mechanical commissioning due to bad workmanship. The Contractor should specify per each technician to be employed, its category along with its qualifications and experience for ensuring the timely and proper completion of the project.

*/ For services relating to procurement, see point 8

c) Number of personnel and duration of services

The Contract should specify per each category of deputed personnel, the number and expected time of stay thereof at the site.

It may be difficult, however, to ascertain with precision the actual length of the period of stay required. For this reason, it is advisable to consider any reference on this point made in the Contract as indicative, and provide for the Purchaser's right to request an extension of the scheduled time or the sending of additional personnel in the stipulated categories. The Contract may also contemplate a periodical review by both parties of the adequacy of the number and scheduled stay of Contractor's personnel.

d) Availability at site

In order to avoid delays, it is crucial to ensure that the Contractor's personnel is available at the site in due time. There should be a clear obligation on the Contractor in this respect.

e) Remuneration

It is customary to remunerate the provision of supervisory services on the basis of a fee calculated for a given period of time (see point 9 below), plus a daily subsistence allowance per each day of stay at the site or away from the personnel's home base. This allowance is generally paid in local currency.

Another modality is that the Purchaser bears all meals, transport and lodging costs of the deputed personnel, as far as they are connected with the execution of the supervisory services provided for.

In addition, the Purchaser will be required to bear the travel costs (normally economy class return air ticket from the home office to the site).

In agreements which are negotiated on a lump sum basis, there may be no specific remuneration for the Contractor's personnel. However, whenever they are deputed for inspection or any other duty outside the site, the Purchaser usually bears travel and daily subsistence expenses, as per schedule of the Contractor's organization.

Illustrative clauses */

7. Supervisory services

7.1 The Contractor shall provide an adequate number of supervisory personnel for erection, pre-commissioning and testing of the Plant.

7.2 For the purposes of the preceding sub-article, the Contractor shall depute to Site the following personnel:

<u>Category</u>	<u>Number</u>	<u>Expected man-months</u>
.....
.....
.....
.....

7.3 The period of stay stated above is indicative and, upon request by the Purchaser, the Contractor shall extend it or provide additional personnel in the required categories. Within months from the Effective Date of the Contract, and thereafter periodically, as may be required, the parties will review the adequacy of the number and period of stay of Contractor's supervisory personnel.

7.4 The Contractor shall ensure that all supervisory personnel are available at Site in due time in order to carry out the work expeditiously and in accordance with the time schedule as agreed upon (Article 10).

7.5 The Contractor's supervisory personnel shall be qualified and competent for the tasks assigned. At least months before any of the Contractor's personnel is sent to Site, the Purchaser shall be informed of his curriculum vitae and the Purchaser shall have the right to satisfy himself of the competence of such a person.

7.6 (Alternative a: The Purchaser shall pay a subsistence allowance of (local currency) per each day of stay of the supervisory personnel in the Purchaser's country).

(Alternative b: The Purchaser will provide the supervisory personnel suitable accommodation, meals, and transport for work free of charge at the Purchaser's country).

*/ See page 5, para.1

The Purchaser shall bear the costs of economic class return air ticket from the home office to the Site.

7.7 While at Site, the Contractor's personnel will comply with all applicable laws, rules and regulations. If any of the Contractor's personnel is guilty of misconduct, the Purchaser shall have the right, after giving reasons thereof to the Contractor in writing to send him back to his home office country, and ask for and obtain an adequate replacement at the Contractor's expense.

7.8 The Purchaser shall provide in good time all permits necessary for the entrance to and stay of the Contractor's personnel in (Purchaser's country).

7.9 The Contractor shall depute his personnel within days of the Purchaser requesting the deputation of any person to Site.

7.10 All supervisory personnel for pre-commissioning and mechanical tests shall be deputed to Site at least before commencement of such operations.

8. Services relating to procurement

The scope of services to be provided by the Contractor in connection with procurement may vary significantly, according to the desire of the parties and the need of the Purchaser to receive assistance in this area.

Like defined before, the procurement is a Purchaser's responsibility and therefore the role of the Contractor in this respect, if any, is limited to various types of assistance, which may comprise of some or all of the following:

a) Provision of a list of would-be-vendors of equipment.

b) Assistance for pre-qualification of vendors, preparation of purchase orders, tender specifications, bid tabulations, technical discussions with vendors, and selection of final suppliers.

c) Approval of fabrication drawings, layout, etc. and inspection and testing of equipment. These services may be important to duly and timely control the manufacture of the equipment, basically in order to: i) verify that it is being manufactured in accordance with the specifications and applicable qualitative and quantitative standards; ii) monitor the compliance with specified terms of delivery, and eventually anticipate delays; iii) obtain the test certificates on the equipment, as required; iv) have the equipment inspected before despatch to the Site.

d) Assistance for repair, replacement and for obtaining remedial action in case of defects.

The Contract should specify which is the material scope of the services to be provided by the Contractor in this area, i.e. which are the pieces of equipment he will be bound to deal with (see point 2 "Definitions", above). The obtainment of the necessary import licenses and permits, if any, normally are part of the Purchaser's obligations.

The enquiries will be normally restricted to a limited number of vendors who are actual manufacturers of repute or their authorized agents. Such enquiries should be, however, as broad-based as possible, keeping in view the process requirements, reputation and standing of the vendor in the specific field.

If the final selection of vendors lies with the Purchaser, there may be differences between the parties as to the convenience of choosing or not a given offer. To the extent that the choice may influence the work and responsibilities of the Contractor, he may request that, if a selection not acceptable to him is made, the proper modifications of his obligations should be introduced.*/ Of course, this would only be appropriate to the extent that it is justified by technical reasons.

It should be noted that in the case of services like liquid nitrogen, inert gas or hydrogen, boiler house, refrigeration, and air-conditioning many suppliers of the major components often prefer to erect the facilities themselves, according to the design, and undertake the performance guarantee tests at Site.

The Contractor should assist the Purchaser to take care to include sufficient spare parts for all the equipment and machinery, in order to have trouble free service for two years, as well as regards to handling, storage and security of such equipment and machinery.

*/ In some cases, contracts stipulate that the opinion of the Contractor as to the selection of vendors is to be deemed binding on the Purchaser.

Illustrative clauses^{*/}

8. Services relating to procurement

8.1 The Contractor shall provide the Purchaser with a list of would-be Vendors of Equipment, and all data and information known to the Contractor on the ability of the Vendors to meet specifications and the delivery terms.

8.2 The Contractor shall advise and assist the Purchaser during the pre-qualification of Vendors, including in the preparation of a general format for the purchase orders, tender specifications for each item of Equipment, bid tabulations, and in the selection of Vendors.

8.3 If the Contractor has sound reasons for the exclusion of certain Vendors, he may so recommend this to the Purchaser. In case the Purchaser intends to select a Vendor who is not acceptable to the Contractor, the Contractor shall indicate the specific changes in his obligations, if any, which would result from such selection. The Purchaser shall thereafter still have the choice of purchasing the Equipment from the selected Vendor subject to the reservations of, and modifications of the Contractor obligations which are reasonably commensurate with the circumstances.

8.4 The Purchaser will be responsible for the final selection of Vendors and shall ensure that all procurement is accomplished so as to enable the Completion of the Plant within the terms specified in article 10.

8.5 The Contractor shall inspect or cause to be inspected the Equipment and obtain certification at all appropriate stages of work by the Vendors, and on completion of the orders.

8.5.1 Following the issue of purchase order(s), the Contractor shall carry out (in accordance with standard procedures) or cause to be carried out the inspection and testing, as per relevant codes given in the specifications at the shops of Vendors during manufacture and before despatch.

8.5.2 During progressive inspection of Equipment fabrication the Contractor shall advise the Purchaser on the appropriate measures the latter should take, in order that the Vendors strictly follow fabrication instructions and codes, and that the quality of workmanship meets acceptable levels to enable the production of Equipment in accordance with the applicable qualitative and quantitative standards.

^{*/} See page 5, para. 1

8.5.3 The Purchaser shall require Vendors to provide the necessary test certificates and all other documents required by the inspecting authorities in the country of manufacture or as may be required by the Purchaser in consideration of the regulations in force in the Purchaser's country.

8.6 The Contractor shall issue or cause to be issued certificates of inspection for all Equipment.

8.6.1 When the Equipment is ready for final inspection, the Contractor shall take appropriate measures in order that the purchase order(s) have been complied with correctly as specified.

8.6.2 The Contractor shall issue or cause to be issued a certificate of inspection in respect of each item of Equipment before despatch, and shall send copies of such certificates to the Purchaser, and certificates of tests carried out in connection with issue of such certificates of inspection.

8.7 Wherever required by the Purchaser, the Contractor shall associate the Purchaser or his representatives with such inspection, and arrange for joint inspection.

8.8 In the event that the Contractor during shop inspection, anticipates delays in delivery of any equipment, the Contractor shall promptly notify the Purchaser and shall suggest measures to overcome delays. In the event that the delays appear inevitable, the Contractor shall anticipate the quantum of such delays, and inform the Purchaser so that the time schedule may be modified accordingly, and the Contractor shall undertake such remedial steps as may be practical, in the circumstances, to alleviate the difficulties that would be caused by the delays.

8.9 If any defect is found during inspection (before despatch) of Equipment of Vendors, or during erection or pre-commissioning tests at the Site of the Plant, the Contractor shall immediately advise the Purchaser as to what action should be taken to have the Vendors replace, or to repair, defective equipment in the shortest possible time. The Contractor shall assist the Purchaser in facilitating any action which may be necessary in such circumstances.

8.10 The Purchaser will be responsible for requiring to the Vendors the proper packaging and transportation of the Equipment to the point of despatch, and for obtaining import permits, transportation and despatch thereof to Site.

8.11 The Contractor shall assist the Purchaser in obtaining remedial action from Vendors, wherever such is necessary.

8.12 The Contractor shall advise and assist the Purchaser in order to ensure that sufficient spare parts of all equipment and machinery are procured as required for a trouble free service for years, and as regards to the proper handling, storage and security of such equipment, machinery and spare parts.

9. Contract price, terms of payment and bonuses

Unlike the know-how or license agreements, where the determination of the price mainly depends upon the relative bargaining power of the parties, in engineering contracts the remuneration to the Contractor may be established by referring to national or international standards on the cost of a man-hour for engineering design work and man-days for field supervision. Thus, it is possible to assess more rationally what would constitute, according to those standards, a reasonable price for hour or day of specified work, including overhead charges and estimate the amount of work required to implement the project.

The Contractor's remuneration may be established in several forms. It may consist of a flat sum plus a fee for supervisory time-related services; it may be based on the reimbursement of actual costs incurred by the Contractor, plus a fixed percentage, or adopt a variety of other combinations.

Whenever the remuneration is stipulated on a time-related basis, it is advisable to include in the Contract an estimate of the time required for the execution of the work. Further, as the type of work varies, and the Contractor employs different categories of personnel, the Contract should specify the remuneration charged for each category thereof.

In some cases, in order to protect the remuneration against the consequences of inflationary processes, the Contractor may require the inclusion of an indexation clause, reflecting, for instance, the increases occurred in the remuneration of its engineering personnel at the home office. In such a case, it is advisable to refer to official indexes, which are publicly available and are reliable for both parties.

When the price is established as lump sum, it may amount from 7.5 per cent up to 15 per cent of the project cost, depending upon the type (size, site, complexity) of the project. In these cases, a time limit for the contract execution may be agreed to in advance. However, if the project is delayed due to reasons beyond the Contractor's control, or the Purchaser is desirous to keep some of the Contractor's personnel after the fulfillment of the agreement, a provision should be made in the contract to provide such services on mutually agreed terms.

Payments may be scheduled in a number of different ways. They may be effected at fixed times (e.g. 30 per cent of the total or estimated fee when the contract is signed; 20 per cent after three months, etc.), either as advances subject to reconciliation at a further stage, or as straight forward payments with only terminal adjustments.^{*} This form, however, does not link the reception of payments with the effective and proper completion of work, and therefore entails a considerable risk for the Purchaser. A preferable alternative is to relate payments (except the advance usually made after signing of the Contract) to the performance of the major Contractor's obligations such as the delivery of documentation on detailed engineering, the mechanical completion of the plant, etc. In order to secure the good performance of all Contractor's obligations, the Contract may establish that a given percentage of the total remuneration is payable after the "final acceptance" of the plant.^{**} An example of payments' schedule may be as follows:

- (i) 10 per cent on the effective date of the agreement against bank guarantee in favour of the Purchaser.^{***}
- (ii) 10 per cent on receipt of layout and architectural drawings.
- (iii) 10 per cent against the receipt of complete civil engineering design (structural design, drawing for Reinforced Cement Concrete (R.C.C.), steel and allied works, foundation drawings of equipment and machinery), equipment and machinery test with specification. Tender documents.
- (iv) 20 per cent on submission of detailed engineering drawings and documents.
- (v) 10 per cent on finalization and award of contracts for equipment supply and award of contracts for civil works.
- (vi) 10 per cent on completion of major civil works of process and utilities building.
- (vii) 10 per cent on completion of mechanical and water testing trial.
- (viii) 10 per cent on completion of commissioning.
- (ix) 5 per cent on fulfillment of performance guarantees.
- (x) 5 per cent on the date of final acceptance of the plant.

^{*} / See UNIDO, Guidelines for Evaluation of Transfer of Technology Agreements, Development and Transfer of Technology Series, no. 12, New York, 1979, page 31.

^{**} / See point 13

^{***} / See point 15

Payments may be effected by direct remittance to the bank designated by the Contractor, against a letter of credit, or any other warranty of bank or government for payment, from the Effective Date of the Contract, or in any other forms agreed upon by the parties. The Contract should establish these modalities, taken the restrictions that may eventually arise from foreign exchange regulations into account.

Finally, the parties may agree to provide for incentives for the rapid completion of the work, in the form of a bonus ^{*/} consisting, for instance, in a certain percentage of the fee due to the Contractor.

*/ A bonus is an amount of money (often established as a percentage of the remuneration) to which one party (Contractor, Licensor, etc.) is entitled in case his obligations have been performed in a time shorter than provided for, or the results are above the parameters originally agreed upon (e.g. as regards to yield, production capacity, quality, etc.)

Illustrative clauses*/

9. Contract price, terms of payment and bonuses

9.1 In full consideration for the performance of the Contract, the Purchaser shall pay to the Contractor the following:

(i) For the supply of detailed engineering and the services supplied under this Contract which are not contemplated in sub-article (ii) below

(Alternative a: a firm price being the sum of (amount and currency).)

(Alternative b: the sum of (currency) per each (hour/day) of work of Contractor's engineering personnel plus an overhead of (currency). The total estimated time of work under this clause amounts to

(ii) For all the supervisory activities at Site concerning erection, precommissioning and testing of the Plant, for each day of absence from Home Office of expatriate personnel the following rate:

<u>Category of personnel</u>	<u>Rate per day</u>	<u>Currency</u>
.....
.....
.....

(iii) The daily rates referred to will be related to a normal working week of hours. Overtime charges shall be paid, except for engineers and any other staff who would not in similar situations be paid overtime charges in their home country, as follows:

- Above hours/week percent of normal rate
- For weekly and public holidays per cent of normal rate.

9.2. The total estimated costs of Contractor's services in accordance with sub-articles, 9.1 (ii) and (iii) above is (currency).

*/ See page 5, para. 1

9.3 The payments due under Article 9.1(i) above shall be made as follows:

- (i) per cent as an advance payment.
- (ii) per cent on receipt by the Purchaser of all the documents relating to detailed engineering.
- (iii) per cent on completion of mechanical and water trials, but not later than from the effective date of the Contract.
- (iv) per cent on fulfilment of performance guarantee.
- (v) per cent on the date of final acceptance of the plant but not later than from the effective date of the contract.

9.4. The advance payment shall be effected by direct remittance by the Purchaser to a bank designated by the Contractor, upon provision by the Contractor of a bank guarantee, as stipulated in Article 15.

9.5. Payments under 9.3.(ii), (iii) and (iv) above shall be made against irrevocable confirmed divisible letters of Credit established by the Purchaser in favour of the Contractor at a specified bank in

(country), upon presentation, respectively, of

- (i) a certificate from the Purchaser that the relevant documentation has been received;
- (ii) a Mechanical Completion Certificate;
- (iii) a Performance Guarantees Certificates;
- (iv) a Final Acceptance Certificate.

9.6. The payments of services referred to in sub-article 9.1.(ii) above, shall be made out of irrevocable letters of credit established days before the commencement of services by the Purchaser in favour of the Contractor for the amount established in article 9.2 above upon presentation of monthly invoices countersigned by the Purchaser.

9.7. In the event that the Mechanical Completion of the Plant is effected in less than after the Effective Date of the Contract, the Contractor shall be entitled to receive as a bonus per cent of the remuneration stipulated in 9.1.(i) above, for each complete of saved time. Payments under this Article shall be made within following the Final Acceptance of the Plant.

10. Time schedule

The need to properly coordinate the whole work involved in the construction of the plant, confers utmost importance to the definition of a viable time schedule for the execution of the project. Such a schedule is crucial for the financial management thereof, and has enormous implications on the overall cost of the project and, thereby, on the ultimate cost of the products to be manufactured.*/

It is usual to establish - in an annex to the agreement - target dates for the different activities involved, and to set down later (upon discussion between the parties) a critical path network for the accomplishment of the specific duties at the Contractor's charge.

The Contract may also specify the schedule for some major events, including those which are under the Purchaser's responsibility, such as the opening of the tendering procedure for the equipment.

The total time required for completion of the project will depend upon its nature and size. In the case of the addition of a production block for 2-3 basic drugs to an existing production complex, 18 to 24 months may be required, as in this case, most of the equipments have short lead time. In the case of a new production complex consisting of 2-3 production blocks and 5-6 drugs, the time required varies between 30 to 36 months, whereas an antibiotic new complex may require 36 to 42 months, depending upon the product complexity and the country. Annex VII indicates the time schedule of implementation of a single product antibiotic plant. The CPM chart attached indicates total activities. For an efficient execution, it is necessary to make a further pert chart of each activity, so that the critical paths are highlighted. These should be progressively revised and reviewed, and the concerned parties should take up the corrective measure, whenever necessary.

*/ See Annex VII, page 117

Illustrative clauses */

10. Time schedule

10.1. The target dates for different elements of the construction and completion of the Plant are given in the pert chart attached see Annex **/ It is agreed that within ... months after the Effective Date of the Contract the Contractor shall prepare a critical path network, generally conforming to the bar chart attached, which shall be discussed between the Purchaser and Contractor and shall be mutually approved, and which shall list significant activities connected with the completion of the Plant.

10.2. Except where otherwise stated, all dates or periods indicated in this Article and in Annex will be counted from the Effective Date of the Contract.

10.3. The bid documents for procurement of the Equipment shall be sent by the Purchaser by the ... (month) and in any event not later than the ... (month).

*/ See page 5, para. 1

**/ See Annex VIII, page 118

11. Changes and additions to the scope of the Contract

The setting up of a plant for the production of bulk drugs (or intermediates) involves a large number of activities and (as contemplated in this document) entails the participation of various parties. It is unlikely that all the requirements of the project could be foreseen at the time of signing an engineering contract, particularly if all technical details are not fixed initially but are decided during the project implementation. Further, as the execution of the Contract may take a considerable time, changes may occur in regulations (e.g. environmental and safety standards) or variations may be required to incorporate improvements in know-how or basic design.

In order to contemplate those and other possible circumstances, it is advisable to confer the Contract sufficient flexibility to incorporate into its scope changes or additions it originally does not provide for. For this purpose a detailed procedure may be established, mainly consisting of the following:

- (a) request by the Purchaser and determination whether the services required are or not within the original scope of the Contract;
- (b) if the changes or additions are outside the said scope of the Contract, the Contractor should state at the outset the implications of every change or variations requested by the Purchaser in terms of cost and time, and, where relevant, its effect on the performance guarantees before obtaining the Purchaser's approval to proceed with the change or variation.
- (c) wherever changes/variations due to statutes or regulations are sought by the Purchaser, the same has to be carried out by the Contractor who should be compensated for the additional work.
- (d) for the case of disagreement on the Contractor's estimate of the cost and/or time delay and/or modification to the performance guarantees, the contract should provide for such contingency, requiring the Contractor to proceed with the execution of the change, pending the settlement of the dispute by reference to a mutually agreed expert of repute.
- (e) often changes are requested orally by the Purchaser's site representatives resulting in subsequent disputes about payments. All changes should be conveyed in writing, by means of a "change order", i.e. a document issued by the Purchaser indicating the changes/variations required, and resulting modifications as regards to contract price, technical specifications, time schedule or other conditions of the Contract.

Illustrative clauses ^{*}/

11. Changes and additions to the scope of the Contract

11.1. Whenever the Purchaser makes a request to the Contractor for change in design, or where services are required to be performed by the Contractor, which in the opinion of the Contractor are in addition to the services which the Contractor is obligated to perform under this Contract, or which in the Contractor's opinion require additional payment by the Purchaser, the Contractor shall advise the Purchaser of the cost of such further services, within days following the Purchaser's request.

11.2. If the Purchaser agrees that the services required of the Contractor are in addition to the Contractor's obligations under this Contract, the Purchaser shall (subject to negotiations as to the cost and extent of such services and effect on the time schedule, if any) agree to pay for such services in accordance with payment terms and time schedules to be mutually agreed.

11.3. The Contractor shall be entitled to claim for additional costs and/or time delays when a modification, change or variation occurs in the event of any one of the following:

11.3.1. Any modification required by the Purchaser which is an addition to the scope of the work as per the obligations of the Contractor under this Contract.

11.3.2. Any additional engineering/re-engineering required for compliance with applicable laws, and in conformity with local statutes consequent on changes in such laws/statutes enacted after the signing of the Contract.

11.3.3. Any additional engineering/re-engineering required for compliance with local statutes consequent on changes in environmental protection standards.

11.3.4. Any additional engineering/re-engineering required relating to incorporation of agreed improvements in know-how or technologies that have become available after the signing of the Contract.

^{*}/ See page 5, para. 1

11.3.5. Any additional engineering/re-engineering required consequent on the Purchaser altering the specifications of the raw materials and/or changing the characteristics of the utilities and/or altering the basis of the meteorological data which had earlier been agreed as the basis of design between the Purchaser and the Contractor.

11.4. In all cases envisaged in Article 11.3. and its sub-articles, the Contractor shall furnish a breakdown in sufficient details to permit an analysis of all material, labour, equipment, sub-contracts and estimate project schedule overruns and specify design changes and shall further include all work involved in the variation and/or modification, whether such work was deleted, to be added or changed. The Contractor and Purchaser will thereafter meet and discuss the implications of such variations.

11.5. Whenever the provisions of Article 11.3. are applicable, the Contractor shall prepare and submit to the Purchaser a detailed cost and/or execution time estimate of the modifications to the Contractor's Services.

11.5.1. The Purchaser shall within days agree or disagree on the adjustments proposed by the Contractor.

11.5.2. If the Purchaser agrees on the (a) cost, (b) execution time and (c) modified guarantees, if any, proposed by the Contractor, the cost shall be either added to or subtracted from the Contract Price as the case may be; and the Contract execution time shall be modified accordingly, wherever necessary.

11.5.3. If the Contractor and the Purchaser do not agree either on the cost adjustments and/or time delays, and/or modifications of guarantees, the Purchaser shall have the right to request the Contractor to proceed to execute the work pending settlement of the dispute in the manner prescribed in Article 11.6 below.

11.6 The Purchaser and the Contractor shall mutually agree to nominate an independent expert and refer the dispute to the independent expert for a decision on the disputed points.

11.6.1 In the event that there is no agreement as to the choice of the independent expert, the parties shall mutually agree to refer the matter to (_____)*/ for the appointment of such independent expert.

11.6.2 The decision of the independent expert shall be without prejudice to the rights of either party to submit the dispute to (arbitration or courts) in accordance with Article; however, and in such event, the Purchaser shall make an "on account" payment to the Contractor of the sum in accordance with the decision of the independent expert but without prejudice to the rights of either party for further adjustments of the amounts so paid consequent on the decision rendered by the (arbitrators or courts).

11.7 Changes/variations as per the provisions in this Article of the Contractor's obligations, and any modifications to the Contract price and technical specifications contained in the Contract and/or time schedule, shall be incorporated in a written change order which shall be signed and issued by the Purchaser.

*/ To be determined by prior negotiations at the time of signing of the Contract.

11.7.1. Upon receiving a change order from the Purchaser either in accordance with Article 11.2. or 11.3. and if in the opinion of the Contractor such variations are likely to prevent or prejudice the Contractor from fulfilling any of his obligations under the Contract, he shall notify the Purchaser thereto in writing and the Purchaser shall decide forthwith whether or not the same shall be carried out. If the Purchaser reconfirms in writing his intention to carry out the variations, then the said obligations of the Contractor shall be modified to such an extent as may be justified.

11.8. Except as specifically provided for in this Article, any change to the Contractor's Services and/or to the work shall be governed by all the other provisions of the Contract.

12. Extension of time

During the execution of the Contract, there may be circumstances beyond the control of the parties, which prevent the Contractor to fulfil his obligations in due time. Besides, as the Purchaser, or his subcontractors, are responsible for civil works, erection of the equipment and other activities essential for the progress in the implementation of the project, their failure to comply with the time schedule may also affect the discharging of the Contractor's obligations.

In order to cover such situations, the Contract may regulate the extension of time for completion of Contractor's work and the effects thereof. In principle, such extension should be granted upon the request of the Contractor for the period reasonably necessary according to the circumstances, and should entail the extension of the bank guarantees provided for at the Contractor's cost, except if the delay is attributable to the Purchaser (or his subcontractor), to the introduction of changes or additions (as commented in point 11 above) or to a suspension of the work required by the Purchaser (see point 21 below).

Illustrative clauses */

12. Extension of time

12.1. If by reason of the happening of any one and/or other of the following occurrences which are beyond the Contractor's or the Purchaser's control, namely:

12.1.1. Vandalism;

12.1.2. Failure on the part of the Vendor or other subcontractor of the Purchaser affecting the contractual time schedule;

12.1.3. Work arising out of the application of Article 11 for which a time extension has been granted;

12.1.4. Temporary suspension of work pursuant to Article 21;

as well as non-fulfilment by the Purchaser of his obligations in a timely fashion (but not including any of the occurrences or events covered by Articles 13 or 26) which affect or delay specific work required to be undertaken pursuant to this Contract shall within days of such occurrence specified above, make written request to the Purchaser for reasonable extension of time for completion of work or any portion of it to the extent that the factor affecting delay prevailed in the circumstances. The Purchaser shall grant such extension in time which shall reasonably make up for the delay(s) suffered by the Contractor. The Contractor shall be responsible for the completion of all of the work and activities affected by the above-mentioned delay or occurrences. The Contractor shall be free of liabilities on account of the said occurrences referred to in this Article in connection with his contractual activities affected by the delays caused. The Contractor shall extend the period of validity of the bank guarantee (s) commensurate with the period of extension granted by the Purchaser, and the Purchaser shall be obliged to bear the cost of such extension of guarantee(s) provided that the circumstances envisaged in Articles 12.1.2., 12.1.3. and 12.1.4. prevailed or where the Purchaser has not fulfilled his obligations. Such costs arising in the circumstances specified in Articles 12.1.1. 12.1.2. and 12.4. and those arising out of the non-fulfilment of the Purchaser's obligations in a timely fashion, shall be to the account of the party at fault, or as may be covered by appropriate insurances taken out.

*/ See page 5, para. 1

12.2. Payments and/or entitlement to any costs pursuant to this Article, or pursuant to the provisions of Article 21 shall be established on a quantum meruit basis, provided, however, that in the circumstances envisaged by Article 21 the suspension of work was not made necessary due to default by the Contractor, and provided that the Contractor has otherwise adhered to the terms of the Contract.

12.3. The conditions of any extension granted shall, if applicable, be included as an amendment to the existing documents governing the activities or work affected or delayed by the occurrences referred to above.

13. Performance guarantee

In principle, the Contractor discharges his obligations where he engineers the plant, in due time, using good engineering practices and in accordance with basic design and engineering data supplied by the Licensor. The Contract should hence provide for a guarantee in this respect, the enforcement of which is based on the carrying out of tests and the corrective and compensatory measures applicable in case of failure.

(a) Mechanical and water trials

The testing of the plant as to its mechanical functioning takes place after the equipment is erected, installed, inspected and initially tested, in accordance with the general procedures set forth in the Contract. The tests are carried out in the presence of both parties' representatives, and the results are ascertained and recorded.

If the tests demonstrate a correct mechanical functioning of the plant, a "mechanical completion certificate" is normally issued (by both parties or by the Purchaser), and the Contractor is often entitled to receive the payments linked to such successful demonstration (see point 9 above).

The drug industry uses different types of services and a wide variety of chemical and intermediates, some of which have corrosive, hazardous, or toxic characteristic. In the case of an antibiotic plant, sterility plays a crucial role. Any leakage of air or cooling water in the fermentor, in pipes or through the valves shall create microbial contamination spoiling the complete batch. Similarly, leakage of cooling water in the reactor will affect the yield and leakage of chemical products from the reactor in the cooling system or in the jacket will contaminate the water circulation system and return condensate system affecting the mass and energy balances resulting in higher cost of production.

The avoidance of prolonged mechanical testing and successful completion depends mostly on the proper supervision at all stages of the construction and erection. Such supervision and inspection would be a routine and some of the important features should be documented jointly by the Contractor and the Purchaser representative. Annex IX gives details regarding various observations for inspection and mechanical tests to be performed for successful completion.

(b) Scope of guarantees and tests

After successful mechanical and water trials, the plant should be started up by feeding raw materials, and operated for a period sufficient to obtain stabilization. After such a period, the performance guarantee tests should be carried out.

It should be recalled here that - as conceived in this document - the execution of the project involves the participation of a number of parties besides the Purchaser and the Contractor: the vendors of equipment, the subcontractors and the Licensor/s. The vendors of equipment have to guarantee the working of the equipment supplied by them as per specifications. The subcontractors are responsible for their individual works. The Licensor, having satisfied himself that the plant has been erected as per his basic know-how, has to fulfil the process guarantee of achieving the desired rated capacity of quality products using specified quantities of raw materials and utilities. Finally, the Contractor's main responsibility lies in the overall guarantee of getting the services in the whole complex as per requirement of the process, and is specifically responsible for obtaining the rated capacity of the plant.

Such a capacity is normally determined in terms of annual capacity. The first calculation could be done on the basis of 275 working days of 24 hours each. Due to the corrosive nature of a large number of chemicals a provision of 65 days in a year is generally made for routine and preventive maintenance.

For the determination of the annual capacity, it is not possible to run the plant for a full year. Instead, it is customary to calculate the capacity on running of 5 consecutive successful batches in the case of antibiotics and 10 consecutive batches in the case of synthetic drugs.

In the case of services, a continuous trouble free running of the services for 24 hours in an individual production block and a week in a complex as whole satisfies the guarantee of the services. ^{*}/

^{*}/ For other details concerning the test run, see document ID/WG.393/1

It should be pointed out that the production of basic drugs involves a large number of stages. Based upon the capacity desired, the size of the equipment is calculated. Non-standard equipment and reactors create additional work of design and are costlier. For this reason, it is a common practice that the standard equipment nearest to fulfil the capacity parameters is selected. In this operation the actual capacity at different stages can vary. It is also the responsibility of the designer Contractor, not to play too safe and choose higher capacity vessels and reactors. This, not only raises the cost of the project, but may present difficulties in matching the sequence of the reactions in an efficient way.

Since the undertaking of the performance guarantee tests implies the participation of the Contractor's personnel, he may require that a time limit be imposed on the period for demonstration. If, by reason of a delay not attributable to the Contractor, the test can not take place within that period, they may be deemed as successfully demonstrated. It is obvious that his solution shifts all the risks to the Purchaser, who should try to prevent the emergence of such a situation (see, as to the suspension of work, point 21 below).

(c) Rectifications

If the tests reveal defects in the plant or some part thereof, the Contractor would be bound to indicate the Purchaser the required changes or rectifications, and to provide according to his responsibilities - without additional payments by the Purchaser - all the engineering, drawings procurement and supervisory services as may be required for that purpose. In the case the Contractor neglects to take such action in a reasonable period, or is unable to eliminate the defects, the Purchaser should be authorized to carry out the necessary work on the Contractor's account.

After the corrections are made, a second demonstration would have to take place. Whenever the tests are satisfactorily run, a performance guarantee certificate is issued and the plant is provisionally accepted.

However, it is customary that the Contractor guarantees against design defects, for a period of 12 months following the test run. Once that period has elapsed, and all the Contractor's obligations have been fulfilled, the "final acceptance" of the plant takes place.

Illustrative clauses^{*}/

13. Performance guarantee

13.1. The Contractor guarantees that the Plant shall be engineered and completed using good engineering practices in accordance with the specifications applicable under the Contract, and that it shall be capable of correct mechanical functioning at a rated capacity of kg per batch per annum.

13.2. As soon as the Plant or any part thereof is substantially complete, it shall be inspected by the Purchaser and Contractor before any tests are carried out.

13.3. When all the items of Equipment in the Plant or part thereof are ready and have been erected, installed and initially tested pursuant to this Contract, the Contractor and Purchaser shall review the procedures and shall undertake the demonstration of the Mechanical Completion of the Plant.

13.4. Immediately after Mechanical Completion, the Plant shall be started up by feeding raw materials by the Purchaser's personnel^{**} and shall be operated thereafter for a period of After this start-up period, the performance test run will be carried out.

13.5. The performance tests shall be undertaken in accordance with Annex The detailed procedures of execution of such tests will be mutually agreed upon before the commencement thereof. Instrument tolerances will be as given by the supplier of equipment.

13.6. During the tests the authorized representatives of the parties will jointly ascertain and record the operating data and results. If the tests are fully and satisfactorily carried out, the Purchaser and the Contractor shall thereupon prepare a certificate which shall be signed by both parties following a joint examination of the Plant.

13.7. In the event that any design defects are found during the tests mentioned above, for which the Contractor is responsible, the Contractor shall advise the Purchaser as to the rectifications, modifications or replacements which in the Contractor's judgement are necessary to eliminate the defects. The Contractor shall provide according to his responsibilities free of charge to the Purchaser all the engineering, drawings, procurement, inspection and supervisory services necessary for such rectifications, modifications or replacements.

^{*} See page 5, para. 1

^{**} This operation as well as the performance test run, are made under the Licensor's supervision. See document ID/WG.393/1

13.8. The parties shall determine a mutually agreeable period to incorporate the changes required, and to repeat the tests. Such a period will not exceed from

13.9. If the Contractor refuses or neglects to take the necessary measures to ensure the elimination of the defects within a reasonable time, or does not observe the term stipulated in the precedent sub-article, or is unable to eliminate such defects, the Purchaser may take such remedial steps as are necessary to carry out or complete the required rectifications, modifications or replacement of equipment. The cost of such remedial steps taken by the Purchaser shall be to the Contractor's account and could be deducted from any payment due to the Contractor. In the case contemplated in this Article, the Purchaser shall also have the right to terminate the Contract.

13.10. The Contractor or the Purchaser, as the case may be, shall in every case keep such contemporary and accurate records of the costs of making good any defect(s) in pursuance of this Contract and as may be reasonably required and each party shall be entitled to receive copies of relevant documents.

13.11. The Contractor's obligation to rectify defects and to take corrective steps shall continue unabated, even if the period of extension granted by Article 13.8. above is exhausted, and the Contractor shall continue his endeavours at his own cost to rectify the defects and take corrective measures provided the Purchaser agrees to allow such further extension(s) in time (in writing), as requested by the Contractor.

13.12. Subject to the completion of any and all work more particularly referred to in this Article and as elsewhere required under the terms of the Contract, the Purchaser shall issue a "Final Acceptance Certificate" within after the date of satisfactory completion of performance test run, unless during that period the Plant has shown defects requiring modifications, which were not apparent or recognizable at the time of such tests. In such case the Purchaser shall issue a Final Acceptance Certificate when all the defects have been removed.

13.13. The obligations of the Contractor shall be deemed to have been fulfilled, if for reasons not attributable to the Contractor the tests under this Article cannot be carried out within months from the Effective Date of the Contract, provided that in the event of Force Majeure the period shall be extended by the period of Force Majeure but not exceeding months.

14. Liquidated damages

Delays in the implementation of the project necessarily entail higher costs for the Purchaser. It is reasonable, hence, that he require from the Contractor proper securities as to the timely compliance of the latter's obligations.

One contractual means for coercing the Contractor in this respect is the establishment of liquidated damages per week or other period of delay. Liquidated damages may operate as a penalty or as a compensation for loss suffered, or as a combination of both. They may be subject to an upper limit, or apply as long as the delay is not remedied. In case of abandonment of the work, the cancellation of the Contract would apply (see point 25 below).

Provisions as those referred to in the precedent paragraph may be stipulated for the case of delay in the compliance of the major Contractor's obligations, such as the delivery of the documentation on detailed engineering, and the undertaking of the mechanical completion of the plant.

Liquidated damages may also apply, according to the parties' established responsibilities, in case the capacity of the plant - as determined by the performance costs - is proven to be below the guaranteed capacity. In such a situation the amount of the penalty may be established in accordance with the extent of the deficiency found.

Illustrative clauses */

14. Liquidated damages

14.1. The Contractor shall pay the amount of
subject to a maximum of per each
(period) of delay in the execution of his obligations under
articles of this Contract, provided that the delay
is attributable to reasons for which the Contractor is responsible.

14.2. Should the Plant capacity fail to conform to the
guaranteed parameters, due to defects or faults attributable to
the Contractor, the Contractor shall pay an amount of
per per cent of deficiency.

*/ See page 5, para. 1

15. Bank guarantees

The Purchaser's security requirements as regards the fulfilment of Contractor's obligations may be satisfied through the stipulation of first or simple demand bank guarantees. They may include:

- (a) Guarantees for advance payment, if any;
- (b) Performance guarantees.

Under this type of guarantee the guarantor - generally a bank or an insurance company - undertakes to pay the Purchaser up to the guarantee's amount upon the simple request of the Purchaser. The guarantor is not allowed to judge whether the Purchaser claim is justified or not, but must effect the payment on the basis of the Purchaser's simple demand. In some cases, the Purchaser may require that the guarantee be granted by a bank of his country with the counter-guarantee of the Contractor's bank.

The amount and term of validity of performance bank guarantees generally are the main issues of discussion and negotiation. The first aspect will be usually determined as a percentage of the contract value, or of the fee agreed upon. It may also be determined on the basis of the liability assumed by the Licensor (see point 16, below).

The term of validity of guarantees may be indefinite, or extendable upon the simple request of the beneficiary. Another possibility is to determine a date of expiry, for instance, after x months from the satisfactory fulfilment of performance tests. The contract may also specify that the guarantee be partially released at the date on which certain events occur, for instance, at the date of delivery of the detailed engineering documentation and at the date of the mechanical completion of the plant.

Illustrative clauses ^{*/}

15. Bank guarantees

15.1. In consideration of the advance payment remitted by the Purchaser the Contractor shall provide a first demand bank guarantee from a first class bank for an amount equivalent to the sum total of the advance payment required to be made by the Purchaser pursuant to Article 9.3.(i). The amount of this bank guarantee shall be released on receipt by the Purchaser of all documentation as provided for in Article 6.2.

15.2. The Contractor shall provide the Purchaser with a first demand Performance Bank Guarantee on receipt of payment stipulated in 9.3.(ii) for an amount equivalent to per cent of the total lump sum stipulated in 9.1.(i).

15.3. This guarantee will remain in force until the Final Acceptance of the Plant.

15.4. The guarantees referred to in this article shall be encashable by the Purchaser in (currency).

15.5. The Contractor shall take all actions, including renewals and extensions, to keep the guarantees valid for the periods provided for.

^{*/} See p. 5, para. 1

16. Liabilities, set-off and waiver

a) Liabilities

The negotiation of the scope and extent of the Contractor's liability is often one of the difficult issues to be dealt with, since each party is likely to support two clearly divergent views on the matter.

Contractor's liability may arise out from:

- i) injury or damage caused to persons or property by negligence or omission by the Contractor, e.g. communication of defective designs;
- ii) losses and damages emerging from the non-compliance with the specific contractual obligations, e.g. failure to successfully demonstrate the tests not remedied by subsequent rectification;
- iii) losses and damages created by delays attributable to the Contractor which affect the implementation of the project as scheduled.

Limitations on the scope of the liability may consist, as it is usual in practice, of the exclusion of consequential losses or damages and losses of anticipated profits.

Limitations as to the amount of total liability have also been common practice in international agreements. They usually take the form of a percentage of the total contract's value or of the fee due to the Contractor. Another possibility is to discriminate such items where the Contractor's liability is limited, from those where a ceiling is not admitted, such as for the works necessary for rectification or correction of the plant.

In cases of damages or losses covered by insurance policies taken out by the Contractor, he may normally discharge - partially or totally - his obligations by reimbursing to the Purchaser any amount received by virtue of such policies.

b) Set-off

During the execution of the Contract, certain events may cause losses or damages to the Purchaser, for which the Contractor is liable. In order to attenuate the burden that such losses or damages impose on the Purchaser and to enforce the Contractor's responsibility therefor, the Contract may recognise the former the right to set off the amount of the loss or damage against any amount payable to the latter. Such a right may be subject, in order to ensure a fair decision for both parties, to a procedure as follows:

i) the Purchaser should, firstly, notify to the Contractor in writing and substantiate the reasons, scope and amount of his claim, giving the Contractor a reasonable term for its consideration;

ii) Secondly, amicable and bona fide negotiations should be undertaken;

iii) Failing such negotiations, the Purchaser may be permitted by the Contract to set-off against any amount payable to the Contractor, without prejudice to the latter's right to resort to the procedures established for the settlement of disputes (see point 28 below, including eventually the nomination of independent experts) and if the issue is still unresolved, the recourse to the competent courts or arbitration as provided for.

c) Waiver

It is generalised practice to set down the principle that no previous waiver of a particular right or remedy under the Contract is to be deemed as a waiver of a future right or remedy. Such a principle confers flexibility to the parties in their reciprocal behaviour, and preserves the stability and integrity of the Contract.

Illustrative clauses ^{*/}

16. Liabilities, set-off and waiver

16.1. The Contractor shall not be liable for any property or equipment of the Purchaser damaged or lost during transportation, erection, start-up and mechanical tests, except where:

- (1) such loss or damage has occurred due to a negligence act or omission of the Contractor, and
- (2) such loss or damage is not covered by the insurance specified in Article 18.

Notwithstanding the above, the Contractor's liability for loss or damage to the Purchaser's property and equipment shall in any event be limited to the amounts recovered by the Contractor from his Third Party Liability Insurance, the coverage and value of which must be reasonable and agreed to by the Purchaser.

16.2. The total liability of the Contractor under the Contract shall not exceed () per cent of the total price as stipulated in Article 9 with the exception of the Contractor's unlimited liability for rectification or modifications necessary for the fulfilment of the guarantee as stipulated in Article 13, as well as the reimbursement to the Purchaser of any amount(s) received by the Contractor, under any insurance policies held by the Contractor as well as through those others specifically taken out for the purposes of this Contract.

16.3. The Contractor shall not be liable under the Contract for loss of anticipated profits or for any consequential loss or consequential damage.

^{*/} See page 5, para. 1

16.4. In the event that the Purchaser considers that he possesses a claim against the Contractor under, arising out of, or in any way connected with, this Contract, the Purchaser may at any time (whether before or after the completion of the work under this Contract and whether such completion is affected by the Contractor, the Purchaser or another person) calculate the amount of the damage or loss upon which such claim is based and (without restricting any right of set-off or counter-claim given or implied by law) and notify the Contractor in writing the reasons, scope and amount of his claim. The Contractor shall consider the claim within ... days from receipt of the notification. In case of disagreement as to the validity or extent of the claim, the parties shall undertake amicable negotiations, failing which, and after ... days from the date of the notification referred to above, the Purchaser shall be entitled to set-off against any amount then or to be subsequently payable to the Contractor, and shall notify the Contractor in writing that the said right is being exercised. At any time up to ... days after the receipt of the notification, the Contractor may resort to the procedures established in article ... for settlement of disputes, but after the expiry of the said ... days, the Contractor shall be deemed to have acknowledged the validity, both as regards quantum and otherwise of the aforesaid claim of the Purchaser. Should the amount of the above-mentioned claim of the Purchaser exceed the amount or value of the set-off, nothing herein shall be construed as a bar to the right of the Purchaser to adopt any other legal measures available against the Contractor for the amount of such excess.

16.5. No previous waiver of a particular right or remedy by either party shall operate as a waiver of a future right or remedy (which would normally be invocable) unless otherwise stated.

17. Indemnification

Each party should be responsible vis-à-vis the other party, for its negligent acts or omissions, as well as for those of its employees and Sub-Contractors. The Contract may specifically state this principle, in order to confer reciprocal protection against any claims or proceedings brought by third parties for personal injury, death or property damage.

Illustrative clauses*/

17. Indemnification

17.1. The Contractor shall indemnify and hold harmless the Purchaser and anyone employed by him from and against all claims, demands, losses, costs damages, actions, suits, expenses (including legal fees) or proceedings by whomsoever made for personal injuries, death or third party property damage brought or prosecuted in any manner based upon, arising out of, related to or occasioned by the proven negligent act or omission of the Contractor or his Sub-Contractors and their employees in connection with this Contract.

17.2. The Purchaser shall indemnify and hold harmless the Contractor, his employees and agents from and against all claims, demands, losses, costs, damages, actions, suits or proceedings for personal injuries, death (other than to Contractor's personnel) and property damage (other than to the Plant) occasioned by the Purchaser's and his Sub-Contractors' and their employees' negligence.

*/ See page 5, para. 1

18. Insurances

It is of utmost importance that the parties take out adequate policy insurances covering at least the main risks involved in the execution of the engineering contract.

On the Contractor's side, as a minimum, the risks arising out of errors, omissions or negligence in engineering or in the supply of the stipulated service should be covered, as well as accident and liability insurances for its personnel.

On its side, the Purchaser should carefully review the different types of insurance cover available and required for the setting up of the plant including, for instance, construction risks, machinery breakdown, cargo insurances, etc. In the context of the agreement considered here, the Purchaser should, for instance, take policies against injuries or damages (including to the Contractor's personnel or property) occasioned by negligent acts of the Purchaser's personnel, at the site or at the Contractor's facilities.

The parties should prove, in due time, that such policies have been taken out and are kept in force. For the case where either of the parties failed to take out or maintain the required policies, the Contract may state the other party's right to do so, at the non-complying party's charge.

Illustrative clauses */

18. Insurance

18.1. Without restricting in any manner the generality of any other provisions of the Contract, and in particular any such provision as pertaining to the liability of the Contractor, it is expressly agreed that, throughout the period beginning from the date of commencement of the work, and continuing until the Mechanical Completion of the Plant, the following policies shall be taken out:

(a) The Contractor shall take out and keep in force insurance policies covering risks arising out of any error, omission or negligence in engineering or in the supply of services stipulated under the Contract, and personnel accident and liability insurances for the Contractor's personnel deputed to Site.

(b) The Purchaser shall take out at his own charge all other appropriate policies, including coverage of the Plant from commencement of work and against any injury or damage derived to persons or property, including Contractor's personnel and property, through acts, omission or negligence of Purchaser's personnel.

18.2. Whenever required from time to time, the Contractor and the Purchaser shall submit to the other party adequate proof that the insurance(s) as contemplated by Article 18.1. have been taken and remain in force. The parties hereto shall also provide each other with certified documentation with regard to the coverage and value of the policies.

18.3. Should the Contractor fail to take out and/or keep in force the insurances contemplated by this Article within the scope of his responsibility, together with any other insurances to be taken out by the Contractor agreed between the Purchaser and the Contractor, then the Purchaser may at the Purchaser's option take out insurance(s) considered appropriate and necessary in the circumstances, in which event any premiums paid or payable by the Purchaser shall immediately constitute a debt due from the Contractor to the Purchaser, the amount of which debt may be retained as the Purchaser's monies out of any amount(s) otherwise payable by the Purchaser to the Contractor.

*/
See page 5, para. 1

18.4. Should the Purchaser fail to take out and/or keep in force the insurance(s) contemplated by this Article within the scope of this responsibility, then the Contractor may at the Contractor's option take out insurance(s) considered appropriate and necessary in the circumstances in which event any premium paid or payable by the Contractor shall immediately constitute a debt due from the Purchaser to the Contractor.

19. Taxes and levies

It is generally understood that the Contractor will bear any taxes, rates, charges and assessments of any kind pertinent to his work under the contract and applicable outside the Purchaser's country.

The Contract should also determine which party will bear the taxes, etc. existing in the Purchaser's country. Under some national laws ^{*/}, the Purchaser would be bound to deduct from the Contractor's fee, whenever a payment is made, the amounts corresponding to the taxes applicable to the latter's income.

*/ E.g. Colombia, Venezuela.

Illustrative clauses ^{*/}

19. Taxes and levies

19.1. Each and every price cited in or contemplated by this Contract as described in Article 9 includes and covers all taxes, rates, charges and assessments of any kind whatsoever (whether Federal, State or Municipal, and whether or not in the nature of excise taxes/duties, land taxes, licence fees, or otherwise) outside the Purchaser's country pertinent to the Contractor's services provided pursuant to this Contract, and/or the performance of the work, and all other costs and charges whatsoever relevant to such Contractor services and/or to such performance of the work by the Contractor.

19.2 All taxes and/or levies under any existing or future law of (Purchaser's country) applicable to the amount payable in accordance with this Contract will be borne by (Alternative a: the Contractor. Upon request, the Purchaser will provide the Contractor with the receipts of payment of such taxes or levies)
(Alternative b: the Purchaser).

^{*/}
See page 5, para. 1

20. Access to work

To the extent that the Contractor is responsible for the supervision of the construction of the plant, and for the proper mechanical functioning thereof, he must be entitled during the execution of the Contract to have access to the plant and inspect the work being done. For this purpose, the Purchaser should obtain the necessary permission, if any, for entering the country (see illustrative clause 7.8. above), and confer the supervisory personnel the necessary authority to instruct the personnel carrying out the work.

Illustrative clauses */

20. Access to work

20.1 The Contractor and any person(s) authorized by him shall at all reasonable times have access to the Plant.

20.2 The Purchaser shall afford every facility and assistance for obtaining the right of access to such information, site workshops or persons within his country as is required in connection with this Contract, and will confer the Contractor's supervisory personnel the necessary authority to fulfil their duties under the Contract.

20.3 The Purchaser shall provide necessary assistance in obtaining permission from his Government, if required. In particular, the Purchaser shall obtain and make available to the Contractor all necessary permits/approvals and/or licenses from local authorities and/or Governments as may be necessary for the timely execution of the Contract inclusive of import licenses, visas for Contractor's personnel, entry permits, work permits etc.

*/ See page 5, para. 1

21. Suspension of work

Among the circumstances that may arise during the construction of the plant some may require the suspension of the work for a certain time. The Contract may include provisions to cover this situation and consider different hypotheses according to the length of the suspension.

If the suspension extends for a brief period (e.g. less than three months) the Contractor may be allowed a commensurate extension of time for the execution of his obligations; for longer periods (e.g. up to twelve months) the revision of the time schedule may be provided for. In any case, the Contractor might be entitled to claim the reimbursement of the additional costs caused by the suspension.

If the resumption of the work is longly delayed (e.g. more than twelve months), and there is no agreement as to the terms for continuation of the work, either of the parties might be allowed to terminate the Contract, in accordance with the specific provisions thereof (see point 25, below).

Illustrative clauses ^{*/}

21. Suspension of work

21.1. The Purchaser may, when in the Purchaser's opinion it is deemed necessary, require the Contractor to suspend the execution of the work, or part of the work, either for a specified or unspecified period by communicating notice to that effect to the Contractor. If the period is unspecified, the Purchaser shall specify the period of suspension within days thereafter.

21.2. The Contractor, upon receiving notice of the Purchaser's requirement pursuant to Article 21.1. above, shall suspend all operations except those which, in the Purchaser's and Contractor's opinion, are necessary for the care or preservation of the Plant.

21.3. During the period of suspension, the Contractor shall not remove from the Site any part of the Plant or Equipment without the consent of the Purchaser.

21.4. If the period of suspension is (.....) days or less, the Contractor, upon the expiration of the period of suspension, shall resume the execution of the Contract in accordance with an extension of time granted by the Purchaser reasonably commensurate with the period during which the execution of the Plant or part of the Plant was suspended and the Contractor shall be reimbursed for his reasonably justified additional costs which should be evidenced by necessary documentation.

21.5. If the period of suspension is more than (.....) days, upon the expiration of the period of suspension, the Contractor shall resume operations and fulfil the Contract in accordance with the terms and conditions of this Contract, provided, however, that the time schedule will be extended accordingly and his reasonably justified costs as evidenced by documentation will be reimbursed to him for the period of suspension subject to any further amendments to the Contract in accordance with Article 11.

21.6. If the period of suspension exceeds days and if either the Purchaser requests the Contractor to recommence the work upon amended terms (to be agreed mutually) and the Purchaser and Contractor are unable to reach agreement on the method for the completion of the Contract, or the Contractor states in writing that he is unwilling in any event to undertake further work, the Contract shall be terminated according to Article 25.

*/ See page 5, para. 1

21.7. Both the Purchaser and Contractor shall make bona fide endeavours to resume the work as expeditiously as possible.

21.8. Payments if any made under this Article shall be governed by the provisions of Article 9.

22. Effective date of the Contract

The effective date of the agreement is the date defined by the parties as the initial point in time for some or all terms agreed upon in the Contract. That date may coincide with the date of execution (signing) or be determined by the date upon which the last of some other events occur, such as the approval of the Contract by the authorities of the Contractor's or Purchaser's country, if required, or the remittance of an advance payment by the Purchaser.

Illustrative clauses */

22. Effective Date of Contract

22.1. The Contract shall become valid upon the formal execution (signing) by the duly authorized officers of the Purchaser and Contractor properly witnessed and sealed and in accordance with the applicable law. The Effective Date of the Contract shall be the date upon which the last of the following requirements has been fulfilled:

22.1.1. (i) Approval of the Contract by the Government of () where the Plant is to be located, such approval to be obtained by the Purchaser, if required.

22.1.2. (ii) Approval of the Government of () where the Contractor resides and has his principal place of business such approval to be obtained by the Contractor, if required.

22.1.3. (iii) The provision by the Contractor of the bank guarantee as provided under Articleto be effected simultaneously with receipt of the advance payment by the Contractor, referred to in Article

*/ See page 5, para. 1

23. Assignment of the Contract

The selection of an engineering firm is normally made on the basis of its experience, reputation and qualifications evidenced for the execution of the specific work to be undertaken. Therefore, the assignment of the Contract by the Contractor is in principle excluded, except if the Purchaser expressly gives his consent to it. Moreover, if the Contractor requires to sub-contract part of the work, the Purchaser should approve each particular transaction, without prejudice to the Contractor's responsibility for the due and timely execution of the sub-contracted work.

As regards to the situation of the Purchaser, there may be situations (such as when a state organization is involved) where the assignment of the Contract may be necessary. The Contract may provide the right to assign subject to adequate guarantees as to payments, or alternatively submit any assignment to the prior consent of the Contractor.

Illustrative clauses*/

23. Assignment of the Contract

23.1. This Contract may not be assigned by the Contractor without the written consent of the Purchaser.

23.2. (Alternative a: The Purchaser shall have the right to assign the Contract provided that such assignment does not increase the Contractor's liabilities over what they would have been if such assignment or transfer had not been made, and provided that the obligations of the Purchaser are binding upon the assignee, with assured guarantees for payment(s) under the Contract.)

(Alternative b: This Contract may not be assigned without the written consent of the Contractor, which shall not be unreasonably withheld).

23.3. Neither the whole nor any part of the Contractor's obligations may be subcontracted by the Contractor without the written consent of the Purchaser.

23.4. The Contractor shall ensure that every sub-contracting by the Contractor shall comply with all terms and conditions of this Contract.

*/ See page 5, para. 1

24. Language of the Contract

The Contract should establish the language in which it should be interpreted, as well as in which all correspondence, data, documentation, etc. should be written.

In cases where more than one version in different languages are made, it is necessary to determine which version will prevail for the purposes of the use and interpretation of the terms of the Contract. As regards to the language of the technical documentation to be supplied by the Contractor, see point 6 c) above.

Illustrative clauses^{*/}

24. Language of Contract

24.1. The governing language of the Contract shall be....., and the definitions in such language shall be final in the use and interpretation of the terms of the Contract.

24.2. All correspondence, information, literature, data, manuals, etc. required under the Contract shall be in..... language.

^{*/} See page 5, para. 1

25. Termination and cancellation of the Contract

(a) Termination

For cases where circumstances beyond the Purchaser's control (which do not necessarily constitute, however, force majeure) prevent him from continuing the construction of the plant, he may be authorized by the Contract to terminate the same, subject to the reimbursement of the costs incurred up to that moment by the Contractor, or to the payment of the remuneration due, whichever is greater.

In such hypothesis, the Purchaser should receive all the technical documentation done by the Contractor at the date of the termination, as well as calculations, data, inspection reports and other materials corresponding to the Contractor's work.

The Purchaser may be also entitled to terminate the Contract, whenever the Contractor does not undertake or abandon the work, or when other grave circumstances (e.g. unauthorized assignment of the Contract, bankruptcy) have arisen out.

One of the main effects of cancellation, which may be either total or partial, is to interrupt payments to the Contractor, without prejudice to his right to institute actions or proceed to arbitration.

The right to cancel the Contract is essential to rapidly solve difficult situations created by the Contractor's failure to undertake or complete the contracted work. It allows the Purchaser to take the Contract out of the Contractor's hands and to complete himself, or by any other designated party, the pending work and thus avoid costly delays in the implementation of the project.

Similarly, the Contractor may declare the contract avoided in case of a fundamental breach by the Purchaser, and particularly if the latter fails to pay the former the amounts due in accordance with provisions relating to remuneration (see point 9 above), or when the Purchaser becomes insolvent or commits an act of bankruptcy.

Illustrative clauses */

25. Termination

25.1. In the event that the Purchaser is subject to any circumstances which are wholly unavoidable and/or beyond his control (but not including occurrences constituting force majeure) then the Purchaser may at any time by giving notice in writing to that effect, terminate this Contract.

25.2. The Contractor shall upon receipt of a notice pursuant to Article 25.1. above cease all operations forthwith.

25.3. If the Contract is terminated pursuant to Article 25.1. the Purchaser will pay to the Contractor an amount equal to the greater of:

25.3.1. The cost of the work properly supplied or done by the Contractor as at the date of the termination, including the cost of terminating commitments made in good faith to his Sub-Contractors, as substantiated by appropriate evidence, less all amounts already paid to the Contractor by the Purchaser, and less all amounts which the Contractor is liable under the Contract to pay to the Purchaser or owing to the Purchaser, or

25.3.2. The amount calculated in accordance with the terms of payment which would have been legitimately payable to the Contractor up-to-date of termination provided the Contractor had in fact fulfilled his contractual obligations to such date.

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See page 5, para. 1

25.4. In any of the following cases, the Purchaser may, without any other authorization, cancel the Contract and take all or any part of the Contract and/or of the work to be undertaken by the Contractor out of the Contractor's hands and may employ such means as the Purchaser sees fit to complete this Contract.

25.4.1. Where the Contractor has delayed commencement of work for months, for reasons attributable to the Contractor, and the Purchaser has given notice to the Contractor and the Contractor has not replied or not taken action to commence work months after such notice was given.

25.4.2. Where the Contractor has become insolvent and/or made and assignment of the Contract without the approval of the Purchaser.

25.4.3. Where the Contractor has committed an act of bankruptcy.

25.4.4. Where the Contractor has abandoned the work.

25.4.5. In any other case where the failure of the Contractor to perform his obligations amounts to a fundamental breach of this Contract.

25.5. Where this Contract or any portion thereof has or have been taken out of the Contractor's hand under Article 25.7. the Contractor shall not, except as provided in Article 25.9. hereunder, be entitled to any further payment including payments then due and payable, but not paid, and the obligation of the Purchaser to make payments as provided for in the terms of payment shall be at an end, and either party at their option may institute actions for recovery of damages.

25.6. Where this Contract, or any portion or portions thereof has or have been taken out of the Contractor's hands under Article 25.7. and is subsequently completed by the Purchaser, the Purchaser shall determine the amount, if any, of retention monies and progress claims of the Contractor unpaid at the time of taking the work out of the Contractor's hands that, in the Purchaser's opinion, are not required by the Purchaser for the purposes of the Contract and subject to any actions already instituted or proposed to be commenced, the Purchaser shall, if he is of the opinion that no financial prejudice to the Purchaser will result, authorize payment of that amount to the Contractor.

25.7 . The taking of this Contract, or of any portion thereof, out of the Contractor's hands pursuant to this Article does not operate so as to relieve or discharge the Contractor from the obligations imposed upon the Contractor by law, except the obligation to complete physically the execution of such portion of the Contract as has been taken out of the Contractor's hands.

25.8. In the event of a termination of this Contract pursuant to this Article, the Purchaser shall be entitled to receive:

25.8.1. All the Technical Documentation completed or done at the date of termination, in accordance with Annexes

25.8.2. All calculation, computer print-outs or other materials pertaining to the detailed engineering, completed at the date of termination.

25.9. The Purchaser shall be given all inspection reports, reports on visits to Vendor's factories and copies of test certificates received from Vendors up to the date of termination.

25.10. Nothing herein shall invalidate the rights of the Purchaser or the Contractor as to contractual grounds of action in relation to damages or costs due to either party.

25.11. The Contractor may terminate this Contract, if the Purchaser fails to effect the payments due under article ... ("Contract price, terms of payment") within days after the Contractor has given notice of such failure to the Purchaser, or when the Purchaser becomes insolvent or has committed an act of bankruptcy.

26. Force majeure

According to the traditional conception of force majeure a contracting party is not deemed to be in default of its obligations if the performance thereof is prevented by contingencies which are unforeseeable (at the time of contract's signing), unavoidable and independent of the parties, and which render impossible the further execution of contractual obligations.

International contractual practice has generally attenuated the strict requirements of such conception. The unavoidableness is, thus, substituted by a reference to events beyond the control (or reasonable control) of the parties. Likewise, instead of the extinctive effect traditionally accorded to force majeure, the practice recommends to suspend the contract until the disturbing contingencies are overcome.

Provisions on this issue should normally include:

- (a) Definition of exonerating circumstances;
- (b) Enumeration of contingencies that may be comprised in the definition, such as force of nature (acts of God), acts of war (whether declared or not), strike, lock-out, governmental order or regulation, etc.;
- (c) Notifications of the occurrence of such circumstances in a given form and delay (and of their termination);
- (d) Proof to be supplied;
- (e) Effects of the force majeure;
 - (i) Exclusion of responsibility for non-performance;
 - (ii) Suspension of execution (eventually extension of contractual terms during the period of suspension);
 - (iii) Renegotiations, rescission or submission to arbitration or the competent courts.

Illustrative clauses */

26. Force Majeure

26.1. In this Contract, Force Majeure shall be deemed to be any cause beyond the reasonable control of the Contractor or the Purchaser (as the case may be) which prevents, impedes, or delays the due performance of the Contract by the obligated party and which, by due diligence, the affected party is unable to control, despite the making of all reasonable efforts to overcome the delay, impediment or cause. Force Majeure may include, but shall not be limited to any one or other of the following:

- any war or hostilities;
- any riot or civil commotion;
- any earthquake, flood, tempest, lightning, unusual weather or other natural physical disaster. Impossibility in the use of any railway, port, airport, shipping-service or other means of transportation or communication (occurring concurrently);
- any accident, fire or explosion;
- any strike, lock-out, or concerted acts of workmen (except where it is within the power of the party invoking the Force Majeure to prevent);
- shortages or unavailability of materials (compounded by the same shortage or unavailability from alternate sources).

26.2. If either party is prevented or delayed in the performance of any of his obligations under this Contract by circumstances of Force Majeure, and if the affected party has given written notice thereof to the other party within days of the happening of such event, specifying the details constituting Force Majeure, with necessary evidence that a contractual obligation is thereby prevented or delayed, and that the anticipated period (estimated) during which such prevention, interruption or delay may continue, then the affected or obligated party shall be excused from the performance or punctual performance (as the case may be) of such obligation as from the date of such notice for so long as may be justified.

*/ See page 5, para. 1

26.5. If the consultations referred to in the preceding clause have not resulted in mutual agreement, or have not taken place because the parties have been unable to communicate with one another

(Alternative a: either party will have the right to terminate the Contract giving written notice to the other party)

(Alternative b: either party will have the right to resort to a decision pursuant to article 28 ("Settlement of disputes").

26.6. Both the Purchaser and the Contractor shall be prompt and diligent to remove all causes or interruption or delay in the work, insofar as each is liable to do so.

27. Applicable law

The parties should determine the law that will govern the Contract.

Some developing countries have encouraged or imposed in transfer of technology agreements, the application of the law of the Purchaser's country.

When arbitration is agreed upon, provided that the law permits or does not prevent it, the parties may choose a law that has a close and real connection with the contract. Arbitrators may be eventually required to decide "ex aequo et bono", without reference to a particular national law.

In order to avoid conflicts with public policies (ordre public) of the countries of either of the parties, and to ensure the enforcement of any decision or award, it might be advisable to stipulate that matters relating to such public policies will be decided in accordance with the applicable law of said countries.

Illustrative clauses^{*/}

27. Applicable law

27.1. (Alternative a: The laws applicable to the Contract shall be the laws of the Purchaser's country).

(Alternative b: This Contract will be construed under and governed by the law of (specified country or jurisdiction thereof), except as to matters relating to public policy of (Purchaser's or Contractor's country) which will be decided in accordance with the applicable law of that country).

^{*/} See page 5, para. 1

28. Settlement of disputes

Like in the case of the applicable law, some developing countries have favoured the position that any disputes in transfer of technology should be decided by the judicial courts of the Purchaser's country.

Another usual approach in international trade practice is to stipulate the recourse to arbitration, provided that the law of the parties allows or does not prevent it. In respect of the law governing the Contract, the parties may choose a law that has a close and real connection with the Contract, or stipulate that arbitrators decide "ex aequo et bono". In any case, the choice of the law should not be effective in matters relating to the internal or international public policy (ordre public) or sovereignty of the country where arbitration takes place and of the countries of the parties. With this reservation, the arbitration may conciliate its procedural advantages with the respect due to imperative rules of the States connected with the transaction, and also ensure its enforcement in the jurisdiction of such States.

If arbitration is provided for, the Contract should specify, at least, the following:

- (a) The number and method of nomination of arbitrators;
- (b) The seat of arbitration;
- (c) The procedure of arbitration (e.g. the Arbitration Rules of the United Nations Commission on International Trade Law).

The pertinent clauses may also refer to the character of the arbitral award, and to the language of the proceedings. In any case, any of the parties could request the submission of the arbitral award to an examination of legality, for instance, before the courts of the country where the arbitration has taken place.

It should be stressed that before submitting any controversy to the courts or arbitration, the parties should endeavour to solve it, first, by means of amicable and bona fide negotiations. If an agreement is not reached, it may be also advisable to provide for the nomination of experts (one by each party), and in the event that they cannot agree either, a third neutral expert may be nominated.

Illustrative clauses */

28. Settlement of disputes

28.1 In the event of any dispute, different of contention in the interpretation or meaning of any of the Articles to this Contract or reasonable therefrom, both parties shall promptly make endeavour to resolve the dispute or differences by mutual discussions and agreement.

(Alternative a: Should the dispute or differences continue to remain unresolved, both parties may each nominate an expert to negotiate and reconcile the dispute or differences to resolve thereby the matter of contention between the parties arising out of the Contract. In the event that these two persons referred to cannot agree, they shall nominate a third Neutral Expert or in case the efforts of the Neutral Expert nominated by the two parties fail to resolve the differences within (6) months, both parties to the Contract shall proceed as provided for in 28.3 below).

28.2 In the event the contract is terminated or cancelled in accordance with article 25, notwithstanding the existence of a dispute, the Contractor and Purchaser shall continue to carry out their obligations under the Contract, and payment(s) to the Contractor shall continue to be made in accordance with the Contract provided that in the appropriate cases the Contractor is entitled to such payment(s), and the Purchaser has not exercised the right conferred under article 16.4.

28.3 Subject to the provisions of this Article, either the Purchaser or the Contractor may institute an action with respect to any claim, dispute or other matter that has arisen between the parties.

(Alternative a:

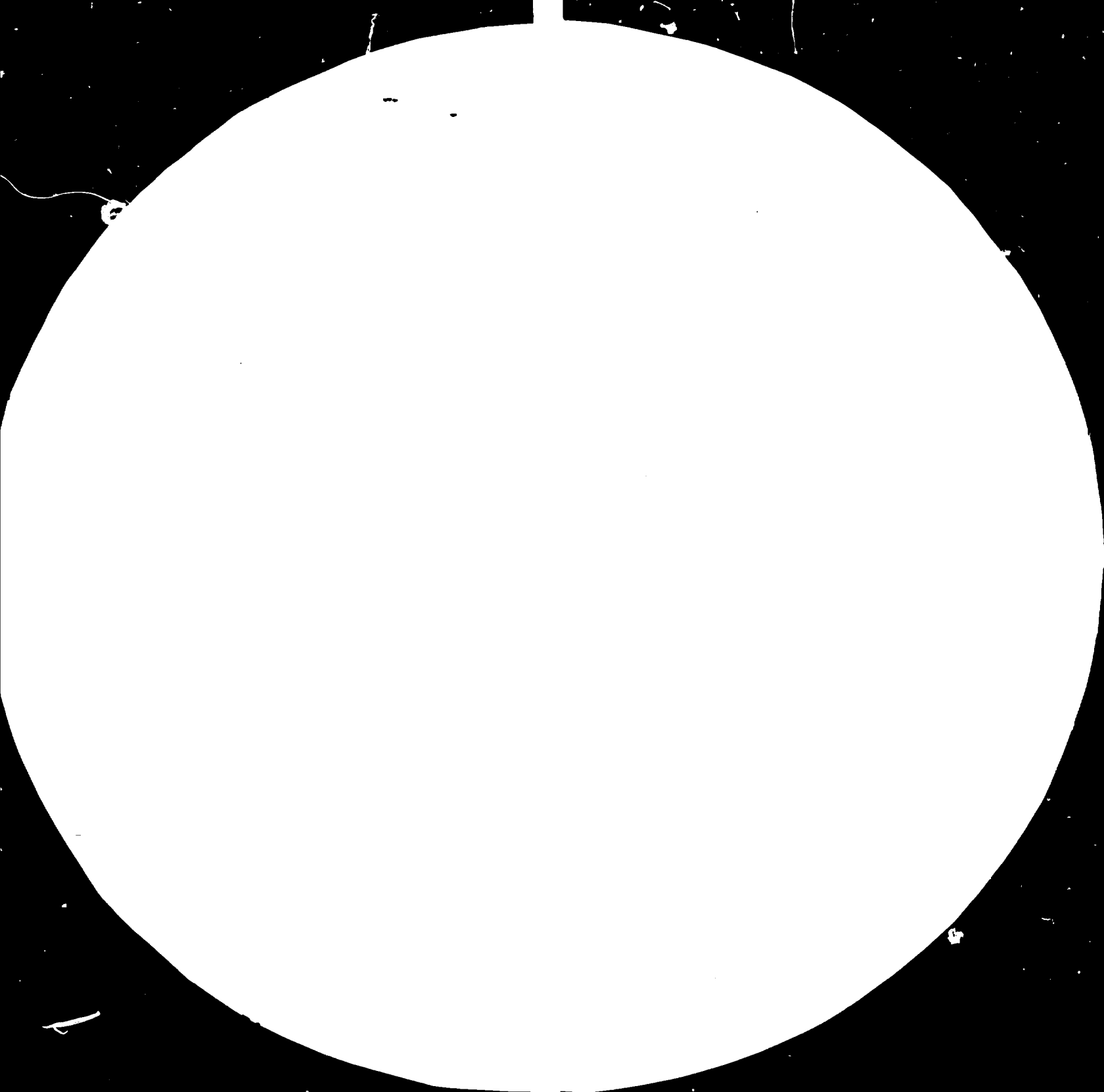
1. However, no demand for any such claim, dispute or other matter shall be made until the later of (a) the date on which the Purchaser or the Contractor, as the case may be, has indicated his final position on such claim, dispute or matter, or (b) the ... day after the Contractor or Purchaser, as the case may be, has presented his grievance in written form to the other, and no written reply has been received within days after such presentation of the grievance.

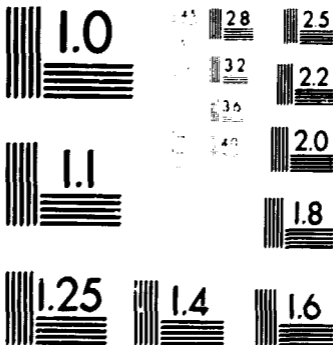
*/ See page 5, para. 1

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 NATIONAL BUREAU OF STANDARDS-
 STANDARD REFERENCE MATERIAL 1010a
 (ANSI and ISO TEST CHART No. 2)

2. No demand shall be made after the (____) day following the date on which the Purchaser or the Contractor, as the case may be, has rendered his written final decision in respect of the claim or dispute. The Purchaser or Contractor, as the case may be, shall be obligated to specify that the written decision is in fact the final decision within the meaning of this Sub-Article. Failure to demand (arbitration or court decision) within said (____) days period shall result in the decision being final and binding upon the other party.)

28.4. All claims, disputes and other matters in question arising out of, or relating to, this Contract or the breach thereof which cannot be resolved by the parties shall be decided by
.....
(Alternative a: the courts of(country).
(Alternative b: arbitration).

28.5.^{*/} Arbitration shall take place in accordance with
(law of arbitration or rules, e.g. Arbitration Rules of the United Nations Commission on International Trade Law).

- i) The award of the Arbitrators will be final and binding on the parties hereto. Judgement upon the award may entered by the court of (country).
- ii) The Contractor and the Purchaser agree that in the event of arbitration proceedings, the Arbitrators will have unrestricted access to the Plant for the purpose of the said Arbitration.
- iii) Arbitration will be in (town) and all proceedings will be in language.

^{*/} This clause would apply in case arbitration is provided for in the contract.

ANNEX I

BRIEF DESCRIPTION OF A PLANT

The object of the Contract is to establish an Antibiotic (or synthetic drug) Plant from the grass-root level. The project has the following basic details:

	<u>Antibiotic</u>	or	<u>Synthetic Drug</u>
Product:	Tetracycline hydrochloride.		Ampicillin trihydrate.
Capacity:	250 Tons/annum		250 tons/annum
No. of working days:	300 days/annum		300 days/annum
Process:	Batch wise		Batch wise
Basic stage:	Fermentation		Starting from Potassium Penicillin-G.
Location:	(country)		(country)
Status of the Project:	New Establishment		New Establishment

The site should be shown on the map along with the rail and road network and nearest town/city/largely populated area.

The Plant shall use (.....) as raw material and will be designed to the process technology of (Licensor) for the Antibiotic (or Synthetic Drug) Plant.

The process is essentially batch (or continuous and the basic steps in the production of Tetracycline hydrochloride (in case of Antibiotic Plant) shall start from fermentation. The strain, Streptomyces aureofaciens, must be well maintained and the culture is transferred from flask to seed vessel having sterilised media. The media and main fermenter is prepared and sterilised with steam, cooled, inoculated with the culture from seed vessel. Compressed air is passed during fermentation with proper control of various parameters like temperature, pressure, pH etc. After completion of fermentation, the broth is treated further for recovery of the product tetracycline base which is again treated with butanol, oxalic acid, carbon, hydrochloric acid, subsequently filtered and dried to get tetracycline hydrochloride.

Basic steps for the production of Ampicillin (in case of Synthetic Drugs) shall be as follows:

Ampicillin trihydrate is manufactured synthetically from (-amino penicillanic acid (6-APA), an intermediate which itself is produced from potassium penicillin-G either synthetically or by enzymatic process.

Production of 6-APA by synthetic route involves conversion of potassium penicillin-G into potassium benzyl penicillin dimethylsilyl ester with dichloro silane. This on further treatment with phosphorus penta chloride gives imido-chloride derivative which on treatment with dimethyl anilin and subsequent hydrolysis gives 6-APA. The method requires very low temperature (-50 to -55°C) and perfect anhydrous conditions. 6-APA thus produced is isolated, purified, dried and packed.

The enzymatic route for production of 6APA consists of two basic steps, namely (i) production of enzyme and (ii) splitting of penicillin into 6-APA and phenyl acetic acid.

The enzyme is produced from the strain of Escherichea coli, tube culture into the seed vessels and inoculating to main fermenter. The media in the main fermenter is prepared from corn steep liquor and other nutrients, sterilised and cooled. Fermentation is carried out by sparging sterile air. The production is centrifuged, stabilized and stored cold.

Potassium penicillin-G is splitted into 6-APA and phenyl acetic acid either by continuous immobilized enzyme column or by batch process and the two components are seperated by solvent extraction under chilled condition (5-10°C). Further pH adjustmant, crystallisation and centrifugation gives 6-APA.

Ampicillin trihydrate is produced by the reaction of 6-APA with triethylamine, then acetylation with phenylglycine chloride hydrochloride and subsequent isolation as naphthyl sulphonic acid salt and further conversion to ampicillin trihydrate. The solvents methylene chloride, acetone and MIBK used in the process are recovered for the re-use. In the alternative process, Dane's salt of phenylglycine chloride is used.

The facilities to be provided shall include generation of steam and power (optional) for which an optimum balance between electric and steam drives shall be made by the Contractor. The plant shall also use sterile compressed air circuit, closed cooling water circuit, process water, demineralized water circuits as well as closed circuit of chilled brine and air conditioners. The water will be available from (source) and power will be available from (purchase or self generation).

All the utilities and off-site including workshops and laboratory facilities shall also be provided as laid down in the Contract.

The quantum of effluents from the Plant will be (-) having major composition (-) and shall be disposed off to (disposal point) should be shown in the map - and effluent treatment facilities will be provided to make the effluents fit for such disposal.

The plant site is located at a distance of (-) kilometers from the nearest town/city large inhabitations should be shown in the map and plant discharges to the air will be controlled. Keeping this in view, the wind directions, temperature inversion and other relevant factors.

Annex II

BASIS OF DESIGN

A. Process Engineering

1. Basic data

Product:

Annual capacity: (-) tons (300 working days/annum)

Process: Continuous/batch and fermentation/synthetic.

2. Finished product specifications

Finished bulk drugs quality will be as per the pharmacopoeia of the respective country or as agreed by the licensee and the licensor.

Storage conditions, self life, packaging, transportation etc. should be mentioned here.

3. Raw material specifications

For antibiotic production:

(i) Dextrosemonohydrate -

(a) Sulphated ash (on dry basis): per cent by weight, maximum.	0.1
(b) Acidity:	to satisfy the test
(c) Sulphur dioxide, ppm. (max.):	70
(d) Arsenic (as AS_2O_3), ppm. (max.):	1
(e) Heavy metals, ppm. (max.):	5
(f) Chlorides:	to satisfy the test
(g) Sulphates:	to satisfy the test.

(ii) Other nutrients: (To be inserted here).

(iii) Strain: *Streptomyces aureofaceus*, Strain No. (-)

(iv) Various other: Maximum potency - 30,000 mcg/ml.

Solvents and chemicals: (To be inserted here).

4. Process parameters

- (i) Temperature: (a) during fermentation (range)
(b) during recovery and processing
(for various operations).

- (ii) Compressed air: (a) Pressure (minimum and maximum range in kg/cm^2)
 - (b) Temperature (-)
 - (c) Humidity at entry to fermenter (-)
- (iii) pH: During fermentation and at various stages of recovery and reaction or operation (in case of synthetic drugs) to be mentioned here.

5. Miscellaneous other important parameters like foaming and foam control, solvent recoveries, etc. to be noted here.

b. Civil and other engineering

1. Meteorological data

Meteorological data for at least ten years should include:

(a) Available average data:

The available meteorological data for Site (or the nearest station to Site) should contain the following information for each month of the year.

- (i) Daily average maximum temperature: (- $^{\circ}\text{C}$)
- (ii) Daily average minimum temperature: (- $^{\circ}\text{C}$)
- (iii) Monthly rainfall: (- mm)
- (iv) Dry and wet bulb (- $^{\circ}\text{C}$), preferably both for morning and afternoon (indicate time).
- (v) Prevailing wind direction (if available, a complete thumb-card indicating the yearly average occurrences of winds in the prevailing direction should be attached).

(b) Extremes recorded:

This should contain data on the extremes recorded for:

- (i) Maximum temperature: (- $^{\circ}\text{C}$)
- (ii) Minimum temperature: (- $^{\circ}\text{C}$)
- (iii) Maximum rainfall recorded in 24 hours (indicate one and two hourly intensity).
- (iv) Maximum recorded wind velocity (indicate occurrence of typhoons etc. or make reference to relevant standards concerning wind load design data at various levels up to the levels of the highest structure to be designed).

2. Soil and seismic conditions

These should include:

- (a) The type of soil conditions.
- (b) The sub-soil water table level at Site (indicate whether water is sweet, saline or sea water).
- (c) The load bearing capacity in the area. If the soil bearing capacity differs considerably in various places of the plot, a plot plan indicating drilling points and findings should be attached.
- (d) Available data on earthquake in or near Site and seismic design data commonly used in the area.

3. Standards and codes

Various standards and codes like British (BS), American (ASIM), German (DIN), Japanese (JIS) etc. are applicable for the equipment fabrications, pipe line engineering, civil engineering and erection, boilers compressors, refrigeration, air-conditioning, pressure relieving system, electrical codes, hazard area classifications, effluent standards etc. These should be decided mutually by the Licensor and Licensee and must be specified accordingly and alternatives, if any, should also be indicated. Where national standards or codes exist these should be clearly stated.

4. Statutory regulations

The statutory regulations relating to standards or other codes, or Factory Acts applicable in the Licensee's country should be specified herein. This particularly refers to boiler codes and acceptance procedures applicable for endorsement of foreign standards prior to manufacturing of the equipment. If required, translation of local standards and regulations should be prepared and noted to point out differences and permissible exceptions for imported equipments.

5. Limitation on transportation of equipment to Site

The data supplied here should include:

- (a) Maximum lift available at port (if ship's derricks can be used this should be stated).
- (b) Maximum dimensions and weights which can be carried by road from port to Site.
- (c) Maximum dimensions and weights which can be carried by rail from port to Site.

If possible drawings of wagon profiles, and section profiles of smallest tunnel/bridge above road/rail etc. should be given.

6. Characteristics of utilities and services and limits of supply

6.1 Electric power:

- (a) All purchased electric power shall have the following characteristics: (indicate voltage including voltage and frequency fluctuations, phases, cycles, 3 or 4 wire system^{*}), power supply in kW).
- (b) All generated power (if any) shall have the following characteristics: (This should be discussed by the Licensee and Licensor and should conform to national standards as far as possible).
- (c) Power supplied outside the Battery Limits shall have the following characteristics: (Indicate voltage, phases, cycles, 3, 4 or 5 wire system).

6.2 Water:

(Specify separately for water from different sources, as river, sea, well-pre-treated water, recycled steam condensate, etc.).

- (a) Source of water: (source)
- (b) Water availability: average cu.m/d
daily variation cu.m/h
seasonal variations ... cu.m/d

(c) Water has the analysis (as given below)

	mg/l	<u>Normal</u>	<u>Variations</u>
Total hardness, CaCO ₃	mg/l		
P. Value, CaCO ₃	mg/l		
M. Value CaCO ₃	mg/l		
Calcium CaCO ₃	mg/l		
Magnesia MgCO ₃	mg/l		
Sodium Na	mg/l		
Iron Fe	mg/l		
Sulphate SO ₄	mg/l		
Chloride Cl	mg/l		
Silica (dissolved) SiO ₂	mg/l		

*) In certain countries a 5 wire system is used: RST+E+N

Total dissolved solids mg/l

Total suspended solids mg/l

pH

Colour and turbidity
(Silica scale) mg/l

Note: If there are large variations these should be explained.

ANNEX III

PROCESS KNOW-HOW AND BASIC ENGINEERING DOCUMENTS TO BE RECEIVED FROM THE
LICENSOR AND SUPPLIED TO THE CONTRACTOR

The following documents are to be supplied in detail:

1. Detailed process description with all parameters and process conditions for production.
2. Specifications of raw materials, utilities etc.
3. Specifications of finished products.
4. Specifications of packaging materials.
5. Consumption co-efficients of raw materials, and utilities.
6. Analytical procedures and methods for raw materials, process, control and finished products.
7. Operating manuals.
8. Process flow-sheets.
9. Master layout.
10. Layout drawings for equipments and services equipment.
11. Suggestions and recommendations for material handling and storage of materials, including finished products.
12. Suggestions and recommendations for industrial safety, identification of hazardous material and areas.
13. Detailed equipment list with specifications.
14. Effluent treatment (whenever applicable).
15. Recovery of solvents (whenever applicable).
16. Strain specifications (whenever applicable).
17. Requirements of manpower.
18. Mass and energy balances.

ANNEX IV
DESIGN CRITERIA

1. Meteorological

- i) The plant and Equipment, particularly the air compressor and auxiliary equipments, air-conditioners, cooling tower will be designed for a maximum temperature of $-^{\circ}\text{C}$ and relative humidity of - % (or kg water/kg air) and dry and wet bulb temperatures of $-^{\circ}\text{C}$ $-^{\circ}\text{C}$ respectively.
- ii) Process and other pipings shall be designed for the required temperatures and pressure. Water piping (shall/ shall not) be designed for freezing conditions. (minimum recorded temperature of last 10 years should be mentioned)
- iii) All designs are for a maximum rainfall of -- mm in 24 hours as well as for maximum wind velocity of - km/hr. (conditions of storms, gales etc. should be indicated.)

2. Seismic Factor

For design purpose, the seismic factor at site can be taken as --. Maximum wind velocity and seismic factor may (or may not) be considered to occur simultaneously for structural design.

3. Water

- i) The analysis of the raw water, available in the site, and as given in Annexure-II shall be considered for designing all water system (Process and utilities)
- ii) Make-up waters to boiler, cooling water system, brine, air-conditioners shall not exceed ---% of actual requirement.
- iii) The cooling water and chilled brine system shall be designed for maximum ΔT of $-^{\circ}\text{C}$. (suggested 10°C and 3°C respectively).

- iv) The demineralised water produced in the plant from raw water (analysis in Annexure - II) shall have the following analysis : (example)

Total dissolved solids : less than 5 ppm.
Conductivity : 10 micro siemens/cm
pH : 6.5 - 7.0
Free from carbon dioxide.

- v) Where sea water is used for cooling purpose, the condition shall be carefully examined by the Licensor and Contractor to guard against fouling, corrosion and other factors.

4. Soil conditions

Design load bearing capacity shall be as in Annexure -II, but is subject to further tests as laid down in the Contract.

5. Electrical Power

- i) The required power in the Plant at 100 per cent capacity is - KW and shall be met from (purchase, self generation/ emergency or partial generation)

(In case of partial generation). The generated power shall be - KW which is - % of the total requirement.

- ii) The characteristics of the electric supply shall be as follows :-

High tension : - V, 3 phase, 3 wire, 50 or 60 Hz, A.C.

3 - phase : - V, 3 phase, (3,4 or 5) wire, 50 or 60 Hz,
.A.C

1 - phase : - V, 1 phase, (2 or 3) wire, 50 or 60 Hz,
A.C.

- iii) Voltages for electrical motors shall be H.T. voltage for motors of - KW or more and L.T. 3 phase voltage for smaller motors.

- iv) Supply characteristics for instruments and control systems should be detailed.

6. Steam

The steam supply in the Plant shall have (three) systems :-

<u>Systems</u>	<u>Pressure</u>	<u>Temperature</u>
High pressure system	10/12 kg/cm ²	(-) °C
Medium Pressure Steam	6/8	(-)
Low Pressure	2.5/3.5	(-)

The condensate (non-contaminated) shall be recycled from the various equipments to the boiler feed, through a polishing units.

Surplus or contaminated condensate shall be cooled locally and discarded into the (sewerage or cooling water system) or any other system (to be indicated)

If steam is used for power generation, the details of feed and used steam to be indicated here.

7. Compressed air (Particularly in case of Antibiotic Plant)

The compressed air to the fermenters shall be made available from (one/two/three) compressors .. (mention standby , if any,). The characteristics of the air available to fermenters is as follows :-

- Capacity : - NM³/hr
- Pressure : Kg/cm²
- Temperature : -°C
- Relative/ : - % (-kg water/kg air)
absolute humidity.

The air is perfectly sterilised by passing through - nos. of air filters.

The details of air filters, condensors, coolers and distribution system should be mentioned.

8. Instrument Air

The plant shall be self sufficient in instrument air supply under the following conditions :-

- Outlet pressure condition from instrument air limit (-)
- Quality : Dew point : ° C
Free from dust and oil.

If part of the compressed air is used for the instrument or

otherwise, may be indicated and should form part of the Design Criteria.

9. Chilled brine/cooling water/air-conditioning

Maximum Load :

Minimum Load :

Average Load :

Temperature :

Variation.

Also other conditions as indicated in this Annexure.

10. Identification of Hazardous areas and safety measures

a) The place where solvents to be used shall be declared as explosion proof area and adequate measures shall be taken for selecting the equipments (explosion proof motors, flame proof vents etc.)

b) Depending on the nature of chemicals used, the areas shall be classified as the flame proof (explosion proof) areas as per international safety cods (specify).

c) Appropriate measures shall be taken for design of storage and handling system for hazardous chemicals/components.

11. Other design criteria

a) All dimensions, weights and measures will be in the metric (or other) system. The dimension of piping, heat exchange units etc. may be indicated in (-) system. (indicate applicable standard)

b) Proper sterile conditions shall be maintained wherever required.

c) Design Criteria for concrete and steel structures (anti-corrosion protection, prilling water, storage, flooring, fire resistance by encasing or painting for 30, 45 or 60 minutes, etc.) are as follows: (give details)

12. Process :-

The process engineering shall follow :-

a) Physical, physicochemical parameters and data, provided in know-how, these data, for example, are as follows:-

- pH : of the mass at various stage.
- Temperature of the reaction or fermentation.
- Rheology of the reaction or fermented mass.
- Compressed air flow rate, temperature, ultimate pressure humidity.
- Concentration of various reactents or ingredients.

b) Consumption of Raw Materials

The consumptions of raw materials and/or intermediates per Kg of the finished drug have been taken as follows: - (ex.)

A m p i c i l l i n

Consumption of raw materials per kg of 6-APA

- Potassium penicillin-G (96 per cent)	Kg
- N,N-dimethylaniline	Kg
- Dimethyl dichloro silane	Kg
- Phosphorous pentachloride	Kg
- N-Butanol	Kg (-)
- Sodium hydroxide 40 per cent	Kg
- Methylene chloride	Kg (-)
- Methanol	Kg (-)
- Acetone	Kg (-)

(-) to be recycled for recovery at per cent.

Consumption of raw materials per kg of Ampicillin

- 6-APA (96 per cent)	Kg
- D-(alfa)-phenylglycine (100 per cent) chloride hydrochloride	Kg

- Triethylamine	Kg
- Dimethyl dichloro silane	Kg
- N,N-dimethylaniline pure	Kg
-0 p-Toluenesulphonic acid monohydrate	Kg
- Methylene chloride	Kg (-)
- Dicalite	Kg
- Decolorizing charcoal	Kg
- Amberlite LA - 1	It
- Methyl isobutyl ketone	Kg (-)
- (-) to be recycled for recovery at ... per cent	

Tetracycline

Consumption of raw materials per kg of Tetracycline.

- Corn steep liquor	Kg
- Maize starch	Kg
- Ground nut oil	Kg
- Calcium carbonate	Kg
- Butanol	Kg
- Oxalic acid	Kg
- Ammonium nitrate	Kg
- Ammonium sulphate	Kg
- Benzyl thiocyanate	Kg
- Manganese sulphate	Kg
- Potassium dihydrogen phosphate	Kg
- Sodium hydroxide	Kg
- Ammonia	Kg
- L. Amylase	Kg
- Charcoal	Kg
- Hydrochloric acid	Kg
- Acetone	Kg
- Magnesium sulphate	Kg

c) The design of process and utilities equipments and machinery shall be based on the optimal capacity utilisation as well as fixed capital investments. As for example, (a) for an antibiotic plant the number of fermenters and the capacity of the fermenters (25 m³ , 50 m³ , 90 m³ or 120 m³) shall be based

on the optimal investment and operating condition etc. The number and capacity of air compressors, with standby, if any, shall be decided by the number of fermenters running at any time (probabilistic analysis) as well as cost of power, maintenance, investment etc.

- d) The potency of the strain (for antibiotic production) has been considered asmcg/ml.
- e) The specification of the raw materials required should also be indicated clearly.
- f) The yields at various stages as well as the qualities of the ultimate product (bulk drugs) are indicated as follows:-

ANNEX V

DEFINITION OF BATTERY LIMITS, UTILITIES AND OFFSITE FACILITIES

The Battery Limits of the area of Plant design should be clearly stated and indicated on the preliminary plot plan with approximate data on elevation of the collecting point above and underground. An example is given below:-

Inputs :- Water shall be provided by (pump or gravity) to the Plant site and will be available (provide separate data on cooling water and/or well water etc. as make-up water and utility water) at a single point in the plant. A plant storage at elevation of (- or ground level) of ---m³ will be provided.

All treatment and pumping facilities for the water are part of the design.

- Steam will be generated in the Plant and will be connected to the respective points through a grid with proper arrangements for condensate return.
- Power will be purchased from outside agency and will be connected to the respective points.
- Power (optional) will be generated in the Plant (whole requirement or partial standby arrangement) and will be connected to the respective point. The generation source will be (thermal or diesel or any other) - other wise indicate type of emergency power source desired. This can also be used for construction).
- compressed air will be supplied from own compressive installed in the Plant and will be connected to the respective points through the pipe line net work.
- Refrigerations (chilled Brine) will be supplied to the respective points from the centralised station constructed inside the plant, through the closed circuit system.

- Air-conditioning and dehumidifying facilities will be constructed in the Plant and will be supplied to the respective points through a net work. Wherever necessary local air-conditioning facilities will be provided.
 - All chemicals, catalysts etc. will be supplied at storage/warehouses at ground level. (or otherwise- indicate location at the construction site or within the plot).
 - All solvents will be properly stored in the yard and will be made available to the place of use by pump (or otherwise)
- Outputs :
- Power : Additional power to the extract of - Kw will be generated for use by the Licensee.
 - Surplus steam and condensate (specify parameters and quantities) will be piped to the point - indicated in the plot plan.
 - The finished drug will be packed in 20kg, 50kg (net weights) bags/containers. (Give details of the bags/containers).
 - Transportation of the drug will be :-
 - % for internal use
 - % by road
 - % by rail
 - % by air
 - (optional) Adequate facilities will be designed for loading/unloading waggons/trucks at the plant site (both for raw materials, solvents and finished drugs) to be finished by the Licensee.
 - Solvents will be recovered in the respective recovery units (or centralised recovery station) and will be made available for re-use by pump) (or otherwise)

within the battery limits, the entire plant, including utilities, and offsites mentioned below shall be designed by the Contractor. It is generally understood that if not specifically mentioned, the connecting points of inlet and outlet pipes will be one meter outside the battery limit (in course of additional production block in the existing production complex).

Offsite facilities

The offsite facilities that should be designed and procured for the work are:

- (a) Workshops for mechanical, electrical and instrumentation maintenance and motor garage.
- (b) Warehouses for spare parts, store, chemicals, lubricants furnace oil etc.
- (c) Administration, quality control laboratory, canteen buildings.
- (d) Transport and communication system.
- (e) Animal house in case of antibiotic plants.
- (f) Fire fighting equipments and health security appliances.
- (g) Public health facilities.

ANNEX VI

Technical documents concerning detailed engineering

A. Architecture and civil engineering

- 1) Detailed plan of the plot and layouts of all buildings, structure and other civil construction.
- 2) Plan for roads, paths, external and internal drainage system, effluent drainage and treatment.
- 3) Basic layouts and schematic architectural drawings.
- 4) Working architectural drawings.
- 5) Layout for underground installations, plans showing trenches, pipes and cables, sewerage disposal and public health etc.
- 6) Foundation layout with location and above ground dimensions.
- 7) Pattern of floorings, structures, walls, shades.
- 8) Complete civil engineering drawings design, structural design and drawings for RCC, steel and allied works including stockade.
- 9) Equipment foundation and drawings.
- 10) Details of lighting protections and safety devices installations.
- 11) Recommendations on air-conditioning and ventilation.
- 12) Schedule of quantities for various items of construction.
- 13) Complete bill of material.

B. Mechanical engineering - equipment and machines documentations

- 1) Loading data for civil and architectural design.
- 2) Detailed specifications for all equipment and machinery, including spare parts for one year trouble-free service, for production and utilities (in case of new plants) for procurement and fabrication (part of the data given by the Licensor has to be co-ordinated) along with their respective duties.
- 3) Mechanical design and fabrication drawings for equipments if required.

- 4) Specifications of maximum and minimum load of services and utilities.
- 5) Sizing of utility systems and their P and F drawings as well as layout drawings.
- 6) Armature sheets for individual equipment and machines.
- 7) Specification and cost for insulation.
- 8) Manufacturers drawings, catalogues and literatures for all equipment and machines.
- 9) Assembly drawings wherever required.
- 10) Specifications of the appropriate codes for fabrication.
- 11) Maintenance manuals for some of equipment and machines (wherever not available).
- 12) Preliminary lubrication schedules and summary list of types and grades of lubricants as recommended by the manufacturers.

C. Piping engineering documents

- 1) List of pipelines along with detailed specifications and insulation requirements for processes and utilities.
- 2) List of valves and other fittings with type, quality, size, duties.
- 3) Terminal point drawing for inter-connection of pipes going in and going out of blocks.
- 4) Isometric and co-ordinated piping drawings (isometric drawing - required by inspection authorities).
- 5) Sizing, drawings and specifications for air ducts for ventilation and air-conditioning system.
- 6) Welding procedures including specifications for electrodes.
- 7) Model of process plant and utilities in case co-ordinated drawings are not made.
- 8) Piping erection drawings and instructions.
- 9) Procedures for treatment of pipes, types of bends and other structural requirements.

D. Electrical engineering

- 1) Complete design of the electrical distribution and fitting works as per statutory rules and regulations.
- 2) Design of outdoor services station, layout of L.T. distribution system starting from supply point.
- 3) Design of distribution system, single line diagram with details of H.T. and L.T. distribution systems starting from supply point.
- 4) Detailed layout drawings for distribution of power, lighting system, lightening arresters, etc., earthing of vessels, with drawings.
- 5) Detailed specifications of all electrical equipment, items such as transformers, generators, motors, H.T. oil circuit breakers, L.T. duct and switchboard, control panels, capacitors, cables, etc.
- 6) Complete list of equipment, cables, machinery.
- 7) Manual pertaining to installation, operation, maintenance and safety.
- 8) Complete bill of materials.

E. Instruments and control engineering

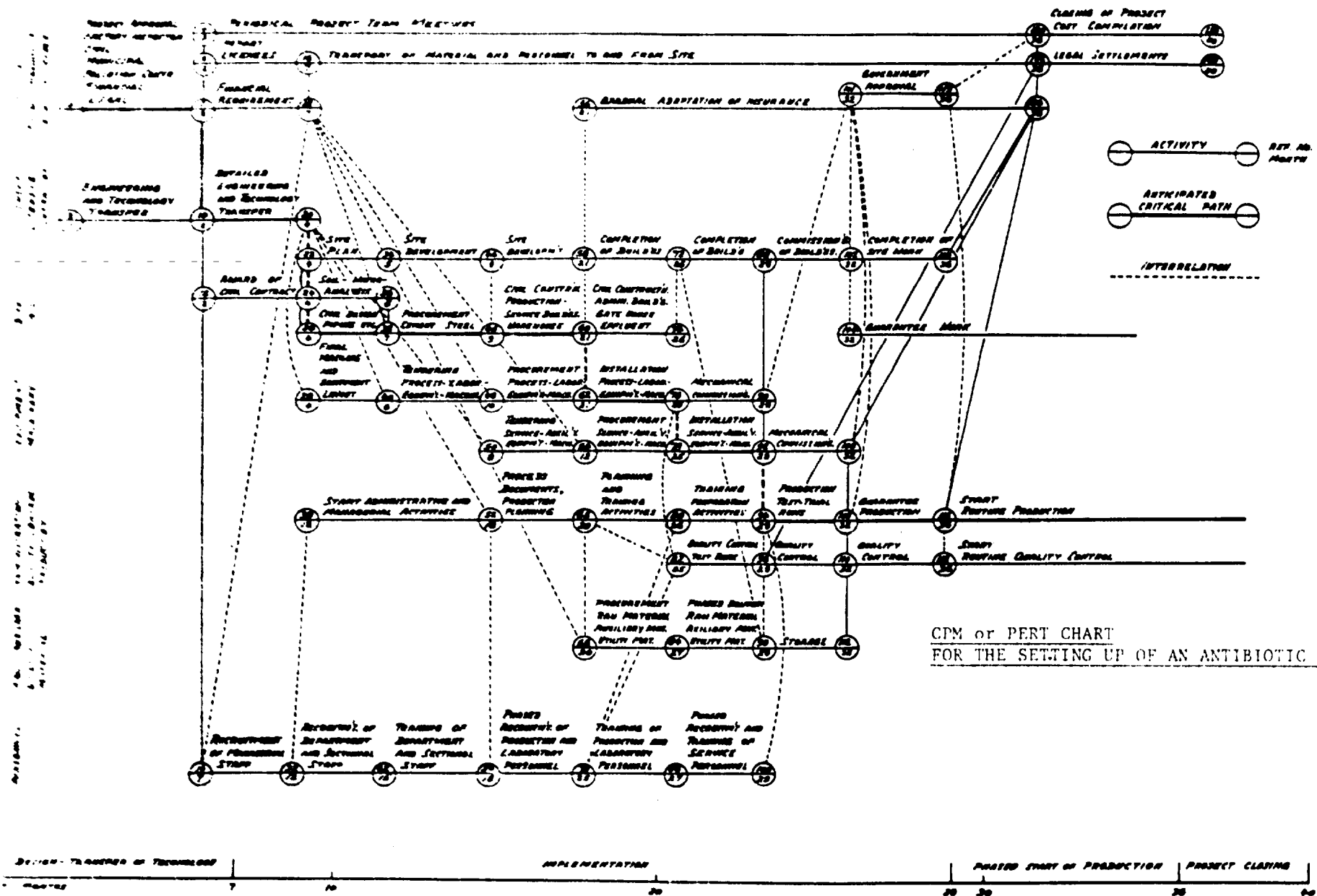
- 1) Detailed specifications of instruments and controls with P and I diagram.
- 2) Detailed drawings for installation of instruments and specification of accessories required.
- 3) Control loop specifications with details of the type of control.
- 4) Location of control room and control panel layout.
- 5) Diagram and layout for cable and pneumatic line routing.
- 6) Compressed air requirements and distribution system with detailed accessories
- 7) Details of interlocking, tripping system and annunciators.
- 8) Specifications of testing and calibration equipments for instrument repairshop and for site.
- 9) Maintenance manual.
- 10) Complete bill of material.

ANNEX VII

TIME SCHEDULE FOR PROJECT IMPLEMENTATION

The time schedule for an Antibiotic Plant (Tetracycline hydrochloride) requiring 36 months for completion herewith attached is based on the following considerations:

- (i) The effective date of signing of the Contract has been taken as the starting point.
- (ii) Critical Path: Procurement and erection of critical and important equipment having longer lead time, obtaining sanctions from financial institutions and obtaining sanctions from various governmental agencies as an obligatory part of the fulfilling of the statutory regulations have been taken as the critical events.
- (iii) Staffing and training of Purchaser personnel should be done in phases, depending upon the requirement and according to an agreed schedule.
- (iv) Civil construction should start at the 9th month and construction of some buildings like administration, finished product store etc. may be taken up in a later stage without affecting the commissioning date.
- (v) The duration of construction and erection has been estimated on the assumption that these will be executed by experienced subcontractors.
- (vi) The formalities of getting import licenses for the import of capital goods and raw materials should be completed as early as possible.
- (vii) Critical Path Method (CPM) or pert chart of each activity should be made to ensure the schedule of receipt of documents in a phased manner, procurements schedules, construction and erection schedules.
- (viii) The sequences of above has to be matched in such a way, to avoid unnecessarily blocking of the capital.
- (ix) CPM or pert should be applied to assess the progress and to take corrective measures.



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DESIGN: 1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12. 13. 14. 15. 16. 17. 18. 19. 20. 21. 22. 23. 24. 25. 26. 27. 28. 29. 30. 31. 32. 33. 34. 35. 36. 37. 38. 39. 40. 41. 42. 43. 44. 45. 46. 47. 48. 49. 50. 51. 52. 53. 54. 55. 56. 57. 58. 59. 60. 61. 62. 63. 64. 65. 66. 67. 68. 69. 70. 71. 72. 73. 74. 75. 76. 77. 78. 79. 80. 81. 82. 83. 84. 85. 86. 87. 88. 89. 90. 91. 92. 93. 94. 95. 96. 97. 98. 99. 100. 101. 102. 103. 104. 105. 106. 107. 108. 109. 110. 111. 112. 113. 114. 115. 116. 117. 118. 119. 120. 121. 122. 123. 124. 125. 126. 127. 128. 129. 130. 131. 132. 133. 134. 135. 136. 137. 138. 139. 140. 141. 142. 143. 144. 145. 146. 147. 148. 149. 150. 151. 152. 153. 154. 155. 156. 157. 158. 159. 160. 161. 162. 163. 164. 165. 166. 167. 168. 169. 170. 171. 172. 173. 174. 175. 176. 177. 178. 179. 180. 181. 182. 183. 184. 185. 186. 187. 188. 189. 190. 191. 192. 193. 194. 195. 196. 197. 198. 199. 200. 201. 202. 203. 204. 205. 206. 207. 208. 209. 210. 211. 212. 213. 214. 215. 216. 217. 218. 219. 220. 221. 222. 223. 224. 225. 226. 227. 228. 229. 230. 231. 232. 233. 234. 235. 236. 237. 238. 239. 240. 241. 242. 243. 244. 245. 246. 247. 248. 249. 250. 251. 252. 253. 254. 255. 256. 257. 258. 259. 260. 261. 262. 263. 264. 265. 266. 267. 268. 269. 270. 271. 272. 273. 274. 275. 276. 277. 278. 279. 280. 281. 282. 283. 284. 285. 286. 287. 288. 289. 290. 291. 292. 293. 294. 295. 296. 297. 298. 299. 300. 301. 302. 303. 304. 305. 306. 307. 308. 309. 310. 311. 312. 313. 314. 315. 316. 317. 318. 319. 320. 321. 322. 323. 324. 325. 326. 327. 328. 329. 330. 331. 332. 333. 334. 335. 336. 337. 338. 339. 340. 341. 342. 343. 344. 345. 346. 347. 348. 349. 350. 351. 352. 353. 354. 355. 356. 357. 358. 359. 360. 361. 362. 363. 364. 365. 366. 367. 368. 369. 370. 371. 372. 373. 374. 375. 376. 377. 378. 379. 380. 381. 382. 383. 384. 385. 386. 387. 388. 389. 390. 391. 392. 393. 394. 395. 396. 397. 398. 399. 400. 401. 402. 403. 404. 405. 406. 407. 408. 409. 410. 411. 412. 413. 414. 415. 416. 417. 418. 419. 420. 421. 422. 423. 424. 425. 426. 427. 428. 429. 430. 431. 432. 433. 434. 435. 436. 437. 438. 439. 440. 441. 442. 443. 444. 445. 446. 447. 448. 449. 450. 451. 452. 453. 454. 455. 456. 457. 458. 459. 460. 461. 462. 463. 464. 465. 466. 467. 468. 469. 470. 471. 472. 473. 474. 475. 476. 477. 478. 479. 480. 481. 482. 483. 484. 485. 486. 487. 488. 489. 490. 491. 492. 493. 494. 495. 496. 497. 498. 499. 500. 501. 502. 503. 504. 505. 506. 507. 508. 509. 510. 511. 512. 513. 514. 515. 516. 517. 518. 519. 520. 521. 522. 523. 524. 525. 526. 527. 528. 529. 530. 531. 532. 533. 534. 535. 536. 537. 538. 539. 540. 541. 542. 543. 544. 545. 546. 547. 548. 549. 550. 551. 552. 553. 554. 555. 556. 557. 558. 559. 560. 561. 562. 563. 564. 565. 566. 567. 568. 569. 570. 571. 572. 573. 574. 575. 576. 577. 578. 579. 580. 581. 582. 583. 584. 585. 586. 587. 588. 589. 590. 591. 592. 593. 594. 595. 596. 597. 598. 599. 600. 601. 602. 603. 604. 605. 606. 607. 608. 609. 610. 611. 612. 613. 614. 615. 616. 617. 618. 619. 620. 621. 622. 623. 624. 625. 626. 627. 628. 629. 630. 631. 632. 633. 634. 635. 636. 637. 638. 639. 640. 641. 642. 643. 644. 645. 646. 647. 648. 649. 650. 651. 652. 653. 654. 655. 656. 657. 658. 659. 660. 661. 662. 663. 664. 665. 666. 667. 668. 669. 670. 671. 672. 673. 674. 675. 676. 677. 678. 679. 680. 681. 682. 683. 684. 685. 686. 687. 688. 689. 690. 691. 692. 693. 694. 695. 696. 697. 698. 699. 700. 701. 702. 703. 704. 705. 706. 707. 708. 709. 710. 711. 712. 713. 714. 715. 716. 717. 718. 719. 720. 721. 722. 723. 724. 725. 726. 727. 728. 729. 730. 731. 732. 733. 734. 735. 736. 737. 738. 739. 740. 741. 742. 743. 744. 745. 746. 747. 748. 749. 750. 751. 752. 753. 754. 755. 756. 757. 758. 759. 760. 761. 762. 763. 764. 765. 766. 767. 768. 769. 770. 771. 772. 773. 774. 775. 776. 777. 778. 779. 780. 781. 782. 783. 784. 785. 786. 787. 788. 789. 790. 791. 792. 793. 794. 795. 796. 797. 798. 799. 800. 801. 802. 803. 804. 805. 806. 807. 808. 809. 810. 811. 812. 813. 814. 815. 816. 817. 818. 819. 820. 821. 822. 823. 824. 825. 826. 827. 828. 829. 830. 831. 832. 833. 834. 835. 836. 837. 838. 839. 840. 841. 842. 843. 844. 845. 846. 847. 848. 849. 850. 851. 852. 853. 854. 855. 856. 857. 858. 859. 860. 861. 862. 863. 864. 865. 866. 867. 868. 869. 870. 871. 872. 873. 874. 875. 876. 877. 878. 879. 880. 881. 882. 883. 884. 885. 886. 887. 888. 889. 890. 891. 892. 893. 894. 895. 896. 897. 898. 899. 900. 901. 902. 903. 904. 905. 906. 907. 908. 909. 910. 911. 912. 913. 914. 915. 916. 917. 918. 919. 920. 921. 922. 923. 924. 925. 926. 927. 928. 929. 930. 931. 932. 933. 934. 935. 936. 937. 938. 939. 940. 941. 942. 943. 944. 945. 946. 947. 948. 949. 950. 951. 952. 953. 954. 955. 956. 957. 958. 959. 960. 961. 962. 963. 964. 965. 966. 967. 968. 969. 970. 971. 972. 973. 974. 975. 976. 977. 978. 979. 980. 981. 982. 983. 984. 985. 986. 987. 988. 989. 990. 991. 992. 993. 994. 995. 996. 997. 998. 999. 1000.

ANNEX IX

INSPECTION AND TESTING

- A. Inspection has to be carried out outside as well as at site.
- i) Outside inspection: Consists of inspection of fabrication, testing of equipments or machines to be supplied by the Vendor at his work-shop. Sometimes, vendors take the responsibilities of getting these tests carried out at the Purchaser's site.
 - ii) Inspection at site: Forms the important feature and consists of the following items:-
 - (a) Use of proper material - proper type of cement mix, particularly in case of jointing of acid proof flooring, proper paints, electrodes etc.;
 - (b) Proper levels of flooring are checked to avoid stagnation of water;
 - (c) In case of sterile area, for protection of moisture seepage, aluminium foil spread over roofs are not ruptured during laying of concrete;
 - (d) Sharp edges, corners, welding joints to be avoided in the sterile area;
 - (e) To see that all pipes, vessels are flushed and cleaned properly;
 - (f) Packing lubricants, and oils are used in the valves, pumps, compressor, blower and electrical equipment and installations;
 - (g) Check motor rotation, speed etc.;
 - (h) Installation of strains in the pump, blower and compressors and orifices in the pipes;
 - (i) Check correctness of instrument and electrical equipment;
 - (j) Remove all the loose material from vessels, reactors, and the area should be clean;

(k) See that special treatment of certain piping vessels and reactors have been carried out;

(l) The welding joints should be free from irregularities, grooves and depressions.

B. Testing and depression.

- i) Some of the services like liquid nitrogen, inert gas, oxygen, hydrogen production units, as well as large compressor tests are carried out by the Vendor. In fact in such services, including boiler-house, refrigeration, air-conditioning unit the Vendor prefers a turn-key job and demonstrate the performance guarantee at the site.
- ii) Statutory tests, tests for x-ray welding, boiler etc. will be undertaken and certified by statutory bodies appointed by government of the country.
- iii) No load/load tests: The following machinery and process equipment shall be subjected to no load/load test:
 - (a) Pumps, centrifuges, centrifugal extractors and washing machines;
 - (b) Driers, sterilisers and steam ejectors;
 - (c) Rotary vacuum filters, filter presses;
 - (d) Air-compressors and accessories;
 - (e) Miscellaneous process equipments with agitators;
- iv) Testing of pipelines: Such tests should include tests for strength and tightness, pneumatic tests and visual inspection.
- v) Testing of equipments, tanks vats etc.: These pertain to the tests for strength and fitness, until and, unless other codes are applicable, the code of practice for such tests are given as over:

S. No.	Description of the equipment	Test for strength	Test for tightness
1.	Steel welded, reactors mixing tank, heat exchangers and measuring equipment.		
	A. Covered by pressure vessels code with code for higher requirements for tightness.		
	1) Mounted on sturdy foundations.	Hydraulic	Hydraulic Pneumatic, if required by the engineer.
	1i) Mounted on light support	Pneumatic	Vacuum, if required by engineer.
	B. Covered by pressure vessels code for ordinary requirements		
	1) Mounted on sturdy foundation	Hydraulic	Hydraulic
	1i) Mounted on light support	Pneumatic	Pneumatic
2.	Tank receptacles working under atmospheric pressure	Filling with water	Filling with water Wetting with kerosene.
3.	Cast iron vessels.		
	1) Non-enamelled	Hydraulic	Hydraulic *)
	1i) Enamelled	As instructed by the engineer	Hydraulic
4.	Rubber lined vessels		
	1) Covered by pressure vessels code.	Hydraulic	Hydraulic
	1i) Not covered by pressure vessels code	As instructed by the engineer	
5.	Hoppers	Wetting with Kerosene Blowing with compressed air.	Wetting with Kerosene Blowing with compressed air.

*) Cracks or small holes in the enamelled layer must be checked by radiation test. These defects are not acceptable and will be either repaired or the vessel is to be rejected.

Illustrative UNIDO List of 26 Essential Drugs

A. ANALGESICS

1. Acetylsalicylic acid
2. Paracetamol

B. ANTI-INFECTIVE DRUGS

Anthelmintic drugs

3. Mebendazole
4. Piperazine

Antibacterial drugs

5. Ampicillin
6. Benzylpenicillin
7. Erythromycin
8. Sulfadimidine
9. Tetracycline

Antifilarial drugs

10. Diethylcarbamazine

Antileprosy drugs

11. Dapsone

Antimalarial drugs

12. Chloroquine
13. Primaquine

Antituberculosis drugs

14. Ethambutol
15. Isoniazid
16. Streptomycin

C. BLOOD PRODUCTS

17. Plasma fractions

D. CARDIOVASCULAR DRUGS

Antihypertensive drugs

18. Hydralazine
19. Propranolol
20. Reserpine

E. DIURETICS

21. Furosemide

F. DRUGS AFFECTING THE BLOOD

22. Hydroxocobalamin

G. HORMONES

Antidiabetic agents

23. Insulin

Oral contraceptives

24. Ethinylestradiol/Levonorgestrel

H. VITAMINS

25. Ascorbic acid
26. Retinol

Note: This list was prepared by UNIDO in consultation with WHO. The classification and nomenclature was updated according to WHO's "The Use of Essential Drugs", Technical Report Series No. 685.

ANNEX XI

To augment our efforts to improve the usefulness of the document, we would appreciate your cooperation in completing the questionnaire given below and returning it to UNIDO, Head of Negotiations Branch, P.O.Box 300, A-1400 Vienna, Austria.

QUESTIONNAIRE

1. Was the information contained in the document useful? YES NO
2. Was some of the information new to you?
If yes, please advise which articles, clauses. YES NO
3. Did you find any difficulty in applying or adopting the provisions included in the documents?
If yes, please advise. YES NO
4. Has the information provided in the document been useful to you in achieving a more favourable contract?
If yes, please indicate articles. YES NO
5. Do you have any suggestions to improve the usefulness of this document?
If yes, please elaborate, specifying the areas, articles. YES NO
6. Do you consider there is a need for updating this document?
If yes, please indicate time span. YES NO
7. Any other suggestions/comments? YES NO

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