OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.

DISCLAIMER

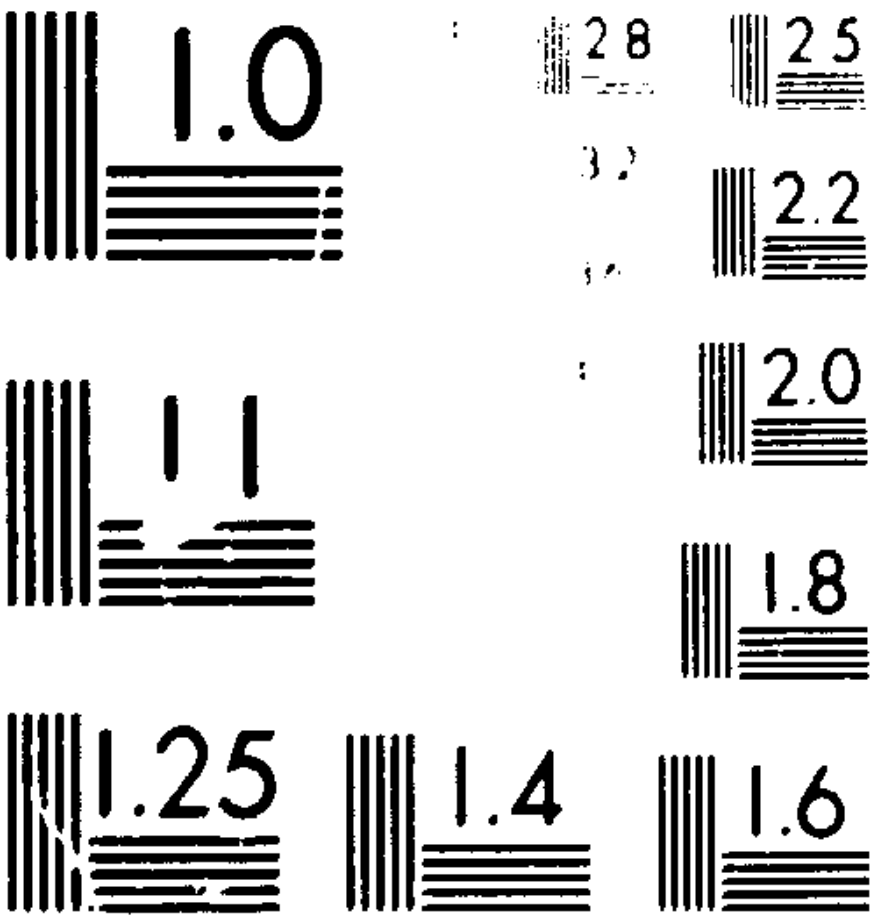
FAIR USE POLICY

CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org


1.0
2.8
2.5
2.2
2.0
1.1
1.8
1.25
1.4
1.6

09547

Distr.
LIMITED

ID/WG.317/2
14 April 1980

ENGLISH

United Nations Industrial Development Organization

Global Preparatory Meeting for
Consultations on the Pharmaceutical
Industry

Cancun (Mexico), 24-27 April 1980

PRELIMINARY DRAFT OF THE MAIN CLAUSES TO BE CONSIDERED IN DRAFTING A LICENSING AGREEMENT ON THE PHARMACEUTICAL INDUSTRY*

prepared by

C. Correa **

000361

* The views expressed in this paper are those of the author and do not necessarily reflect the views of the secretariat of UNIDO. This document has been reproduced without formal editing.

** UNIDO expert

80 40805

INTRODUCTION

a) Purpose and methodology of this document

The purpose of this document is to present a preliminary outline of the main guidelines that are to be taken into account when drafting license agreements in the pharmaceutical sector. It considers two broad categories of agreements:

1) agreements for the manufacture and marketing of products (formulations in different dosage forms), and

2) agreements for the manufacture of basic drugs.

The document is essentially concerned with agreements that take place between enterprises of developed and developing countries. It highlights the main issues to be considered when drafting the agreements referred to, taking into account the specific elements and features of the pharmaceutical sector. No attempt at being exhaustive has been made. As a method of presentation and systematization of further discussion, the document includes a number of selected possible provisions to be contained in such agreements, which are intended to reflect issues of outstanding relevance in the negotiations between the parties. These provisions should not be considered as "model clauses"; for practical purposes, they shouldbe revised and completed according to the pertinent factual circumstances and applicable legal framework. Among the variety of situations that should be taken into account when drafting such agreements, the document considers (on the side of the recipient of technology) the availability of installed productive capacities, and indicates possible specific clauses to be included in agreements whereby the supplier undertakes the provision of technology and services for the setting up such facilities.[a]

---

[a] In order to avoid repetition, these clauses are presented in a systematic manner in the third part of this document. In the first and second parts provisions related to the setting up of manufacturing facilities are included in square brackets.

Patents are dealt with here exclusively in connection with licensing issues related to such rights. This paper does not attempt to consider the complex issues involved in the procedures and substantive rules which govern the granting and maintenance of such rights, or which are concerned with the existence and extent of protection for inventions. Without prejudice to this, it is necessary to point out that the existence of patent protection in pharmaceuticals is likely to constitute a constraint for the development of national industries in developing countries, as recognized by many of theses countries (specially in Latin America) who have decided to severely limit or eliminate the granting of patents for processes and/or products in this field.

b) Terminology

In the context of this document, "License" is used in a very broad sense, comprising agreements for the use of industrial property rights, the transfer of know-how, the provision of engineering services and related supplies (including machinery). That concept also applies to agreements on formulation products (dosage forms) where tha main consideration by the supplying party may be the sale of basic drugs needed for the manufacture of formulations. Although this terminological choice may be imprecise from a strict technical point of view, it tries to reflect the current business practice in this field.

"Licensor" and "Licensee are used here to name, respectively, the supplier and recipient parties in agreements referred to

"Products" is deemed to describe the form of a final pharmaceutical formulation, in different dosage forms, such as tablet, capsule, elixir.

"Basic drug" means the basic chemical entities or active ingredients in a pharmaceutical product.

"Manufacturing" means preparation and compounding of the products from the basic raw materials and active ingredients, processing, filling , packaging and control procedures until the final dosage form.

c) Agreements for the manufacture and marketing of formulation products

Very commonly, agreements entered into by enterprises of developing countries simply consist of the supply of basic inputs plus certain information that allows the acquirer to obtain the necessary governmental authorizations for the formulations to be marketed. In these cases, the actual transfer of technology is limited; when such agreements only provide a basis for ensuring the supply of basic drugs necessary for the manufacture of formulation products, payments should generally be confined to the value of basic drugs supplied. Eventually a lump-sum for the transfer of technical and scientific information might be considered in the light of the importance and nature of the information to be transferred, such as when the licensee has no productive facilities and the licensor provides the technology and technical assistance for the setting up of a plant for the production of dosage forms. Particularly, when the Licensor is the only producer of the supplied raw-materiales or basic drugs, the payment of royalties will not be advisable from the point of view of the Licensee. Whenever the stipulation of royalties is agreed upon by the parties and approved by the competent authority, the following guidelines should apply:

1) range of royalties for formulation products (dosage forms)

(i) based on essential drugs in WHO list	0 to 1%
(ii) based on speciality drugs (according to the level of the technology transferred)	1% to 2%, (in exceptional cases royalty may be raised to 3%)

2) In any case, royalties should be calculated on net ex-factory sales price of the products, after deduction of allowances, rebates, discounts, sales or turnover taxes. In case the basic drugs are supplied by the Licensor or by a source indicated by it, the value of such drugs should also be deducted from the total net sales value.*

On the other hand, agreements for the manufacture and sale of formulation products should not contain restrictions that impair the commercial and technological freedom of the Licensee.

d) <u>Agreements for the manufacture of basic drugs.</u>

Payment conditions for the technology in these agreements may vary significantly. The agreements may provide for a lump-sum payment, royalties or a combination thereof. In any case, a breakdown of the price according to the different items involved in the agreement should be established, taking into account that the majority of payments are to be done after production starts. Whenever the modality of royalties is selected a basis of 2% (in exceptional cases it may be raised to 3% according to the level of the technology provided and the drug produced) on sales (net ex-factory value, after

---

*Some Latin American governments have proposed this method of royalty calculation, either in general or in specific connection with the pharmaceutical sector. See Correa, Carlos, Regímenes de control de la transferencia de Tecnología en América Latina, Monografía Nº 5, INTAL, Buenos Aires 1979.

deduction of bonuses, discounts, taxes and, eventually, the value of basic drugs or ingredients supplied by the Licensor) for a period of 5 years maximum should be taken into consideration.

Like in other transfer of technology transactions, these agreements may be associated to joint-venture arrangements with the foreign licensor. In such a case, the participation of the foreign company is recommended not to exceed 40% of the total capital (which should be deposited) .It can be also suggested that -in these cases-. the rate of royalty to be paid to the foreign partner should be inversely proportional to the percentage of its equity in the capital, and that a portion of its profits be spent in research and development in the host country.

PART I

MAIN CLAUSES TO BE CONSIDERED IN DRAFTING A LICENSE AGREEMENT FOR THE MANUFACTURE AND MARKETING OF FORMULATION PRODUCTS (DOSAGE FORMS).

PREAMBLE (intention of the parties)

WHEREAS the Licensor has developed a substantial body of technology in the manufacture and marketing of drugs and pharmaceutical products;

AND WHEREAS the Licensee has facilities for the manufacture, packaging and marketing of dosage forms [is desiring to set up a plant for the manufacture of formulation products in different dosage forms and their distribution and sale]*;

AND WHEREAS the Licensor is able to transfer technical information and to provide necessary inputs for the manufacture of the products indicated below, and the Licensee is willing to receive such information and inputs;

AND WHEREAS the Licensor and the Licensee intend to conclude and execute this agreement in a manner that is beneficial to the development of the pharmaceutical industry in the country of the Licensee and in conformity with the health policy of such country;

NOW THEREFORE the Licensor and the Licensee hereby agree as follows:

1) OBLIGATIONS OF THE LICENSOR

a) Supply of technical information and data ("know-how")

The Licensor shall provide the Licensee with technical information and data ("know-how") necessary for the manufacture and marketing of the formulation products listed in ..... (hereinafter referred to as "the Products"), including but not limited to, [design, plant layout] production process, quality control methods, engineering, machinery and equipment needed, and full specifications of raw materials, excipients, products and packaging

* Texts in square brackets indicate provisions to be included when the agreement involves the setting up of productive facilities.

materials.

b) Technical assistance

Licensor shall, at the request of the Licensee, send qualified technicians in its employ to the plant of the Licensee, in order to consult with and provide /engineering and other/ technical advice and assistance to the Licensee, in respect /of the engineering and construction of its facilities and/ of the manufacture of the Products. The Licensor will, in accordance with this provision, provide a maximum of ..... man-months of technical assistance.

c) Supply of medical and scientific information

(i) The Licensor shall supply all the medical, scientific and related literature and data on pharmacological and clinical trials on all the Products, including all information, reports, samples and documents required for the registration of the Products with the National Health Authorit of the Licensee's country.

(ii) Moreover, the Licensor shall inform the Licensee in due time hazards, adverse or side effects of the Products, as well as the registration status and subsequent changes of the Products in the country of the Licensor and in any other country where such Products are marketed or registered.

d) Improvements

The Licensor shall communicate to the Licensee, without delay, any improvements, rationalizations and other technical changes in items indicated above developed by or otherwise known to and applied by the Licensor, during the lifetime of this agreement.

d) Training

The Licensor shall provide an aggregate of ..... training time, to be used by not less than ..... qualified employees of the Licensee to visit, upon appropriate notice, the Licensor's domestic manufacturing facilities in order to be trained in the various methods of production and control, and to participate in the production and control of at least ..... batches from the beginning to the end.
(See also Part III of this document).

f) Supply of drugs

(i) The Licensor shall be ready to supply the Licensee with the basic drugs (as listed in .....) produced by the Licensor and entering in the formulations of the Products, as required by the Licensee, and at a price no less favourable than the price usually charged by the Licensor or other suppliers for such basic drugs in conformity with the specifications agreed upon by the parties;
(ii) Notwithstanding the foregoing, the Licensee shall be free to buy such basic drugs from other sources, provided that if the Licensor is willing and able to offer the Licensee such basic drugs at the same price as the Licensee could obtain from alternative sources or at a lower price, then in this case the Licensee shall grant preference to the Licensor.
(iii) In case the Licensor's trademarks are used on the Products, samples of the basic drugs intended to be purchased by the Licensee from other sources should be sent to the Licensor for analysis in Licensor's laboratories to ascertain their conformity with the relevant specifications. Any dispute arising from differences in analytical results of said samples will be finally determined by (a neutral drug control institute, preferably the state laboratory for control of drugs in Licensee's country).

g) Exclusivity

The Licensor shall provide items referred to in this agreement exclusively to the Licensee and to no other party in the Licensee's country.

2) OBLIGATIONS OF THE LICENSEE

a) Royalties

In consideration for the supply of technical information and data ("know-how") as provided for in 1 (a) Licensee shall pay to Licensor a royalty equivalent to .....% of the net ex-factory sales price of the Products, after deduction of discounts,, allowances, rebates, sales or turnover taxes. In case the basic drugs are supplied by the Licensor or other source indicated by it, the value of such drugs shall also be deducted from the net sales value.

b) Consideration for technical assistance by the Licensor

The Licensee shall bear travel expenses of technicians sent by the Licensor in conformity with clause 1(b) and will recognize a fee of ..... per day-man of effective work performed at Licensee's plant.

c) Confidentiality

The Licensee shall keep secret during the lifetime of the agreement the technical information specifically indicated by the Licensor as being of a confidential nature, provided that this obligation: (i) shall not apply to information which is or becomes publicly known independently of the Licensee; (ii) shall not prevent the Licensee to pass on such information to governmental authorities for registration purposes in the Licensee's country, or to grant sublicenses as stipulated in para. (4) below under similar safeguards for the confidential information as agreed upon by the Licensee.

3) USE OF THE TECHNOLOGY

No clause in this agreement shall be interpreted as directly or indirectly:

(i) limiting the field of use by the Licensee of the technology and information received thereunder, except with regard to products similar to the Products in this agreement;

(ii) preventing the Licensee from using the technology transferred after the expiration of the agreement;

(iii) preventing the Licensee from exporting the Products to any country, and in particular to neighbouring countries;

(iv) preventing the Licensee from freely determining the price and volume of production of the Products.

4) SUBLICENSING

The Licensee shall have the right to sublicense any or all of the items contained in para. 1 to any party, on terms to be mutually agreed upon between the Licensee and the Licensor.

5) GUARANTEES

a) The Licensor guarantees that:

(i) the information to be transferred is suitable for the purposes of this agreement, and that it is correct and complete;

(ii) he will indemnify the Licensee from and against all actions, proceeding, claims, damages, costs, expenses and demands by third parties in respect to the infringement or alleged infringement of any patents belonging to such parties which may be involved in the manufacture, use and sale of the Products in accordance with the terms of this agreement;

(iii) the drugs to be supplied will comply with specifications agreed upon by the parties and international pharmaceopeal standards applicable to them.

b) The Licensor will be liable for any direct loss, damage or injure arising out of vices or defects of the drugs to be supplied by him, or of the information to be transferred, provided that such information has been used in accordance with Licensor's instructions.

6) TRADEMARKS

The Licensee will have the right to use on the Products a Licensor's trademark or trademarks of his property.

7) SETTLEMENT OF DISPUTES AND APPLICABLE LAW

(i) Without prejudice to 1 (f) (iii), any dispute or claim arising out or relating to this agreement shall be finally determined by the competent courts of the licensee's country.

(ii) This agreement shall be governed by the law of the Licensee's country,

NOTE: For other provisions related to the setting up of productive facilities, see Part III

ANNEXES TO A LICENSE AGREEMENT FOR THE MANUFACTURE, PACKAGING AND MARKETING OF DOSAGE FORMS

Annex I - List of Products (referred to in para. (1) (a))

Annex II - List of basic drugs (referred to in para. (1) (ב) (i))

Annex III - Specifications of basic drugs (referred to in para. (1) (ד) (ii) and (iii)).

PART II

MAIN CLAUSES TO BE CONSIDERED IN DRAFTING A LICENSE AGREEMENT FOR THE MANUFACTURE OF BASIC DRUGS.

PREAMBLE (intention of the parties)

WHEREAS the Licensor has developed a substantial body of technology in the manufacture and marketing of basic drugs and pharmaceutical products;

AND WHEREAS the Licensee has a plant for the production of basic drugs [is desiring to set up a plant for the production of basic drugs];

AND WHEREAS the Licensor is able to transfer the technology and information necessary for such production, which the Licensee is willing to receive;

AND WHEREAS the Licensor and the Licensee intend to conclude and execute this agreement with a view to enhancing the industrial development of pharmaceuticals in the Licensee's country, and in conformity with the health policy of such country;

NOW THEREFORE, the Licensor and the Licensee hereby agree as follows:

1) OBLIGATIONS OF THE LICENSOR

a) Supply of technical information

The Licensor shall supply all necessary technical information, including but not limited to process know-how, production instructions, flow sheets, safety instructions, [plant layout, consumption coefficient, manpower requirements], specifications of equipments, intermediates and basic chemicals, to enable the Licensee to produce the basic drugs listed in ..... (hereinafter referred to as "the Drugs").

b) Patents

The Licensor grants to the Licensee a License on his patents as listed in ..... for the manufacture and sale of the drugs covered by this agreement.

c) Technical assistance

The Licensor shall, at the request of the Licensee, send qualified technicians in its employ to the plant of the Licensee, in order to consult with and provide [engineering and other] technical advice and assistance to the Licensee, in respect [of the engineering and construction of its facilities and] of the manufacture of the drugs. The Licensor will, in accordance with this provision, provide a maximum of ..... man-months of technical assistance.
(See also Part III of this document)

d) Training

The Licensor shall provide an aggregate of .... training time, to be used by not less than ..... qualified employees of the Licensee to visit, upon appropriate notice, the Licensor's domestic manufacturing facilitiss in order to be trained in the vaious methods of production and control, and to participate in the production and control of at least ..... batches from the beginning to the end.
(See also Part III of this document)

e) Supply of medical and scientific information

(i) The Licensor shall supply all medical, scientific and related literature and data on pharmacological and clinical trials on the Drugs, including information and/reports required for the approval of the Drugs by the National Health Authority of the Licensee's country;

(ii) Moreover, the Licensor shall inform the Licensee in due time any hazards, adverse or side effects of any of the Drugs in the agreement.

f) Supply of intermediates and basic chemicals

The Licensor shall supply the Licensee with intermediate(s) and basic chemical(s) necessary for the manufacturing of the Drugs, as required by the Licensee, at a price no less favourable than the price usually charged by the Licensor and other equivalent sources for the same ingredients.

g) Improvements

The Licensor shall communicate to the Licensee. without delay, any improvements, rationalizations and other technical changes in items indicated above developed by or otherwise known to and applied by the Licensor, during the lifetime of this agreement.

h) Exclusivity of this agreement

The Licensor shall provide items referred to in this agreement exclusively to the Licensee and to no other party in the Licensee's country.

2) OBLIGATIONS OF THE LICENSEE

a) Lump sum/royalties

(See Introduction, para d.)

b) Consideration for technical assistance by Licensor

The LIcensee shall bear travel expenses of technicians send by the Licensor in conformity with clause 1(c) and will recognize a fee of ..... per day-man of effective work performed at its plant.

c) Confidentiality

The Licensee shall keep secret during the lifetime of the agreement the technical information received from the Licensor and specifically indicated by the latter as being of a confidential nature, provided that this obligation shall not apply to information which is or becomes publicly known independently of the Licensee.

3) Use of the Technology

Nothing in this agreement shall be interpreted as directly or indirectly:

(i) limiting the field of use by the Licensee of the technology and information received hereunder, except with regard to drugs similar to the Drugs in the agreement;

(ii) restricting the use of such technology and information after the expiration of the agreement;

(iii) preventing the Licensee from exporting the Drugs to any country, in particular to neighbouring countries;

(iv) imposing prices or restricting the volume of production of the Drugs;

(v) designating or restricting the sources of supply of intermediate and basic chemicals to be used by the Licensee.

4) GUARANTEES

a) The Licensor guarantees that the technology and information to be transferred in suitable for the purposes of the agreement, and that it is correct and complete;

b) The Licensor represents that on the date of signing of this agreement he is, to the best of his knowledge, not aware of third parties valid patent rights or similar protection for inventions which would be infringed by the use of the technology in accordance with this agreement;

c) The Licensor will indemnify the Licensee from and against all actions by third parties in respect to the infringement or alleged infringement of any patents belonging to such parties which may be involved in the manufacture, use and sale of the Drugs.

provided that the technology is used for the purposes specifically agreed upon herein;

d) The Licensor shall be liable for any direct loss, damage or injure arising out of vices or defects of the technology and information to be transferred, but in any case such liability will not exceed the total amount received by the Licensor in conformity with para (2) (a)

e) The Licensor guarantees that the Drugs to be obtained by the Licensee will meet the unit ratio of raw materials/and quality, to final product purity, stability and all other standards specified in ... . . , provided that (i) the technology is properly used in accordance with Licensor's instructions; and (ii) intermediate, basic chemicals and other inputs employed meet the specifications agreed upon as indicated in ..... Wihtin ..... months from the signing of this agreement, tests will be carried out, in the presence of authorized representatives of the Licensor and the Licensee, in .... consecutive batches. The Licensor will be deemed to have fulfilled this guarantee if the average of the ..... batches produced meets the process guarantee and Drug standards as specified in .....

5) SETTLEMENT OF DISPUTES AND APPLICABLE LAW

a) any controversies or claims between the parties shall be finally determined by the competent courts of the Licensee's country;

b) This agreement is governed by the law of the Licensee's country

Note: For provisions more sepcifically related to the setting up of production facilities see Part II of this document.

ANNEXES TO A LICENSE AGREEMENT FOR THE MANUFACTURE OF DRUGS AND DOSAGE FORMS

I. List of Drugs (referred to in para. (1) (a))

II. List of Patents (referred to in para. (1) (b))

III. List of raw materials and intermediates (referred to in para. (1) (f))

IV. Specifications and standards for the guarantee of production (referred to in para. (4) (e))

PART III

Main specific clauses to be considered in drafting a License agreement for the manufacture of basic drugs and/or formulation products (dosage forms) including the setting up of productive facilities

Process know-how and design data, information, drawings, specifications and other requisite documents, as well as, in the case of active drugs ingredients the know-how for the production thereof from the starting materials

The know-how shall comprise:

(a) Process

(i) Process description, summary and detailed basic chemistry of the process;

(ii) Material balance (block diagram) for process streams including chemicals and catalysts. These are calculation data and not guaranteed figures; number of block diamgrams to be such to cover the operating range of the unit that is variations in quantity and/or quality of the 15 drugs;

(iii) Process flow-sheet (tabulating also composition and physical characteristics of the stream);

(iv) Utilities balance (block diamgram). These are calculation data and not guaranteed figures. Number of block diagrams as above;

(v) Utilities flow-sheet;

(vi) Mechanical flow-sheet;

(vii) Guaranteed figures.

(b) Equipment

(i) Equipment list and data sheets (for each item, duties, sketch, material specifications and other critical specifications, required dimensions, relevant notes, etc.)

(ii) Instruments list and data sheets (indicating also the control loops);

(iii) Electrical one line diagram, motor list and data sheet;

(iv) Piping specifications;

(v) Insulations and painting.

(c) Indicative layout

(i) Drawings;

(ii) Description indicating the philosophy of required arrangements.

(d) Operating instructions

(i) Production schedules;

(ii) Testing and preparation for operation;

(iii) Start-up procedures - for initial operations
- for conventional start-up
- after emergency shut-down

(iv) Normal operation;

(v) Normal shut-down procedures;

(vi) Emergency shut-down procedures;

(vii) Emergency procedures;

(viii) Safety and hazards: regulations and procedures;

(ix) Toxicity (including first-aid treatment);

(x) Maintenance manual and inspections schedule except for specific instruction on machinery;

(xi) Personnel and responsibilities;

(xii) Quality control.

(c) Chemistry

(i) Chemical and physiochemical data;

(ii) Specifications of raw materials, intermediates, finished products (standards and ranges);

(iii) Analytical and testing procedures and instruction and list of testing and analytical equipment;

(iv) Toxicity, explisivity and hazards; comments and data

(f) Supervision and approval of the plan and design of the plant, which may be prepared by the LICENSEE, from the technical point of view, prior to commencement.

(g) Supply of machinery and equipment, either directly by the LICENSOR or through his sub-contractors subject to the following:

(i) The LICENSOR shall inspect all the machinery and equipment before it is packed and shipped to the project area.* The inspection shall be performed in the project area and all costs in connexion therewith shall be solely for the account of the LICENSOR. The LICENSOR shall advise the LICENSEE at least one (1) month in advance (to the extent possible) of all such inspections and the LICENSEE shall have the right to have one or more of its representatives to witness the inspections. If at the issue of the inspections, the machinery and equipment and/or any part thereof is found to be defective or not in accordance with the relevant specifications, the LICENSOR shall, with all speed and at his own cost and expense, make good such

---

*/ For the purposes of this document, "project area" means the place where production facilities are to be set up.

defect or deficiency, or arrange for the replacement of the defective machinery and equipment. Thereafter, if LICENSEE so requires, the inspections shall be repeated and this at no cost to LICENSEE;

(ii) The LICENSOR shall be responsible for arranging for packing, insurance and shipment of the machinery and equipment to the project area. The LICENSOR ascertains that the machinery and equipment is packed in accordance with the best-established practices so as to protect them from damage during shipment under conditions which may involve multiple handling, transport by ship, rail and road, storage, exposure to heat, moisture, rain and possibility of pilferage. Shipment may be made in one or more consignments. The machinery and equipment shall be marked and dispatched according to the instructions contained in which is attached hereto and made a part hereof. All costs in connexion with the forwarding, shipping and insurance of the machinery and equipment from FOB LICENSOR port of shipment to the project area are to be paid separately by the LICENSEE. If a suitable carrier carrier cannot be found within 30 days from the time the equipment is ready for shipment, the LICENSOR shall be at liberty to make the shipment by another convenient carrier, at LICENSEE's expense.

(iii) The LICENSOR shall make a diligent effort to insure the machinery and equipment against all loss and damage from the moment it is delivered FOB LICENSOR's port of shipment until yake-over of the plant by LICENSEE at LICENSEE's cost. In such case such comprehensive insurance is not possible, LICENSOR's responsibility will cease when he has insured the equipment up to delivery at port of entry, in the country of the LICENSEE.

(iv) The Contractor shall be responsible for establishing the performance of the Pilot Plant by means of performance tests. The test run(s) period(s) shall be adequate to ensure continuous Pilot Plant operation. The test run(s) shall be considered to have been performed successfully when the performance guarantees stipulated in paragraph (1) hereinafter have been met. In the event the Pilot Plant does not meet the performance guarantees, the stipulation of paragraph (1)(iv) hereinafter shall apply.

(v) The LICENSOR guarantees that the machinery and equipment supplied through him under this Contract are new, of appropriate design and manufacture, free from defects in material and workmanship and suitable for the tasks agreed between the two parts. The LICENSOR undertakes to remedy, at his sole cost and ex[illegible]se, any defect resulting from faulty machinery and equipment design, poor materials and/or workmanship. If, for the purpose of repairing any equipment, such equipment has to be transported to LICENSOR's country and returned to LICENSEE's country, the cost of transportation both ways between the project site and LICENSOR's port of entry shall be to the account of LICENSEE. The above provision will apply, to the extent appropriate, also with respect to replacement of any equipment or part.

(vi) The guarantee referred to in paragraph (g) (v) hereinbefore shall cease on the day of the successful completion of the plant performance tests referred to in paragraph (g) (iv) hereinbefore.

(vii) In the case of equipments or parts supplied in replacement of defective equipment or parts, respectively, the guarantee period shall be 12 months from the date of shipment from the manufacturer's plant, but in any event, never less than the time required to properly test, once installed, in the case of delayed or lost shipments.

(viii) In order to be able to avail itself of its rights in this connexion, LICENSEE shall notify the LICENSOR in writing, without undue delay, of any defects that have appeared and shall give the LICENSOR ample opportunity to inspect and remedy, as appropriate, all such defects.

(ix) All defective parts replaced by the LICENSOR shall become the property of the LICENSOR, unless the LICENSOR decides to abandon them. In any event, LICENSEE shall assume no responsibility regarding the storage or safekeeping of such parts.

(x) If the LICENSOR refuses to fulfil his obligations under paragraph (g) (v) hereinbefore or fails to proceed with due diligence with the repair or replacement of defective equipment or part(s) therof, after having been required in writing by LICENSEE to do so, LICENSEE may proceed with the necessary repair or replacement work and this at the LICENSOR's sole risk, cost and expense. LICENSEE shall, under such circumstances, be obliged to take all reasonable steps to hold such repair/replacements costs to a minimum.

(xi) The LICENSOR's liability under paragraph (g) (v) hereinbefore shall apply only to defects that appear under normal conditions of operations. It does not cover defects due to causes arising from faulty maintenance after acceptance of the Plant by LICENSEE or from equipment alterations carried out without the LICENSOR's written agreement, or from repairs carried out by LICENSEE in disregard of the instructions found in the maintenance and repair manuals by the LICENSOR and/or other written instructions, nor shall they cover normal wear and tear of the equipment. The LICENSOR's liability does not apply to defects arising out of materials provided by the LICENSEE.

(h) Demonstration/Training

As part of the services and equipment referred to hereinbefore, the LICENSOR shall provide, in the Project Area and at his Home Office, such personnel services and facilities as may be necessary for:

(a) necessary and adequate demonstration to LICENSEE's personnel during the Plant establishment and commissioning operations; and

(b) the training at the LICENSOR's facilities and/or any other facilities arranged by the LICENSOR in his country of LICENSEE's personnel as for a total of engineer days. In addition, the LICENSOR shall receive the LICENSEE designers for the co-ordination of designing work. The maximum stay of the LICENSEE designers will be engineer days.

(i) Personnel Services

For the performance of his obligations under this Contract, the LICENSOR shall make available a total of man-months of service as follows:

(a) man-months of service in the Project Area shall be provided by a team comprising a Team Leader and other personnel, as named in paragraph (j) (1) hereinafter. A man-month of service in the Project Area is defined as a period of time equivalent to a calendar month of six (6) working days per week and eight (8) working hours per day.

(b) man-months of service at the LICENSOR's Home Office shall be provided by a team comprising the personnel named in paragraph (j) (1) hereinafter, and any other staff members whom the LICENSOR may deem necessary to assign to the work hereunder. A man-month of service at the LICENSOR's Home Office is defined as a period of time equivalent to a calendar month of six (6) working days per week and eight (8) working hours per day.

(c) In addition to the personnel services referred to in sub-paragraphs (a) and (b) of this paragraph, the LICENSOR shall provide, at his Home Office, such other personnel and technical facilities as may be necessary for the back-stopping support to the personnel assigned to the Project Area.

(j) LICENSOR's Personnel

(1) The personnel to be provided by the LICENSOR and the duration of their assignment in the Project Area and/or the Home Office shall be as follows:

Name	Field of Activity	Duration of Assignment (man-months) Project Area/Home Office
....	.....	.....

(2) The personnel set forth hereinbefore are considered essential for the work to be performed under this Contract, accordingly:

(a) prior to replacing any of the named personnel, the LICENSOR shall notify the LICENSEE reasonably in advance and shall submit detailed justifications together with the curriculum vitae of the proposed replacement personnel to permit evaluation by the LICENSEE of the impact which such personnel replacement would have on the work programme;

(b) no personnel replacement shall be made by the LICENSOR without the prior written consent of the LICENSEE, and in any event the LICENSEE shall be obliged to reply to the LICENSOR's nomination(s) within days of receipt of the same.

(3) The LICENSOR's Team Leader shall be responsible for ensuring thatthe work in the Project Area is performed in accordance with the terms of this Contract and for supervising, directing and co-ordinating the LICENSOR's other personnel in the performance of their duties.

(k) Training of LICENSEE's Personnel

Provide at his production facilities in LICENSOR's country, such engineering and technical services, personnel and facilities as may be necessary for:

(i) the training of designers' from LICENSEE. During this stage of training, the LICENSOR shall, in particular, assist the trainees in their design work. The duration of the training shall not be less than month consisting of no less than five (5) working days per week and eight (8) working hours per day.

(ii) the on-the-job training in the manufacture of the drug of technicians from LICENSEE. The duration of the on-the-job training shall not be less than calendar months as defined in item (i) hereinbefore.

The schedule and contents of the two (2) training programmes shall be agreed upon, in due time, between the LICENSOR, and LICENSEE. LICENSEE and the LICENSOR agree that the cost of the trainees' food and board whilst in LICENSOR's country, travel from LICENSEE's country to LICENSOR's country and return and out-of-pocket expenses shall be borne by LICENSEE.

(l) Process Demonstration and guarantee

(i) Provide all the engineering and technical services and personnel as well as the equipment required to demonstrate the Drug production process and prove the guaranteed results and efficiencies of the Know-how. This demonstration shall be witnessed by LICENSEE's and LICENSOR's representatives and shall be carried out and satisfactorily completed no later than .

(ii) Provide all the engineering and technical services and personnel required to demonstrate the Drug production process at the LICENSEE's facilities in the Project Area and to prove the guaranteed results and efficiencies of each step of the Know-how. This process demonstration shall be carried out in three (3) consecutive batches. The LICENSOR shall be deemed to have fulfilled his obligations under this Contract if the average of the three (3) batches produced meets the process guarantees and Drug standards agreed before. The protocol setting forth the results of the process demonstration in the Project Area shall be subject to the verification of, and approval by the LICENSEE. Prior to the commencement of the process demonstration in the Project Area, the LICENSEE will make available for the purpose, the production facilities and all the equipment, raw materials, intermediates, and auxiliaries, as well as a sufficient number of suitably trained personnel.

(iii) The LICENSOR warrants that after the test runs. the plant installed and commissioned with the LICENSOR's assistance and supervision and in accordance with the specifications, instructions, operating manuals and other reasonable recommendations furnished by him, is capable of performing as follows:

(iv) If for reasons solely attributable to the LICENSOR, the guarantee figures set forth in paragraph (iii) hereinbefore are not reached, the LICENSOR shall at his own cost and expense, correct or modify any faulty engineering supplied by him. If either repair in LICENSEE's country or replacement is necessary for the purpose of fulfilling the above performance guarantees, the provisions of paragraph (9) (v) hereinbefore will apply. After execution of these corrections, modifications, changes, repairs and/or replacements, which shall be carried out by the LICENSOR without delay, new performance test runs shall be carried out.

(m) LICENSOR's General Responsibility

In addition to the services, equipment and machinery specified to be supplied under this Contract, the LICENSOR shall supply such other engineering and technical services and personnel which, while not specifically provided for hereunder, are implied by generally accepted professional standards.

(n) Plant take-over by LICENSEE

After satisfactory completion of the Plant performance tests referred to in paragraph (1) hereinbefore, the LICENSOR shall hand the Plant over to LICENSEE and LICENSEE shall take the Plant over from the LICENSOR. A proper hand-over/take-over certificate shall stipulate, inter-alia, that the Plant has satisfactorily fulfilled the performance tests and met all Contract guarantees up to that period. A list of defects observed during the start-up and commissioning of the plant will be made and agreed upon at the time of hand-over. In case of defects which can be remedied with parts or materials available in LICENSEE's country, the defects shall be rectified within one month. Where parts have to be imported, the LICENSOR shall exercise all due diligence to effect necessary repairs as soon as possible, in any case within a period of six months.

If for any reason such rectification is unlikely to be completed in less than six months from the date of completion of the second test run, the LICENSEE may at its discretion decline to accept LICENSOR recommendations and in the event, the last test run completed or any subsequent test run carried out on the request of the LICENSOR within a period of six months from the date of completion of the second unsuccessful test run shall be treated as final for purposes of working out any compensation that may be payable by the LICENSOR to the LICENSEE in accordance with paragraph(o) hereof. In any event, LICENSEE shall not be obliged to take over the Plant until it is deemed satisfactory by LICENSEE and the LICENSOR's liability in this regard shall cease when all listed defects have been adequately remedied.

(o) Compensation by the LICENSOR

In the event the LICENSOR is unable to demonstrate the fulfilment of the aforesaid guarantees in a test run for reasons attributable to the LICENSOR, the LICENSOR shall pay to the LICENSEE by way of compensation an amount arrived at as follows:

(i) In the event the final test run shall indicate non-fulfilment of the guarantees in regard to production guaranteed, the LICENSOR shall pay to the LICENSEE in compensation an amount of per every 1% or fraction of 1% of the deficiency.

(ii) In the event the final test run shall indicate non-fulfilment of the guarantee in regard to consumption of , the LICENSOR shall pay to the LICENSEE in compensation an amount of per every 1% or fraction of 1% of the excess consumption.

(iii) In any event, the LICENSOR shall be responsible for all expenses incurred by the LICENSEE to correct any defect attributable to the LICENSOR.