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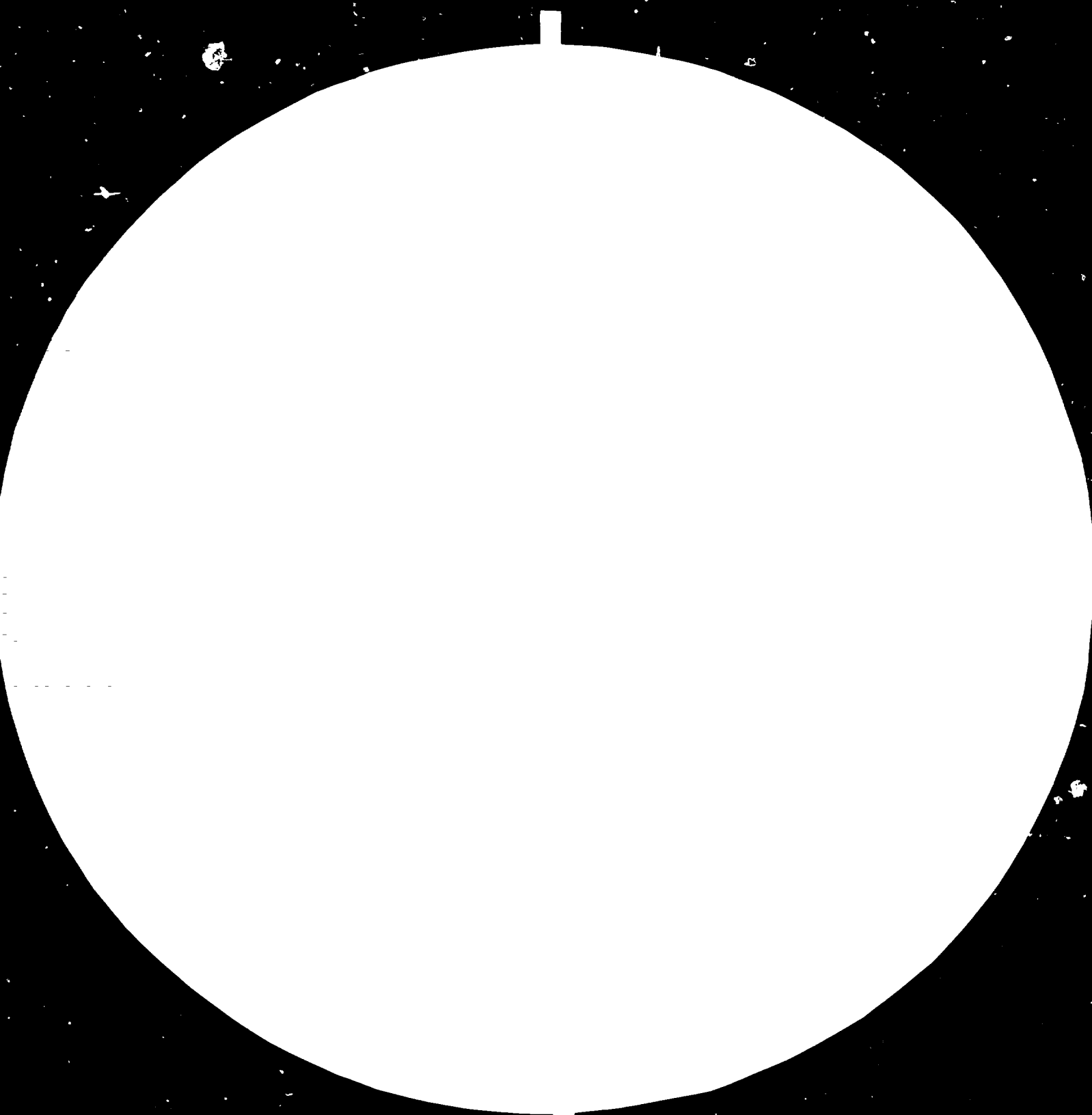
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TURN-KEY ARRANGEMENTS FOR THE
TRANSFER OF TECHNOLOGY FOR
THE PRODUCTION OF BULK DRUGS

DRAFT*

Obligations of the contractor
(specimen clauses)

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SUMMARY

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Preface

In accordance with the recommendation No. 2 of the First Consultation on the Pharmaceutical Industry 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) further recommended to concentrate part of the work on contractual arrangements on the transfer of technology for the production of bulk drugs.

As it is known, only a few developing countries currently produce bulk drugs, and there is a pressing need for fostering and improving the terms of transfer of technology to such countries, particularly for enabling the local production of essential drugs by the setting up of plants for that purpose.

Given the different degrees of technical and economic development existing in those countries, the various policies applied, with regard to transfer of technology, and the range of contractual modalities available for implementing such transfer, it seems necessary to consider at least the most important forms under which transfer of technology for the setting up of plants may take place. Among such forms, turn-key contracts may be used in cases where there are limited capabilities in the recipient country to divide and coordinate the work among various suppliers.

In a full turn-key contract, the contractor assumes all the responsibility vis-à-vis the purchaser for the construction of the industrial works and takes the latter's place vis-à-vis other participants in the project. However, turn-key arrangements are rarely total since civil engineering and construction are often excluded from the contractor's obligations. In effect, though the licensor assumes the full responsibilities for construction of a new unit and fulfilment of the performance guarantees, it is not possible for the licensor, which in the case of developing countries is a foreign party, to depute large numbers of their own technical personnel during the execution of the agreement. On the other side, materials, expert man power and other requirements may be obtained in the recipient country. Keeping this in mind various works pertaining to civil construction, erection etc. are given to local contractors and sub-contractors. Similarly, as far as possible, materials both for construction and mechanical erection (equipment, machinery and fitting etc.) may be purchased from local vendors. Both activities are carried out under the direct supervision and approval of the licensor.

In the case of turn-key contracts for the construction of drugs and pharmaceutical plants, the following alternative arrangements for remuneration to the licensor are in practice:

- (a) The licensor charges 15% of total cost of the project for the following services:
 - (i) Process know-how - basic engineering
 - (ii) Detailed design engineering
 - (iii) Procurement of equipment
 - (iv) Project management of construction, erection and commissioning
 - (v) Fulfilment of performance guarantee
 - (vi) Training of licensee personnel
 - (vii) Deputation of licensor personnel.

Payments to vendors for supplies and to contractors for construction and erection are made by the licensee after they are certified by the licensor.

(b) The remuneration varies from 8 to 10 percent of the total cost of the project depending upon the size of the plant and status of the technology. In this case the expenses concerning travel, lodging, boarding of licensor's personnel deputed to the site are borne by the licensee.

(c) 5 to 7 percent of the project cost, in addition, to the royalty for the process know-how (this mostly applies to case of formulations).

Some developing countries have designed policies aiming at the unpackaging of comprehensive contracts, in order to reduce costs, stimulate the participation of local suppliers and facilitate the absorption of the technology. Such policies may be incompatible with the "turn-key" type of transactions, and other forms of transfer should be applied there.

Purpose, scope and content of this document

This document has been prepared in line with the recommendations referred to above, and is primarily addressed to enterprises in developing countries which opt for turn-key arrangements in order to create productive facilities for the production of bulk drugs.

In the preparation of this document, the general principles for the transfer of technology in pharmaceuticals, as stated in a previous UNIDO document ^{*/}, have been taken into account.

The content of this document is limited to a set of specimen clauses on the main obligations undertaken by the contractor (or licensor) in a typical turn-key contract. Its purpose is to provide guidance on the scope and drafting of such obligations, and in particular, with regard to the guarantees to be accorded to the purchaser (or licensee). Of course, the provisions considered here should be properly integrated with carefully drafted provisions on the remainder issues, particularly on the purchaser's obligations including payments to the contractor, and on the contractor's liabilities for the performance of the contract.

OBLIGATIONS OF THE LICENSOR

1. Turn-key supply

The LICENSOR shall provide know-how, equipment, basic and detailed engineering of the plant, design and construction of civil works, erection of the plant and equipment, commissioning and start-up of the plant.

2. Know-how

The LICENSOR shall supply know-how comprising the following items:

(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 diagrams to be such to cover the operation 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 diagram). 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.

(*) "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.12, 17 October 1981.

(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) Indication 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.

(e) 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, explosivity and hazards; comments and data.

3. Supply of equipment

The LICENSOR shall be responsible for the 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 connection 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 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 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 connection with the forwarding, shipping and insurance of

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

the machinery and equipment from FOB LICENSOR port of shipment to the Project Area to be paid separately by the LICENSEE. If a suitable 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 take-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 LICENSOR shall be responsible for establishing the performance of the pilot plant by means of performance tests. The test run 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 (8) (iii) hereinafter have been met. In the event the pilot plant does not meet the performance guarantees, the stipulation of (8) (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 parties. The LICENSOR undertakes to remedy, at his sole cost and expense, 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 (3) (v) hereinbefore shall cease on the day of the successful completion of the plant performance tests referred to in paragraph (3) (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 connection, 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 decided 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 (3) (v) hereinbefore or fails to proceed with due diligence with the repair or replacement of defective equipment or part(s) thereof, 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/replacement costs to a minimum.
- (xi) The LICENSOR'S liability under paragraph (3)(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.

4. 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.

5. 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 (6)(1) hereinafter, and any other staff member 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.

6. 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:

<u>Name</u>	<u>Field of Activity</u>	<u>Duration of Assignment (man-months) Project Area/Home Office</u>
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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 that the 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.

7. 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 months 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.

8. Process demonstration and guarantee

The LICENSOR shall:

- (i) Provide all the engineering and technical services and personnel as well as the equipment required to demonstrate in the LICENSOR'S plant 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 guarantees 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 3(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.

9. 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.

10. Plant take-over by LICENSEE

After satisfactory completion of the plant performance tests referred to in paragraph (8) 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 be established at that time and shall be dated and signed by the representatives of the two parties. The plant 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 this is not possible, he shall be bound to fully justify any extension of time asked for. 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 satisfactorily remedied.

If for any reason such recification 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 (11) 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.

11. Liquidated damages

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.

