

DRUGS (IMPORT & EXPORT) RULES, 1976

(Copied from Manual of Drug Law, Pakistan)

S R O. 890 (I)/76. In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said. section) namely :--

CHAPTER I

1. Short title and commencement. (1) These rules may be called the Drugs (import and Export) Rules, 1976.

(2) They shall come into force at once.

2. Definitions. In these rules unless there is anything repugnant in the subject or context :-

(a) "Act" means the Drugs Act, 1976 ('XXXI of 1976); and

(b) "form" means form appended to these rules.

CHAPTER 11

IMPORT OF DRUGS

3. Import of finished drugs. Finished drugs may be imported subject to the following conditions, namely :-

(i) the importer possesses a licence to sell by way of retail wholesale, the drug intended to be imported and has adequate facilities for proper storage to preserve its properties

(ii) the importer shall, within fifteen days of establishing the letter of credit, intimate such action on Form I to an officer authorised by the Federal Government in this behalf;

(iii) the drug shall be imported in containers intended for retail sale or supply to hospitals, dispensaries or such other institutions; and

(iv) the drugs shall be imported against indents issued by the authorised indentors or local agents of the manufacturers.]

Provided that such drug may be imported in bulk containers by any person who possesses a licence for re-packing and has obtained permission in writing to such import from an officer authorised by the Federal Government in this behalf.

4. Types of licences to import drugs. Licences to import drugs shall be of the following types, namely :--

(i) licence to import drug other than the finished drugs; and

(ii) licence to Import small quantities of drugs for the purpose of clinical trial, examination, test or analysis.

5. Licences for import of drugs manufactured by one manufacturer. A single application shall be made, and a single licence shall be required, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer:

Provided that if a manufacturer front whom the drugs are to be imported has two or more premises manufacturing the same or different drugs. a separate application shall be made,. and a separate licence shall be required, in respect of the. drugs manufactured in each such premises.

6. Application for licence to import drugs. (1) An application for licence to import drugs other than finished drugs shall be made to the licensing authority in Form 2 and shall be accompanied by a fee of fifty rupees and by an undertaking in Form 3, signed by or on behalf of the manufacturer:

Provided that in the case of a subsequent application by the same importer for addition to the import licence of any drug manufactured by the same manufacturer, the fee to accompany each such application shall be twenty-five rupees.

(2) A fee of twenty. five rupees shall be paid for a duplicate copy of licence issued under this Chapter if the original is defaced, damaged or lost.

(3) An application for a licence to import small quantity of drugs for the purpose of clinical trial, examination, test or analysis shall be made to the licensing authority in Form 4; and the licensing authority may require such other particulars to be supplied as it may consider necessary.

(4) Any fee deposited under sub rule (1) or sub rule (2) shall in no case be refunded.

7. Licence to import drugs. A licence to import drugs other than finished drugs shall be issued in Form 5 and for the import of small quantity of drugs for clinical trial, examination, test or analysis shall be issued in Form 6.

8. Duration of licence to import drugs. Licence to import drugs, unless earlier suspended or cancelled, shall be valid for two years.

9. Licensing authority. For the purpose of this Chapter, "licensing authority" means the authority appointed by the Federal Government to issue licences to import drugs and includes any person subordinate to it to whom such authority may, with the approval of the Federal Government by an order in writing, delegate the power to sign licences and such other powers as may be specified in the order.

10. Grant of licence to import drugs. On receipt of an application for licence to import drugs the licensing authority shall, on being satisfied that, if granted, the conditions of the licence will be observed issue an import licence.

11. Conditions of licence to import drugs other than finished drugs: A licence to import drugs other than finished drugs shall be subject to the following conditions, namely :--

(i) the manufacturer shall at all times observe the undertaking given by him or on his behalf in Form 3;

(ii) the licensee shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice, any premises where the imported drug is stocked to inspect the means, if any, employed for testing the drug and to take samples;

(iii) the licensee shall on request furnish to the licensing authority from every batch of each drug or from such batch or batches as the licensing authority may from time to time specify as sample in such quantity as the licensing authority may consider adequate for any examination, test or analysis required to be made, and the licensee shall, if so required furnish full protocols of the tests, if any which have been applied;

(iv) the licensee shall ensure proper storage facilities for preserving the properties of the imported drug;

(v) the licensee shall maintain a complete record of utilization of the imported drug, showing particulars of the substance manufactured from it and such further particulars, if any as the licensing authority may specify and such record shall be open to the inspection of licensing authority or any person authorised in this behalf by the licensing authority

(vi) the licensee shall comply with such further requirements, if any applicable to the holders of import licences, as may be specified in any rules subsequently made under the Act in this behalf and of which the licensing authority has given to him not less than three months notice.

12. Conditions of licence to import small quantities of drugs for clinical trial, etc : A licence to import small quantities of drugs including drugs the import of which is otherwise prohibited under the Act for the purposes of clinical trial, examination, test or analysis shall be subject to the following conditions, namely:-

(a) the licensee shall exclusively use the drug for the purpose for which it has been imported and at the place specified in the licence, or at such other place as the licensing authority may from time to time authorise;

(b) the licensee shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice, the premises where the drugs are kept and to inspect the premises and investigate the manner in which the drugs are being used and to take samples thereof;

(c) the licensee shall keep record of, and shall report to the licensing authority, the drugs imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer;

(d) the licensee shall comply with such further requirements if any, applicable to the holders of licences for clinical trial, examination, test or analysis as may be specified in any rules subsequently made under the Act and of which the licensing authority has given to him not less than .one month's notice.

13. Import of drugs for personal use: Small quantities. of drugs including drugs the import. of which is otherwise prohibited tinder the Act may be imported for personal use subject to the following conditions. namely :--

(a) the drugs shall form part or a passenger's bona fide baggage and shall be intended for the exclusive .personal use. of the passenger;

(b) the quantity of any single drug so imported shall not exceed one hundred average doses:

Provided that any drug imported for personal use but not forming part of bona fide personal baggage may be allowed to be imported subject to the following conditions, namely :-

(i) the licensing authority on an application being made to it prior to the import, and. being satisfied that the drug is for bona tide personal use has granted permission for the import of the said drug; and

(ii) the quantity to be imported is, in the opinion of the licensing authority, reasonable and is covered by a prescription from a registered medical practitioner.

14. General provisions regarding import: An importer of drugs. except where such import is for personal use, shall comply with the following general provisions, namely :--

(a) the importer shall allow any person authorised in. this behalf to enter, with or without prior notice, any premises where the imported drugs are stocked, to inspect the storage facilities and to take samples for testing ;

(b) the importer shall, on being informed by the Registration Board or the licensing authority or an officer authorised by it in this behalf or the Chairman .of the Provincial Quality Control Board that any part of any batches of a drug has been found to be in contravention of the provisions. of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from sale and, so far as practicable, recall the issues already made from that batch and dispose of in such manner as the Board or, as the case may be, the authority, may direct;

(c) the importer shall maintain a record of all sales by way of wholesale made by him of the imported drugs, and such record shall be open to the inspection by any person authorised in this behalf;

(d) the importer shall ensure that the import of each batch of a drug is accompanied by--

(i) a batch certificate in Form 7 from the competent health authority or any other such agency of the country of export or from the manufacturer;

(ii) a copy of the test report of the drug from the competent health authority or any other such agency of the country of export or from the manufacturer;

(e) the importer shall maintain an inspection book on which a member of the Registration Board or of the licensing authority or an Inspector shall record proceedings of each of his visits, his impressions and the defects notified by him and such inspection book shall be signed by him as well as the. licensee or his authorised agent;

(f) the importer, shall on receipt of information of arrival of the consignment of drugs at the port of importation report in Form 8 alongwith three copies of the invoice to the officer authorised by the Federal Government to grant clearance under rule 15.

15. Procedure at customs-ports: (1) No drug shall be released from the customs unless a clearance certificates has been obtained by the importer from an officer authorised in this behalf by the Federal Government.

(2) If the Collector of Customs or an officer authorised by him has reason to suspect that any drug does not comply with the provisions of the Actor the rules made thereunder, he may, or if requested by as officer authorised in this behalf by the Federal Government shall, take samples of any drugs from the consignment and forward them to the officer-in charge of the laboratory appointed for the purpose by the Federal Government and may detain the drugs from the consignment of which samples have been taken until the report of the officer-in charge of the said laboratory on such samples is received:

Provided that if the importer gives an undertaking in writing not to dispose of the drugs without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs shall make over the consignment to the importer.

(3) If an importer who has given an undertaking under the proviso to sub-rule (2) is required by the Collector of Customs to return the consignment or any portion thereof. he shall return the consignment or portion thereof within ten days of receipt of the notice.

(4) If the officer-in-charge of the laboratory appointed for the-purpose by the Federal Government reports to the Collector of Customs that the samples of any drug in a consignment do not conform to the specification or that the drug contravenes in any other respect the provisions of the Act or the rules made thereunder and that the contravention is such it cannot be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the

importer who shall within two months of his receiving the communication, either export all the drugs of that description in the consignment to the country from which they were imported or surrender them to the Federal Government for disposal in such manner as it may deem fit:

Provided that the importer may, within fifteen days of the receipt of the report make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the Registration Board which after obtaining, if necessary, the report of the officer-in-charge of the Federal Drugs Laboratory, shall pass orders thereon which shall be final.

(5) If the officer-in-charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any drug contravene in any respect the provisions of the Act or the rules made thereunder and that the contravention is such that it can be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer and permit him to import the drug on his giving an undertaking in writing not to dispose of that drug without remedying the said contravention.

(6) A Federal or a provincial Inspector or a person authorised in this behalf by the Federal Government may physically inspect the consignment and draw samples from each batch for test and analysis as may be necessary and, if the consignment has been released by the customs, may order the importer not to sell or offer for sale or dispose of the drug for a reasonable period not exceeding one month with a view to obtain a test report:

Provided that the Federal or a provincial Inspector or such authorised officer may prohibit the disposal of a drug for a longer period if he has sufficient reason to believe that the import, in any way, is in contravention of any or the provision of the Act or these rules in which case the importer shall not dispose of that drug until a certificate authorising the sale of the batch has been issued to him.

16. Suspension and cancellation of licence to import drugs: If the manufacturer or licensee fails to comply with any of the conditions of a licence to import drugs or violates any of the provisions of the Act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being heard, by an order in writing stating the reason therefor, suspend or cancel the licence for such period as it thinks fit or cancel for all times, either wholly or in respect of some of the drugs to which it relates or, if the nature of offence is so serious that it is likely to endanger the public health, may prohibit the import of all other drugs of the said manufacturer:

Provided that a person who is aggrieved by the suspension or cancellation of his licence, may, within sixty days of the receipt of such order, appeal to the Appellate Board.

CHAPTER III

EXPORT OF DRUGS

17. Export of finished drugs: Finished drugs may be exported subject to the condition that the exporter possesses a licence to manufacture or sell by way of retail sale or wholesale.

18. Licences for export drugs: A licence to export drugs shall be required in Form 9 for the export of drugs other than the finished drugs.

19. Licences for export of drugs manufactured by one manufacturer: A single application shall be made, and a single licence shall be required in respect of the export of more than one drug or class of drugs manufactured by the same manufacturer:

Provided that if a manufacturer has two or more premises manufacturing the same or different drugs, a separate application shall be made, and a separate licence shall be required, in respect of the drugs manufactured in each such premises.

20. Application for licence to export drugs: (1) An application for licence to export drugs shall be made to the licensing authority in Form 10 alongwith an undertaking on Form 11 signed by the manufacturer and shall be accompanied by a fee of fifty rupees:

Provided that in the case of a subsequent application by the same exporter for addition to the export licence of any drug manufactured by the same manufacturer, the fee to accompany each such application shall be twenty-five rupees.

(2) A fee of twenty-five rupees shall be paid for a duplicate copy of licence issued under this Chapter if the original is defaced, damaged or lost.

(3) An application for a licence to export small quantity of drugs, including drugs the export of which is otherwise prohibited under the Act, for the purpose of clinical trial, examination, test or analysis shall be made to the licensing authority in Form 12; and the licensing authority may require such other particulars to be supplied as it may consider necessary.

(4) Any fee deposited under sub-rule (1) or sub-rule (2) shall in no case be refunded.

21. Duration of a licence to export drugs: A licence to export drugs, unless earlier suspended or cancelled, shall be valid for two years:

Provided that if application for a fresh licence, is made three month, before the expiry of the existing licence, the current licence shall continue to be in force until orders are passed on the application

22. Licensing Authority: For the purpose of this Chapter. "licensing authority" means the authority appointed by the Federal Government to issue export licences and includes any person subordinate to it to which such authority may, with the approval of the Federal Government by an order in writing, delegate the power to sign licences and such other powers as may be prescribed in the order.

23. Grant of export licence: On receipt of an application for an export licence, the licensing authority shall, on being satisfied that, if granted, the conditions of the licence will be observed, issue an export licence.

24. Conditions of licence to export drugs: A licence to export drugs other than finished drugs shall be subject to the following conditions, namely :-

(i) the licensee shall allow any person authorised by the licensing authority in this behalf to enter, with or without prior notice, any premises where the drug to be exported is stocked to inspect the means, if any employed for testing the drug and to take samples;

(ii) the licensee shall on request furnish to the licensing authority from every batch of each drug or from such batch or batches as the licensing authority may from time to time specify samples in such quantity as the licensing authority may consider adequate for any examination, test or analysis required to be made and the licensee shall, if so required furnish full protocols of the tests, if any, which have been applied;

(iii) if the licensing authority so directs, the licensee shall not export or offer for export any batch in respect of which a sample is, or protocols are, furnished under clause (ii) until a certificate authorising the export of the batch has been issued to him by or on behalf of the licensing authority:

(iv) the licensee shall, on being informed by the licensing authority that any part of any batch of a drug has been found by the licensing authority not to conform to

the required specifications and on being directed so to do, withdraw the remainder of that batch from export and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that batch;

(v) the licensee shall maintain a record of all exports made by him of each drug showing particulars of the drug and of the person to whom exported and such further particulars, if any, as the licensing authority may specify, and such record shall be open to the inspection of any inspector authorised in that behalf by the licensing authority and such records shall be preserved for three years from the date of the export of the drug;

(vi) the licensee shall cause the drugs to be packed and labelled in conformity with the requirements of the consignee;

(vii) the licensee shall ensure proper storage facilities for preserving the properties of the drugs to be exported during storage;

(viii) the licensee shall comply with such further requirements, if any, applicable to the holders of export licenses, as may be specified in any rules subsequently made under the Act in this behalf and of which the licensing authority has given to him not less than three months' notice.

25. Export of drugs for the purposes of clinical trial, examination, test analysis or personal use: Small quantities of drugs, including drugs the export of which is otherwise prohibited under the Act, may be exported for the purposes of clinical trial examination, test, analysis or personal use with the written permission of the licensing authority.

26. Statement to accompany drugs for export: All consignments of drugs sought to be exported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the names and quantities of the drugs.

27. General provisions regarding export: An exporter of drugs, except where such export is for personal use, shall comply with the following general provisions, namely:-

(a) The exporter shall allow any person authorised in this behalf to enter with or without prior notice, any premises where the drugs to be exported are stocked, in inspect the storage facilities and take samples for testing.

(b) The exporter shall, on being informed by the Registration Board or the licensing authority or an officer authorised by it in this behalf or the Chairman of the Provincial Quality Control board that any part of any batch of a drug has been found in contravention of any of the provisions of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from export and so far as practicable, recall the issues already made from that batch and dispose of it in such manner as the Board, or, as the case may be, the licensing authority, may direct.

(c) The exporter shall maintain a record of all exports of drugs made by him and such record shall be open to inspection by any person authorised in this behalf.

(d) the exporter shall maintain an inspection book on which a member of the Registration board or the licensing authority or an Inspector shall record proceedings of each of his visits, his impressions, and the defects noticed by him and such inspection book shall be signed by him as well as the licensee or his authorised agent.

28. Procedure at customs port: (1) If the Collector of Customs or an officer authorised by him has reason to suspect that any drug does not comply with the provisions of the Act or the rules make thereunder, he may, and if requested by an officer appointed for this purpose by the Federal Government shall, take samples of any drugs from the consignment and forward them to the officer-in-charge of the laboratory appointed for the purpose by the Federal Government and may

detain the drugs from the consignment of which samples have been taken until the report of the officer-in-charge of the said laboratory on such samples is received:

Provided that if the exporter gives an undertaking in writing not to export or dispose of the drugs without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs shall make over the consignment to the exporter.

(2) If an exporter who has given an undertaking under the proviso to sub-rule (1) is required by the Collector of Customs to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of the receipt of the notice.

(3) If the officer in-charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any drug in a consignment do not conform to the specifications or that the drug contravenes in any other respect the provisions of the Act or the rules made thereunder and that the contravention is such that it cannot be remedied by the exporter, the Collector of Customs shall communicate the report forthwith to the exporter who shall cause them to be destroyed or surrender them to the Federal Government for disposal in such manner as it may deem fit:

Provided that the exporter may, within fifteen days of the receipt of the report, make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the Registration Board which after obtaining, if necessary, the report of the officer-in-charge of the Federal Drugs Laboratory, shall pass orders thereon which shall be final.

(4) If the officer-in-charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any drug contravene in any respect the provisions of the Act or the rules made thereunder and that the contravention is such that it can be remedied by the

exporter, the Collector of Customs shall communicate the report forthwith to the exporter and permit him to withdraw the drug on his giving an undertaking in writing not to export that drug without remedying the said contravention.

29. Suspension and cancellation of license to export drugs: If the manufacturer or licensee fails to comply with any of the conditions of license to export drugs or violates any of the provisions of the Act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being heard, by an order in writing stating the reasons therefor, suspend or cancel it for such period as it thinks fit or cancel for all times, either wholly or in respect of some of the drugs, to which it relates or, if the nature of offense is so serious that it is likely to endanger the public health, may prohibit the export of all other drugs of the said manufacturer:

Provided that a person who is aggrieved by the suspension or cancellation of his license, may within sixty days of the receipt of such order, appeal to the Appellate Board.

FORM 1

[See rule 3 (ii)]

INTIMATION REGARDING IMPORT

I/We.....of.....have established the letter of credit to conduct import of drug(s) details of which are as follows:--

(i) Name of the drug(s) -----

(ii) Drug Registration number(s) -----

(iii) Name and address of Manufacturer -----

(iv) Name and address of exporter -----

(v) Date of establishing L/C -----

(vi) Quantity to be imported -----

(vii) Rate per unit -----

(viii) Total C & F value -----

(ix) Mode of shipment -----

(x) Expected date of arrival -----

(xi) Nature of Drugs Sale License -----

Date-----

Signed-----

FORM 2

[See rule 6 (1)]

APPLICATION FOR LICENSE TO IMPORT DRUG(S)

*I/We -----hereby apply for import of drug(s) specified below
manufactured by----- of-----.*

NAME OF DRUG(S)

*I/We-----enclose herewith an undertaking in Form 3 signed by or
on behalf of the manufacturer as required by the rule under the Drugs Act, 1976.*

FORM 3

[See rule 5 (1)]

*FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR LICENSE TO
IMPORT DRUGS*

*Whereas-----of-----intends to apply for a license under
the Drugs (Import and Export) Rules, 1976, for the import into Pakistan of the
drug(s) specified below manufactured by us. We-----of-----
-----hereby give this undertaking that:*

*(1) the said applicant has made a contract with us for import of drug(s)
mentioned in the undertaking;*

*(2) we declare that we are bonafide licensed manufacturer of the drugs covered
under this undertaking at the premises specified below and we shall report
change, if any, in the said premises;*

*(3) we shall comply with the conditions imposed on a license by the rules under
the Drugs Act, 1976 and such other requirements as may be laid down by the
Government of Pakistan in this behalf;*

*(4) the drug(s) mentioned below conform(s) to the provisions of the Drugs Act,
1976, and the rules made thereunder.*

NAME OF THE DRUG(S)

Particulars of the premises where manufacture is carried on.

Date----- Signature of Manufacturer-----

FORM 4

[See rule 6 (3)]

APPLICATION FOR LICENSE TO IMPORT DRUGS FOR THE PURPOSE OF CLINICAL TRIAL, EXAMINATION, TEST OR ANALYSIS

I/We-----of-----by occupation-----hereby apply for a license to import the drug(s) analysis at-----and I/We undertake to comply with the conditions applicable to the license under rule 12 of the Drugs (Import and Export) Rules, 1976.

Name of drug(s)----- Quantities-----

Manufactured by-----

Date----- Signature-----

Name and address of applicant

FORM 5

(See rule 7)

LICENSE TO IMPORT DRUG(S)

Number of license-----M/s----- of-----is/are hereby licensed to import into Pakistan during the period for which this license is in force the drug(s) specified below, manufactured by-----of-----
-----.

2. This license is subject to the conditions prescribed in the Drugs Act, 1976 and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said Rules:

Name of Drug(s) to which this license applied:

(1) -----

(2) -----

(3) -----

Date----- Licensing Authority-----

FORM 6

[See rule 7]

LICENSE TO IMPORT DRUG(S) FOR CLINICAL TRIAL, EXAMINATION, TEST OR ANALYSIS

No. of license-----M/s-----of----- is/are hereby licensed to import from-----the drug(s) specified below for the purpose of clinical trial, examination test or analysis at----- or in such other place as the licensing authority may from time to time authorise.

2. This license is subject to the condition prescribed in rule 12 of the Drugs (Import and Export) Rules, 1976, and such other conditions as may be prescribed by the Federal Government in this behalf.

3. This license shall, unless, previously suspended or cancelled, be in force for a period of two years from the date specified below:

Name(s) of drug(s) with quantities which may be imported

Date----- Licensing Authority-----

FORM 7

[See rule 14 (d) (I)]

BATCH CERTIFICATION

Name and Registration No. of drug -----

Batch number of drug -----

Name and address of the Manufacturer -----

Date of Manufacture -----

Date of expiry, if any -----

It is hereby certified that the above-mentioned drug (s) has/have been manufactured and labelled in conformity with the provisions of the Drugs Act, 1976, and the rules made thereunder.

It is further certified that this/these drug (s) has/have been manufactured under a valid permit/license issued by the competent Health or any other authority to manufacture this/these drug(s).

Signed -----

*Name, designation and official seal of the Signatory -----
-----*

Place and date -----

FORM 8

[See rule 14 (f)]

Intimation of arrival of consignment (s) of imported drug (s) other than those imported for personal use.

Name and address of importer.

Status (whether commercial importer or industrial consumer).

Drugs Manufacturing License No (in case of industrial consumer).

Drug Import License No. (in case of industrial consumer).

C.C.I., &E License No. with date and value of the License.

Import Policy Order applicable.

Name and address of exporter/manufacturer.

Name of drug (with dosage form for finished drug)

Drug Registration No. finished drug

Rate (for C & F/F.O.B.)

Packing

Quantity

Total Value

FORM 9

(See rule 18)

LICENCE TO EXPORT DRUG (S)

Number of licence.....M/s.....of.....is/are hereby licensed to export during the period for which this licence is in force the drug specified below manufactured.....

(2) This licence is subject to the conditions prescribed in the rules under the Drugs Act, 1976, and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said rules.

Name (s) of drug (s) to which the licence applied:

Dated..... Licensing Authority

FORM 10

[See rule 20 (1)]

APPLICATION FOR A LICENCE TO EXPORT DRUG

I/We of hereby apply for licence to export the drugs specified below manufactured by.....

Name (s) of drugs

I/Weenclose herewith an undertaking in form 11 signed by the manufacturer/exporter as required by rule under Drugs Act, 1976.

Date Exporter

FORM 11

See rule 20 (2)]

FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR AN EXPORT LICENCE

Whereasofintends to apply for licence under the Drugs (Import and Export) Rules, 1976 for the export of the drug (s) specified below manufactured by

(1) the said applicant has made a contract with use for thc purchase of drug (s) mentioned in the undertaking;

(2) we shall comply with the conditions imposed on a licensee made the Drugs Act, 1976;

(3) we declare that we are carrying on the manufacture of drug (s) mentioned in this undertaking at the premises specified below and we shall from time to time, report any change of premises on which the manufacture will be carried on and, in cases where manufacture is carried on in more than one factory, any change in the distributions between the factories;

(4) every drug manufactured by us for export under licence shall conform with the provisions of the Drugs Act, 1976 and the Rules made thereunder;

(5) we shall comply with such further requirements if any, as may be specified by rules made by the Federal Government under the Act and of which the licensing authority has given to the licensee not less than three months notice.

List of drug (s)

Particulars of premises where manufacture is carried on.

Date Signed by the manufacturer.

FORM 12

[See rule 20 (3)]

APPLICATION FOR EXPORT OF SMALL QUANTITIES OF DRUG (s) FOR THE PURPOSE OF CLINICAL TRIALS, EXAMINATION, TEST OR ANALYSIS OR FOR PERSONAL USE

I/We of hereby apply for permission to export the drug (s) specified below manufactured by of for the purpose of clinical trials, examination, test or 2analysis or for personal use

Name (s) of drug (s)

Date..... Exporter