Guidance Document on Common Submission Format for Import & Registration of Drug(s) (Bulk & Finished Formulations) in India

General Considerations for Import of Drugs as per
Drugs & Cosmetic Act, 1940 and Rules, 1945

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Import & Registration Division
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health and Family Welfare
Government of India

Notice: This guidance document is aimed only for creating public awareness about registration and import of Drugs and is not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act 1940 and Drugs Rules 1945 and respective Guidelines/Clarifications issued by CDSCO from time to time for all their professional needs.

Abbreviation

API	Active Pharmaceutical Ingredient
BD	Bulk Drug
CAPA	Corrective and Preventive Action
CDSCO	Central Drugs Standard Control Organization
COA	Certificate of Analysis
COPP	Certificate of Pharmaceutical Product
CTD	Common Technical Document
DCG(I)	Drugs Controller General (India)
DDA	Deputy Decision Authority
DMF	Drug Master File
ECS	Electronics Clearance System
EDQM	European Directorate for the Quality of Medicine and Health Care
EOU	Export Oriented Unit
FF	Finished Formulation
FSC	Free Sale Certificate
GMP	Good Manufacturing Practice
GSR	General Statutory Rules
IL	Import License
JDC	Joint Drug Controller
LA	Licensing Authority
NDCT	New Drugs and Clinical Trials Rules
NOC	No Objection Certificate
NO	Nodal Officer
PAC	Post Approval Change
POA	Power of Attorney
RC	Registration Certificate
RO	Reviewing Officer
SMF	Site Master File
SOP	Standard Operating Procedure
WHO	World Health Organization

Contents

1. Introduction

1.1 General Considerations

The Central Drugs Standard Control Organization (CDSCO) previously published the Guidance Document on Common Submission Format for Import & Registration of Bulk Drugs and Finished Formulations in India (Document No. IMP/REG/200711). Since its publication, the application processes for import and registration have been transitioned to the online SUGAM portal—an e-Governance initiative of CDSCO to facilitate efficient processing, enhance transparency, and promote ease of doing business, hence the revised guidance to be published for awareness of the public/stakeholders.

This revised Guidance Document (Version 1.0) has been prepared to reflect the current regulatory framework and online submission procedures. It serves as a comprehensive reference for applicants by outlining the standard procedures, documentation requirements, and regulatory provisions governing the import and registration of drugs (for human use) under the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945 made thereunder. The document is intended to assist stakeholders in ensuring compliance with the applicable regulatory requirements prescribed by the Central Drugs Standard Control Organization (CDSCO) under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.

1.2 Purpose of the Manual

It is intended to ensure uniformity, transparency, and efficiency in the execution of activities related to the import and registration of drugs and pharmaceutical products in India. In India, the import, manufacturing, sale, and distribution of drugs are regulated under the Drugs and Cosmetics Act, 1940, and Rules, 1945, with the import of drugs specifically governed by the provisions of Chapter III of the Act and Part IV of the Rules, and applications for registration certificates and import licenses processed in accordance with Rules 24A and 24, respectively.

At present, bulk drug (Active Pharmaceutical Ingredients) and finished formulations are regulated under the said Act & Rules. Any substance falling within the definition of drug (Section 3b of the Act) required to be registered before import into and use in the country. Not only drug but the manufacturing site needs to be registered for import. If the drugs, fall within the definition of New Drug (As per Rule 2 (w) of the

NDCT Rules, 2019), the new drug approval is the pre-requisite for submission of application for Registration and or import of drug. The application for Registration and import can be made to the Licensing Authority under the said Act i.e. to the Drugs Controller General (I) at CDSCO, FDA Bhawan, Kotla Road, Near Bal Bhawan, New Delhi by the Indian Authorized Agent of the foreign manufacturer having either manufacturing or sale license or by the foreign manufacturers having a wholesale license in the country.

1.3 Scope

The manual outlines the step-by-step processes from application submission to document evaluation, approval, and post-approval compliance for the import and registration of drugs (for human use) - to ensure uniform and effective implementation of the regulatory provisions prescribed under the provisions of the Drugs and Cosmetics Act, 1940, and Rules, 1945 thereunder.

1.4 Objectives

- To regulate the import of drugs in accordance with the provisions of the Drugs and Cosmetics Act, 1940, and the Drugs Rules, 1945.
- To ensure that all imported drugs comply with the prescribed standards of quality, safety, and efficacy.
- To process and approve applications for registration certificates and import licenses in a transparent and time-bound manner.
- To establish and maintain an efficient, accountable, and technology-driven system for the regulation of drug to be imported.
- To collaborate with national and international authorities and stakeholders to ensure effective enforcement and regulatory compliance.

1.5 Functions

The Import & Registration Division is responsible for processing of applications for the approval, regulation, and monitoring of import of drugs i.e. bulk drug (BD)-Active Pharmaceutical Ingredients and finished formulations for Human use in India. It ensures that products comply with the standards laid out in the Drugs and Cosmetics Act, 1940,

and Drugs Rules, 1945 thereunder.

- Issuance of Registration Certificate in Form 41 for Bulk drug and finished formulation under Rule 24-A.
- Issuance of Import License in Form 10 / Form 10A for Bulk Drug and Finished formulation under Rule 24.
- Processing of Post Approval Change application.
- Issuance of No Objection Certificate for the import of drugs with residual shelf life less than 60% under Rule-31
- Issuance of No Objection Certificate for the grant of permission for overprinting/stickering/stamping on label imported drugs under Rule 104-A
- To grant further packing permission under Rule-37 for patent or proprietary medicines.
- To grant No Objection Certificate for imports of drugs by by charitable hospital free of cost under Rule 36A.
- Coordination with CDSCO Zonal/Sub-Zonal/Port Offices for port clearance, sampling, and testing of imported consignments.
- Providing guidance and clarification on regulatory requirements to stakeholders.
- Maintenance of digital and physical records, databases, for effective monitoring and compliance.

1.6 Reference

- Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 thereunder as amended.
- Schedule D(I) (for registration of the manufacturing Premises)
- Schedule D(II) (for registration of the drugs).

1.7 Responsibility

CDSCO is responsible for implementing these provisions and revising them as notified by the Competent Authority from time to time.

2. Process for Registration and imports of Drug(s)

"Registration Certificate" means a certificate issued under Rule 27A by the Licensing Authority in Form 41 for registration of premises and the drugs manufactured by the manufacturer meant for import into and use in India.

"Import Licence" means either a licence in Form 10 to import drugs, excluding those specified in Schedule X, or a licence in Form10A to import drugs specified in Schedule X.

All the applications for Registration Certificate (RC) and Import License (IL) are to be made online on the Sugam portal of the CDSCO at https://www.cdscoonline.gov.in.

There are three types of RC Applications:

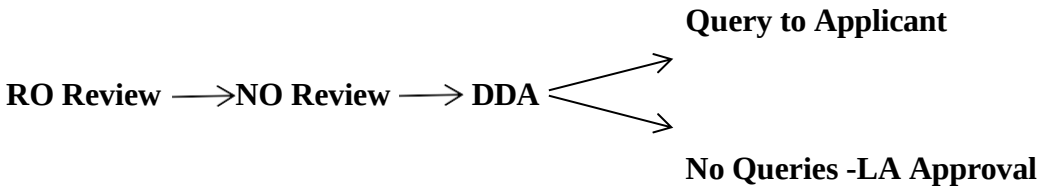
(1) Fresh,

(2) Re-registration (renewal) and

(3) Endorsement

2.1 Step-by-step Process: Registration Certificate (Form-41)

1. **Application Submission**: The applicant submits (Form-40) application in SUGAM portal along with required documents for the import of drugs in India
2. **Document Review**: CDSCO reviews the submitted documents as per SUGAM Checklist.

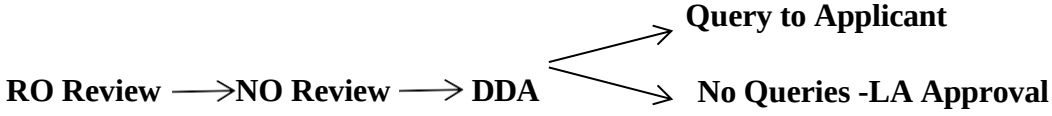


3. **Issuance of Registration Certificate:** After approval, LA issues a Registration Certificate for registration of foreign manufacturing site with drugs i.e. bulk drug (BD)-Active Pharmaceutical Ingredients and finished formulations.

2.2 Step-by-step Process: Import License (Form-10)

1. **Application Submission**: The applicant submits (Form-I0) application in SUGAM portal along with required documents for the import of drugs in India.

2. **Document Review**: CDSCO reviews the submitted documents as per SUGAM Checklist.

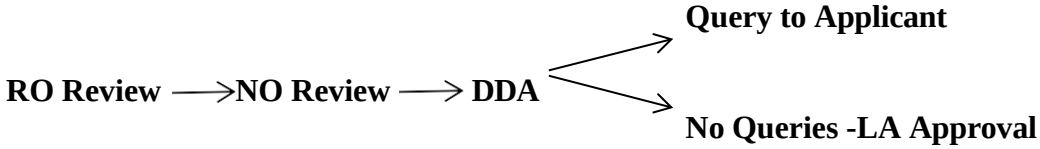


3. **Issuance of Import License**: After approval, LA issues an import license allowing the product to be brought into India.

2.3 Step-by-step Process: Post Approval Change-

If there is any amendment in RC then Post Approval Change (PAC) application has to be applied.

1. **Application Submission**: The applicant submits PAC application in SUGAM portal along with required documents for the import of drugs in India.
2. **Document Review**: CDSCO reviews the submitted documents as per SUGAM Checklist



3. **Issuance PAC**: After approval, LA issues PAC allowing amendment in Registration Certificate.

2.4 Brief about application review process-

1. NOC - Importing drugs having <60% shelf life as per Rule 31
2. NOC - Importing drugs by charitable hospital free of cost as per Rule 36A
3. NOC - Stickering/overprinting/stamping/code as per 104A
4. NOC – further packing permission as per Rule 37

3. Documents and Forms

3.1 Registration Certificate Checklist

S. No	Item Name
1.	Covering Letter
2.	Original Power of Attorney
3.	Copy of Import permission for new drug (s) in Form-45 (formulation) or in Form- 45A (new bulk drug substances)
4.	Copy of Wholesale License (20B/21B) or Manufacturing License of the Indian agent
5.	**Authorization letter**
5.1	A legal undertaking from Indian agent providing the name, designation, signature telephone number, e-mail & fax of the authorized person responsible for the signing of documents Form 40, Power of Attorney & Form 9 for the registration & issue of Import License
5.2	A legal undertaking from manufacturer providing the name, designation, signature telephone number, e-mail & fax of the authorized person responsible for the signing of documents Form 40, Power of Attorney & Form 9 for the registration & issue of Import License.
5.3	Company's authorization letter (in original) for the bearer to submission and collect letter.
5.4	A legal undertaking from manufacturer for submitting of fresh Power of Attorney at the time of renewal application
6.	**Schedule D (I)**
6.1	Schedule D (I) and Undertaking duly signed, dated and seal/stamped with name and designation of the authorized signatory of the manufacturer or his authorized Indian agent.
6.1.1	Any other supportive document to be given with respect to Schedule D (I)
6.2	Notarized Plant Master File
6.2.1	List of Major equipment in Production and QC
6.2.2	List of key personals with qualifications, experience and their responsibilities
6.2.3	Organizational Chart
6.2.4	QA functional Chart
6.2.5	Plant Layout
6.2.6	HVAC system drawing
6.2.7	Water system drawing
6.2.8	Pressure differential drawing
6.2.9	Personal movement drawing
6.2.10	Material movement drawing
6.2.11	Distribution, Complaints & products recall SOP
6.2.12	List of Contract Manufacturing/analysis
7.	**Schedule D (II)**
7.1	Schedule D (II) and Undertaking duly signed, dated and seal/stamped with name

	and designation of the authorized signatory of the manufacturer or his authorized Indian agent.
7.1.1	Any other supportive document to be given with respect to Schedule D II.
7.2.1	Process flow chart
7.2.2	Manufacturing process development report.
7.2.3	Control of critical steps.
7.2.4	Process validation report of three batches.
7.2.5.	List of Impurities and related substances
7.2.6	List of Residual solvents and its limits.
7.2.7	Testing procedure of impurities, related substances and residual solvents.
7.2.8	Source and maintenance of reference standards.
7.2.9	Container and closure system and its testing procedure.
7.2.10	Batch determination: batch numbering system & batch size.
7.2.11.	Specification of the products & material used in its manufacturing
7.2.12	Justification of the Specification.
7.2.13	Certification of analysis of five batches.
7.2.14	Labels and Package insert.
7.2.15	MSDS
7.2.16	Details of PMS studies.
7.3.1	Long term stability data
7.3.2	Accelerated stability data
7.3.3	Stability study summary
8.1.	**Manufacturing License/Product authorization certificate, in case of China**
8.1.1	Manufacturing License/Product authorization certificate, in case of China.
8.2.1	GMP Certificate (Duly Apostilled/Notarized copy).
8.3.	**COPP Certificate (Duly Apostilled/Notarized copy)**
8.3.1	COPP Certificate (Duly Apostilled/Notarized copy)
8.4.	**FSC Certificate (Duly Apostilled/Notarized copy)**
8.4.1	FSC Certificate (Duly Apostilled/Notarized copy)
9.	**Attested/Apostilled copy of**
9.1	Product Registration Certificate (SFDA), in case of China.
9.2	Certificate of suitability from EDQM
10.	Original label /specimen label complying with Rule 96 & 97 and indicating name of the drug with pharmacopoeia specification, the importer name & address as per Wholesale license and Import License number. If proposed draft label/package insert wherever applicable, then duly attested either by the authorized Indian Agent or by the manufacturer is required to be submitted along with the application.
11.	CDTL/CDL/IPC test report of consecutive three batches for fresh/endorsement of RC.
12.	Upload Form 40.
13	TR-6 Challan of Fees paid/Bharat Kosh Challan

3.2 Requirements for Common Submission Format for Registration of bulk drug(s) and finished formulation(s) in India

The documents are required to be submitted in the following manner and order for the Import & Registration of the bulk drug(s) and finished product(s) in India:

3.2.1 Covering Letter

The covering letter is an important part of the application and should clearly specify the intent of the application (whether the application for the registration of the manufacturing site is being submitted for the first time, whether the application is for re- registration/renewal or is for the endorsement of additional products to an existing Registration Certificate) the list of documents that are being submitted (Index with page no's) as well as any other important and relevant information may be provided in the covering letter. The covering letter should be duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory along with the name and address of the firm. Any exemption to the submission requirement be clearly specified in the covering letter on the firm/company letter head and justified in the submissions.

A Resolution shall be submitted by the proprietor of the firm in case of proprietorship firm and by the board of Directors in case of Private Limited Company/ firm.

3.2.2 Power of Attorney

The authorization by a manufacturer to his agent in India shall be documented by a Power of Attorney executed and authenticated either in India before a First-Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate. Apostille Power of Attorney from Hague convention member countries is also acceptable. Performa for Power of Attorney is enclosed at **Annexure I.**

While submitting the Power of Attorney, the following points should be kept in mind: -

It should be co-jointly signed and stamped by the manufacturer as well as the Indian Agent indicating the name & designation of the authorized signatories (along with the name and address of the firm).

It should clearly list the names of all the proposed drugs if possible, along with their specific Indication and/or intended use. Further, the names of the proposed drug should correlate with those mentioned in Form 40, Free Sale Certificate or Certificate of pharmaceutical product (COPP) as per WHO-GMP certification scheme.

The names & addresses of the manufacturer (Contract manufacturer name from different sources) as well as the Indian Agent stated in the Power of Attorney should correlate with the Form 40. Multiple sites are in tabular form. It should be valid for the period of said Registration Certificate. It implies that a fresh POA is to be submitted at the time of revalidation of RC.

3.2.3 Copy of Import permission for new drug (s)

Copy of Import permission for new drug (s) in Form-45/ CT-20 (Finished Formulation) or in Form- 45A/CT-19 (New bulk drug substances/API) is to be submitted wherever applicable.

3.2.4 Wholesale License / Manufacturing License

A duly attested/notarized (in India) and valid copy of Wholesale License or it's retention certificate for sale or distribution of drugs under Drugs Rules in Form 20B & 21B to its agent by the State Licensing Authority in India.

If the agent is a manufacturer, a duly attested/notarized (in India) and valid copy of manufacturing License or it's retention certificate with the concerned product permission with flow chart, wherever applicable issued by the State Licensing Authority.

3.2.5 Authorization letter

A legal undertaking (notarized copy) from issued by the Director/Company Secretary/Partner of the Indian Agent (along with the name and address of the firm)

providing the name, designation, signature telephone number, e-mail & fax of the authorized person responsible for the signing of documents Form 40, Power of Attorney & Form 9 for the registration & issue of Import License is to be submitted.

A legal undertaking (notarized copy) from manufacturer providing the name, designation, signature telephone number, e-mail & fax of the authorized person responsible for the signing of documents Form 40, Power of Attorney & Form-9 for the is to be submitted.

Form- 40 shall be signed by the (manufacturer or his authorized agent in India). Form 40 proforma is enclosed at **Annexure –II.**

3.2.6 Schedule D(I)

Schedule D(I) & undertaking as per the proforma prescribed in the Drugs & Cosmetics Act & Rules, signed & stamped by the manufacturer or his Authorized agent indicating the name and designation of the authorized signatory is required to be submitted as per proforma for **Schedule D(I)** is enclosed at **Annexure III.**

3.2.7 Schedule D(II)

Schedule D(II) as per the proforma prescribed in the Drugs & Cosmetics Act & Rules, signed & stamped by the manufacturer or his Authorized agent indicating the name and designation of the authorized signatory is required to be submitted as per proforma for **Schedule D(II)** is enclosed at **Annexure IV.**

3.2.8 Label Submission

As per Rule 96 and 97 of the Drugs Rules, the firm is required to submit a scannable/readable QR code enabled label artwork wherever applicable, and the storage conditions should be in line with the IP General Chapter based on stability study data of climatic Zone IVb condition (s).

3.2.9 Testing of Drugs

In case of registration of Bulk drugs (Active Pharmaceutical Ingredient) /Finished Formulation (s), the consecutive three batches are asked to be submitted to the designated laboratory for testing for which fee is to be paid by the applicant to the Laboratory as per

their norms.

The applicant should have enclosed adequate samples for re-analysis purposes from each of the three consecutive batches along with specifications, Method of analyses, COA tested in their laboratory, impurity Standards, marker compounds, Reference Standard along with its COA wherever is applicable.

3.2.10 Stability Data

The firm shall submit stability data of recent batches generated under Zone IV B conditions (30°C ± 2°C / 75% RH ± 5% RH). Annual stability data for these batches shall be provided in accordance with the requirements specified under Schedule M. The stability studies shall be designed and conducted in compliance with the applicable regulatory guidelines, including ICH Q1A(R2), WHO Technical Report Series No. 1010 (Annex 10), and the Schedule M. The data generated should be scientifically robust and sufficient to establish the product's shelf-life and ensure its continued quality, safety, and efficacy throughout the proposed storage period.

3.2.11 Manufacturing License

Duly notarized/Apostilled/Attested (by Indian Embassy the country of origin) and valid copy of the Manufacturing License and or Market Authorization Certificate in respect of applied drugs issued by the National Drug Regulatory Authority of the country of origin.

3.2.12 GMP Certificate

Duly notarized/Apostilled/Attested (by Indian Embassy the country of origin) and valid copy of Good Manufacturing Practice (GMP) certificate as per WHO -GMP guidelines or Certificate of Pharmaceutical Products (CPP) or written confirmation for active substances exported to European Union which is equivalent to GMP certificate issued as per WHO -GMP guidelines, by the National Regulatory Authority of the country of origin or a copy of the certificate equivalent to GMP certificate as per WHO GMP guidelines issued by National Regulator of United States of America or Japan or Australia or Canada or the European Union or CEP (EDQM certificate) for the purpose of marketing of the drugs in their country, in relation to bulk drugs or formulations or special product meant for import into India.

3.2.13 COPP Certificate

Duly notarized/Apostilled/Attested (by Indian Embassy the country of origin) and valid copy of COPP Certificate for each drug issued by the National Drug Regulatory Authority of the country of origin.

3.2.14 Free Sale Certificate

Duly notarized/Apostilled/Attested (by Indian Embassy the country of origin) and valid copy of Free Sale Certificate/Certificate to Foreign Government/ Certificate of Marketability for each drug issued by the National Drug Regulatory Authority of the country of origin. Free Sale Certificate should state that the proposed drug is freely sold in Country of Origin and can be legally exported.

3.2.15 Renewal of Registration or Re-registration

At the time of application for renewal of registration or re-registration, the application is to be made 9 months before the expiry of the Registration Certificate. In addition, regulatory documentary compliance like Form 40, POA, GMP / COPP, Registration certificate, DMF (soft copy if no change), License (sale or manufacturing License of drugs of the agent) etc., the following undertaking / information is to be submitted as per the pre-defined Checklist for application on the Sugam portal i.e www.cdscoonline.gov.in

- Undertakings by the manufacturer or his authorized agent in India in respect of any administrative action taken due to adverse reaction, viz. market withdrawal, regulatory restrictions, or cancellation of authorization, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed.
- Undertaking by the manufacturer or his authorized agent in India in respect of any change in manufacturing process, or in packaging, or in labeling or in testing, or in documentation of any of the drug pertaining to this Registration Certificate.
- Undertaking by the manufacturer or his authorized agent in India in respect of any change in the constitution of the firm including name and /or address of the registered office/ factory premises operating under this Registration

Certificate.

- Details of drugs imported in India during last three years.
- Submission of original RC issued

3.2.16 Fees

- A fee of [ten thousand US dollars] [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs intended for import into and use in India.
- A fee of [five thousand US dollars] [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 for the registration of a Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India for single drug meant for import into and use in India and an additional fee at the rate of [five thousand US dollars] for each additional drug:

  Provided that in the case of any subsequent application for registration of additional drugs by the same manufacturer, the fee to accompany shall be [five thousand US dollars] [or its equivalent in Indian rupees] for each drug.
- The fees shall be paid online through the Bharatkosh portal (https://bharatkosh.gov.in). After payment, the Bharatkosh receipt must be uploaded along with the application in the SUGAM portal.
- The applicant shall be liable for the payment of a fee of [twenty five thousand US dollars] [or its equivalent in Indian rupees] for expenditure as may be required for inspection or visit of the manufacturing premises of drugs, by the be required for inspection or visit of the manufacturing premises of drugs, by the Licensing Authority or by any other persons to whom powers have been delegated in this behalf by the Licensing Authority under rule 22
- The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of drug.
- A fee of [one thousand eight hundred US dollars or its equivalent in Indian rupees shall be paid for making amendment in the registration certificate.

3.3 Import License Checklist

Sr. No.	Item Name
1.	Covering Letter
2.	Copy of wholesale License/ Manufacturing License with list of products approved.
3.	Copy of Valid RC duly attested by the Indian Agent/ manufacturer
4.	Copy of permission under Rule 122A of Drug Rules, 1945/Rule 76 of NDCT Rules, 2019 in case of New Drug in the name of importer.
5.	If any condition is mentioned in RC, it should be fulfilled before making application for Form -10
6.	Original Labels/Specimen label attested by the importer for bulk drugs/ finished formulation as per Rule 96 & 97 of the Drugs Rules 1945 to be imported in the country
7.	Upload Duly signed and stamped filled Form 8/8A
8.	Form-9 undertaking
9.	TR-6 Challan of Fees paid/Bharat Kosh Challan.

3.4 Import License in Form 10/10A of Bulk Drug (s) and Finished Formulation(s) for import of drugs in India.

The following documents are required to be submitted in the following manner and order for issue of the Import License in Form 10/10A of the drugs for import into India:

3.4.1 Covering Letter

The covering letter forms an integral part of the application and must clearly specify the intent of the submission. The letter should include a list of all enclosed documents and may also highlight any other important or relevant information pertaining to the application. The covering letter shall be duly signed and stamped by the authorized signatory, indicating the name, designation, name of the firm, and complete address.

3.4.2 Copy of wholesale License/ Manufacturing License with list of products approved

A duly attested and valid copy of wholesale License for sale or distribution of drugs or manufacturing License with the concerned product permission list under Drugs Rules issued by the State Licensing Authority.

3.4.3 Copy of Valid RC duly attested by the Indian Agent/ manufacturer

A Valid copy of Registration Certificate in Form-41 issued by CDSCO with respect to proposed Drug, duly authenticated by Indian Agent.

If the Registration Certificate (RC) has been issued with specific conditions, the compliance status of those conditions before importing the drug(s) into the country is to be submitted.

3.4.4 Copy of New Drug Permission

Clearly mention whether applied drug is New Drug/Old Drug. Enclose New Drug Permission/ Copy of IP 2010 Monograph (or Addendum 2012) or earlier IP monograph/ Approval Status from CDSCO Database for Drugs being imported (API/Formulation). Further, Regularization Status of API in the country if any.

3.4.5 Label

A duly attested (by the importer) original label / specimen label for bulk drugs or finished formulations in accordance with Rule 96 and Rule 97 (as applicable) of the Drugs Rules 1945. In the case of Active Pharmaceutical Ingredients, the label shall mandatorily bear a readable QR code in compliance Rule 96 of the Drugs Rules, 1945.

3.4.6 Form 8/8A

As per the format prescribed under the Drugs Rules 1945, an application for the grant of an import license shall be submitted to the Licensing Authority in Form-8 for drugs other than those specified in Schedule X and in Form-8A for drugs covered under Schedule X. The application must be duly filled, signed, and stamped by the importer or the authorized Indian agent, clearly indicating the name and designation of the authorized signatory (**Annexure-V & VI).**

3.4.7 Form-9 Undertaking

A duly filled Form-9 (Form of Undertaking to accompany an application for an Import License), as prescribed under the Drugs Rules 1945, shall be submitted. The form must be duly signed and stamped by the Authorized Indian Agent or the manufacturer, clearly indicating the name and designation of the authorized signatory **(Annexure- VII).**

3.4.8 Fees

As prescribed under the Drugs Rules 1945, a fee of ₹10,000/- for one drug and ₹1,000/- for each additional drug shall be paid. The fees shall be paid online through the Bharatkosh portal (https://bharatkosh.gov.in). After payment, the Bharatkosh receipt must be uploaded along with the application in the SUGAM portal.

3.4.9 Validity

A license, unless it is sooner suspended or cancelled, shall be valid from the date of issuance until the period indicated in the corresponding Registration Certificate. Provided that if application for a fresh license is made three months before the expiry of the existing license the current license shall be deemed to continue in force until orders are passed on the application.

3.5 Post Approval Change Application

This section provides procedure to Registration Certificate (RC) holders and their Authorized Indian Agents regarding procedures, documentation, and fee requirements for post-approval changes (PACs) or amendments in the Registration Certificate (Form 41) of imported drugs.

Applications for PAC are made online on the Sugam portal. Various categories are defined and accordingly applicants can choose the type of PAC and submit their application accordingly as per the checklist prescribed therein.

3.5.1 Types of Post Approval Changes (PACs)

Certain example of type of PAC are tabulated as below-

Category	Description	Example
Major Changes	Substantial modifications that may impact product quality, safety, or efficacy, along with amendments that require Licensing Authority evaluation but do not have a major impact on these parameters.	• Change/modification in manufacturing process or dosage form (e.g., wet granulation to direct compression, change in route of synthesis of API) • Change in testing method (HPLC → GC/Microbiological) • Change in address or name (without constitution change) • Shelf-life change (extension/reduction) • Change in pharmacopoeia specification • Change in storage temperature • Deletion/addition of manufacturing site • Relaxation of test/specification limits
Minor Changes	Editorial or administrative updates with negligible impact on product characteristics.	• Tightening of test/specification limits • Editorial updates in package insert with approval from concerned division • Inclusion of warnings/precautions • Change in source of excipient (no formulation impact).

3.5.2 Post-Approval Amendment Fee Requirement

Registration fee for the amendment is required to be submitted for such amendments as stipulated under clause (ii) of sub rule (3) and sub rule (7) of Rule 24A the Drug Rules 1945. Certain type of amendment with their fee is described as below-

Sr. No.	Types of Amendment	Fee (USD)
1.	Change in foreign manufacturer address (No location change)	1800
2.	Change of shelf-life (Extension/Reduction)	1800
3.	Change in address of registered manufacturer (No location change)	1800
4.	Change of manufacturer name (without constitution change)	1800
5.	Change of Pharmacopoeia specification	1800
6.	Change of Pharmacopoeia specification of drug ingredients in finished formulation	1800
7.	Change in storage condition	1800
8.	Addition of pack size or change in pack presentation with approval from concerned division	1800
9.	Deletion of site involved in manufacturing	1800
10.	Addition of manufacturing site	10000
11.	Major change/modification in manufacturing, or in processing or in testing, or in documentation	5000
12.	Addition of Co-marketer	1800

3.5.3 Cases Requiring Fresh Registration Certificate (RC)/ not covered under PAC

As per Condition 6 of Form 41, the RC is valid for a maximum of three months after the change occurs unless a new RC is obtained.

A fresh RC must be applied for in the following circumstances:

1. Change of name of foreign or registered manufacturer with constitution change
2. Change of Indian agent with constitution change
3. Change in foreign manufacturer address with location change
4. Change in address of Indian agent with location change
5. Change in address of registered manufacturer with location change
6. Change in constitution of manufacturers

3.5.4 PAC for co-marketer

The application for PAC for co-marketer to be included in the Label, package insert of the

drug products wherein following documents are required to be submitted.

Checklist for PAC for co-marketer

S. No	Description
1.	Covering Letter.
2.	Legal undertaking between the importer (marketer) and Co-marketer
3.	Quality agreement between the importer (marketer) and Co-marketer
4.	Approval of NRA
5.	Copy of the label of the drug, with package insert
6.	Old Registration Certificate
7.	Fee of USD 1800

3.5.5 PAC Intimation and Approval

- The manufacturer or Indian agent must inform CDSCO immediately in writing regarding any change in constitution or address.
- In case of major changes, application for approval must be submitted within 30 days along with the applicable fee.
- The existing RC remains valid for up to 3 months' post-change, pending issuance of a fresh certificate.

4. Processing of Application for Import of Drugs

4.1 Processing of Application for Import of Drugs with residual Shelf Life Less Than 60%

As per Rule-31 of Drugs Rules, 1945 Standard for Imported drugs is laid down which states that "No drug shall be imported unless it complies with the standard of strength, quality and purity, if any", provided that the Licensing Authority shall not allow the import of any drug having less than sixty per cent residual shelf-life period as on the date of import. However, in exceptional cases the Licensing Authority may, for reasons to be recorded in writing, may allow, the import of any drug having lesser shelf-life period, but before the date of expiry as declared on the container of the drug. The issue of import of such drugs by the importers in our country holding valid Import License has been examined by the office of DCGI.

The special conditions/circumstances under which the permission for import of drug with residual shelf life less than 60% may be considered are as follows:

1. For charity purposes (it should be ensured that the drug is used within the shelf life).
2. The drugs which are required under the National Health Programs/schemes or for use in emergency situations where there is no substitute available.
3. The drugs required for treatment of diseases which are specific to be of Indian origin.
4. The drugs which are imported only for the testing/analysis purpose.
5. Orphan drugs for rare diseases.
6. Drugs required for control of sudden outbreak of diseases.
7. Import of unapproved/approved new drug/banned bulk drugs for manufacturing of formulation exclusively for export.

It is required for importers who would import such drugs shall give proper justification for the import. The application for import of the drug with residual shelf life of less than 60% should be made to the DCG(I) for necessary No Objection Certificate.

Checklist for Import of Drugs with residual Shelf Life Less than 60%

S. No	Description
1	Covering Letter.
2	Reasons of rejection from foreign customers or Justification for import with supporting documents.
3	Copy of Packing list and commercial invoice.
4	Copy of Purchase order.
5	Copy of Certificate of Analysis.
6	Copy of Valid manufacturing license along with product permission.
7	Copy of 100% EOU/ Advance license.
8	Copy of Shipping bill/Bill of entry.
9	Legal undertaking 100 Rs. (non-judicial) stamp paper for no part of the consignment of the imported drug shall be used for domestic purposes in any circumstances.
11	Copy of the label of the drug.
12	Proposed reconciliation of quantity to be manufactured (as per master formula) by using such API versus quantity to be exported.
13	SOP for reprocessing in case of re-import.
14	SOP for destruction in case of re-import/import for destruction purpose.
15	Any other supporting documents like CAPA.

4.2 Processing of Application under Rule 104A

In accordance with the provisions of the Drugs and Cosmetics Act, 1940, and the Drugs Rules, 1945, the processing of applications under Rule 104A pertains to the technical review of requests seeking permission for overprinting/stickering/stamping of imported drugs. **Rule 104,** which lays down the prohibition against altering inscriptions on containers, labels or wrappers of drug states that no person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any drug, provided that nothing in this rule shall apply to any alteration, any inscription or mark made on the container, label or wrapper of any drug at the instance or direction or with the permission of the Licensing Authority. Accordingly, every application for overprinting, stickering, or stamping shall be carefully examined by the Licensing Authority to ensure compliance with all applicable statutory and regulatory requirements prior to the grant of approval. In this regare, a clarification has been issued by this office vide File No. r-DNA-15011(11)/26/2025-eoffice dated 26.05.2025, which is already available in public domain and same can by accessed through https://cdsco.gov.in/.

Checklist for comprehensive permission for products imported for Overprinting/Stickering/ Stamping as per Rule 104A of the Drugs Rules, 1945

S. No	Description
1	Covering Letter.
2	Copy of valid Registration certificate and import license.
3	Copy of manufacturing license along with product permission for proposed site where overprinting, stickering, stamping is carried out.
4	Specific purpose for import of each individual drug as per the office memorandum issued vide File No. r-DNA-15011(11)/26/2025 dated 26.05.2025, along with Comparative details of proposed label artwork reflecting the purpose of overprinting, stickering, stamping versus labels submitted at the time of New Drug Permission/RC/Import License.
5	The Licensee shall have adequate facility for storage, ancillary areas, Labelling facility etc. and will appoint at least one manufacturing and QA personnel to the satisfaction of the SLA. The QC Laboratory and personnel may not be required for such labeling activities.
6	The labeling shall comply with the current provisions of Drugs Rules. The said activity will not conceal the original label. The License number and the activity carried out for this purpose should also be mentioned beside alterations made as per Rules 104A.
7	Any other supporting documents.

4.3 Processing of Application under Rule 37

In accordance with the provisions of the Drugs and Cosmetics Act 1940, and the Drugs Rules 1945, the processing of applications under Rule 37, pertains to the technical review of requests seeking permission for packing of patient or proprietary medicines to be imported. Rule 37, as laid down, states that packing of patent or proprietary medicine shall be imported in containers intended for retail sale, provided that such medicine may be imported in bulk containers by any person who holds a license to manufacture, if such person has obtained permission in writing to import such medicines from the Licensing Authority at least three months prior to the date of import and the imports are made within a period of twelve months from the data of issue of such permission. Accordingly, every application for packing of patient or proprietary medicines to be imported shall be examined by the Licensing Authority to ensure compliance with all applicable statutory and regulatory requirements prior to the grant of approval.

Checklist of documents for Import of Drugs under Rule 37

S. No	Description
1.	Cover Letter clearly stating the intent of application duly signed by the applicant
2.	As per Rule 37, whether the Drug is patent and propriety medicine
3.	A copy of valid Registration Certificate for import of drug in Bulk quantity
4.	A copy of Valid Form 10 License for import of drug in Bulk quantity
5.	A copy of Valid Manufacturing License for the activity performed, viz., Filling/packing/Labelling
6.	Original labels for Bulk Container
7.	Original labels for innermost and outer carton of the finished formulation
8.	S.O.P employed for assigning the Shelf Life to the product
9.	Hold Time Stability data to justify the hold time/transport duration/temperature excursions

4.4 Processing of Application under Rule 36A

In accordance with the provisions of the Drugs and Cosmetics Act 1940, and the Drugs Rules 1945, the processing of applications under Rule 36A for Import of drugs by charitable hospital free of cost-

(1) Small quantity of drugs received in donation by a charitable hospital for the purpose of treatment of the patients in the said hospital may be imported provided the drugs are given or administered to the patients free of cost.

(2) The drugs shall not be prohibited for import and permitted to be marketed in the country with residual shelf life of one year or more.

Checklist of documents for Import of Drugs under Rule 36A

S. No.	Description
1.	Copy of certificate of gift donation
2.	Copy of certificate of Humanitarian aid
3.	Copy of commercial invoice and packing list.
4.	Copy of registration certificate issued by Ministry of Social Justice & Empowerment.
5.	Copy of Certificate of Analysis for each drug products.
6.	Statement regarding guarantee of quality medicines.
7.	Actual origin of medicinal goods, i.e., where from the donor has received the medicinal goods, i.e., from the market or from the manufacturer.
8.	Undertaking from donor as well as from recipient regarding responsibility in case of problems related to adverse reactions and quality of subject medicines.
9.	Whether the drugs are allowed to be used in country of origin.
10.	Details regarding temperature & humidity control during shipment & storage.
11.	Copy of Utilization Certificate.

5. ANNEXURES

5.1 ANNEXURE-I POWER OF ATTORNEY FOR ISSUE OF REGISTRATION CERTIFICATE AND/OR IMPORT LICENSE FOR IMPORT OF DRUGS IN INDIA

POWER OF ATTORNEY FOR ISSUE OF REGISTRATION CERTIFICATE AND/OR IMPORT LICENSE FOR IMPORT OF DRUGS IN INDIA

Whereas, M/s……., having Registered Office at... at… , (Telephone…., Fax …, email:.....) hereinafter to be known as Authorized Agent/Manufacturer of us intends to apply for a Registration Certificate and/or Import License under the Drugs Rules, 1945, for the import, use and marketing into India, the. (Product name), Manufactured by (Full address/ telephone no., /e-mail) hereafter to be known as the Manufacturer, having the factory premises at (Full address/ telephone no., /e-mail), hereby delegate Power of Attorney that for the duration of the said Registration and /or License period: -

1. The said applicant shall be our Authorized for the Registration Certificate and/or Import License of drugs imported into India, under rule 27-A and 24 of the Drugs and Cosmetics Rules; respectively for purposes of representations and /of signing of the Registration Applications in Form 40, Schedule D(I), Schedule D(II), Form 9 undertaking and /other allied documents.
2. We shall comply with all the conditions imposed on the Registration Certificate and/or Import License, with relevant rules of the Drugs rules, 1945.
3. We hereby declare that we are engaged in the manufacture of the drugs listed in this Schedule at the premises specified above. We undertake to promptly report any change in the manufacturing premises, and, in cases where manufacture is carried out at more than one factory, any modification in the distribution of manufacturing functions among such factories.
4. We shall comply with the provisions of Part IX of the Drugs Rules, 1945.
5. Every drug manufactured by us for import under the Registration Certificate and Import License into India shall be as regard strength, quality and purity conforms with the provisions of Chapter III of Drugs and Cosmetics Act, 1940 and Part IV of the Drugs Rules, 1945, and their amendments from time to time.
6. We shall from time-to-time report for any change of manufacturing process, or in packaging, or in labeling, or in testing, or in documentation of any of the drugs,

pertaining to the Registration Certificate, to be granted to us. Where any change in respect of any of the drugs under the Registration Certificate and Import License has taken place, in respect of any of the above matters, we shall inform the same to the Licensing Authority, in writing within 30 days from the date of such changes. In such cases, where there will be any major change/modification in manufacturing or in processing or in testing, or in documentation, as the case may be, at the discretion of the Licensing Authority, we shall obtain necessary approval within 30 days by submitting a separate application, along with the registration fee as specified in clause (ii) of sub rule (3) of rule 24-A.

7. We shall from time-to-time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and/or "not of standard quality report" of any drug pertaining to the Registration Certificate and/or Import License declared by any Regulatory Authority of any country where the drug is marketed/sold or distributed. The dispatch and marketing of the drug in such cases shall be stopped immediately, and the Licensing Authority shall be informed immediately. Further action in respect of stop marketing of drug shall be taken as per the directions of the Licensing Authority. In such cases, action equivalent to that taken with reference to the concerned drug(s) in the country of origin or in the country of marketing will be followed in India also, in consultation with the Licensing Authority. The Licensing Authority may direct any further modification to this course of action, including the withdrawal of the drug from Indian market within 48 hours' time period.
8. We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the rules, made there under.
9. We shall allow the Licensing Authority and/or any person authorized by him in that behalf to enter and inspect the manufacturing premises and to examine the process/procedure and documents in respect of any drug manufactured by us for which the application for Registration Certificate and/or Import License has been made.
10. We shall allow the Licensing Authority or any person authorized by him in that behalf to take samples of the drugs concerned for test, analysis or examination, if considered necessary by the Licensing Authority.
11. We shall comply with the any instructions or directions for the purpose of registration

and Import of drugs in the country given by the Licensing Authority.

PRODUCT (S) INFORMATION

NAME (S) OF THE PRODUCT:	
Active Ingredients	
Pharmacological Classification	
Dosage Form	

Signature on behalf of manufacturer, with name, designation, date and place

Name:.....

Place: . . . . . .

Date: . . . . . .

Signature: . . . . . .

(*Signatory Authority should be authorized by the Board of the Company/Directors)

Signature on behalf of Authorized Agent in India with name, designation, date and place.

Name:.....

Place: . . . . . .

Date: . . . . . .

Signature: . . . . . .

*Delete whichever is not applicable.

5.2 ANNEXURES-II – Form 40

Form 40
(*See* rule 24-A)

APPLICATION FOR ISSUE OF REGISTRATION CERTIFICATE FOR IMPORT OF DRUGS INTO INDIA UNDER THE DRUGS AND COSMETICS RULES, 1945.

I/We*……. (name and full address) hereby apply for the grant of Registration Certificate for the manufacturer, M/s……(full address with telephone, fax and E-mail address of the foreign manufacturer) for his premises, and manufactured drugs meant for import into India.

1. Names of drugs for registration
2. I/We* enclose herewith the information and undertakings specified in Schedule D(I) and Schedule D (II) duly signed by the manufacturer for grant of Registration Certificate for the premises stated below.
3. A fee of.....for registration of premises, the particulars of which are given below, of the manufacturer has been credited to the Government under the Head of Account "0210- Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs Rules, 1945-Central *vide* Challan No……..dated ……..(attached in original).
4. A fee of.....for registration of the drugs for import as specified at Serial No. 2 above has been credited to the Government under the Head of Account "0210- Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs Rules, 1945-Central *vide* Challan No....., dated…….. (attached in original).
5. Particulars of premises to be registered where manufacture is carried on:
   Address (es).....
   Telephone .....
   Fax.....
   E-mail.....

   I/We* undertake to comply with all terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.

Place: _____
Date: _____
Signature:_____

Name.....
Designation.....

Seal/Stamp of manufacturer or his authorized Agent in India.

(**Note**: In case the applicant is an authorized agent of the manufacturer in India, the Power of Attorney is to be enclosed).

*Delete whichever is not applicable.

5.3 ANNEXURE-III SCHEDULE D (I)

SCHEDULE D (I)
(*See* rule 21(d) and rule 24A)

Information and undertaking required to be submitted by the manufacturer or his authorized agent with the Application Form for a Registration Certificate.

(The format shall be properly filled in for each application in Form 40. The detailed information, secret in nature, may be furnished on a Computer Floppy.)

1. Particulars of the manufacturer and manufacturing premises.

1.1 Name and address of the manufacturing premises (Telephone No., Fax No., E- mail address) to be registered.

1.2 Name(s) and address of the Proprietor /Partners / Directors.

1.3 Name and address of the authorized Agent in India, responsible for the business of the manufacturer.

1.4 A brief profile of the manufacturer ‘s business activity, in domestic as well as global

1.5 A copy of Plant Master File (duly notarized)

1.6 A copy of Plant Registration / approval Certificate issued by the Ministry of Health/National Regulatory Authority of the foreign country concerned (duly notarized)

1.7 A brief profile of the manufacturer ‘s research activity.

2. Particulars of the manufactured drugs to be registered under Registration Certificate.

2.1 Names of drugs (Bulk/Formulation/Special product) to be registered meant for import into and use in India.

2.2 A copy of the approved list showing the bulk drugs/formulations/special products mentioned in 2.1 above are permitted for manufacturing / marketing in the country of origin (duly notarized).

2.3 A copy of Good Manufacturing Practice (GMP) certificate, as per WHO- GMP guidelines, or Certificate of Pharmaceutical Products (CPP), issued by the National Regulatory Authority of the foreign country concerned, in relation to the bulk drugs or formulations or special products, meant for import into India.

2.4 The domestic prices of the drugs to be registered in India, in the currency of the country of origin.

2.5 The name(s) of the drug(s) which are original research products of the manufacturer.

3. Undertaking to declare that:

3.1 We shall comply with all the conditions imposed on the Registration Certificate, read with rules 74 and 78 of the Drugs and Cosmetics rules, 1945.

3.2 We declare that we are carrying on the manufacture of the drugs mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

3.3 We shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945.

3.4 Every drug manufactured by us for import under the Registration Certificate into India shall be as regard strength, quality and purity conforms to the provisions of Chapter III of Drugs and Cosmetics Act, 1940 and Part IV of the Drugs and Cosmetics Rules 1945, and their amendments from time to time.

3.5 We shall from time-to-time report for any change or manufacturing process, or in packaging, or in labeling, or in testing, or in documentation of any of the drugs, pertaining to the Registration Certificate, to be granted to us. Where any change in respect of any of the drugs under the Registration Certificate has taken place, in respect of any of the above matters, we shall inform the same to the Licensing Authority in writing within 30 days from the date of such changes. In such cases, where there will be any major change/modification in manufacturing or in processing or in testing, or in documentation, as the case may be, at the discretion of the Licensing Authority, we shall obtain necessary approval within 30 days by submitting a separate application, along with the registration fee as specified in clause (ii) of sub rule (3) of rule 24-A.

3.6 We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and/or ―not of standard quality report‖ of any drug pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the drug is marketed/sold or distributed. The dispatch and marketing of the drug in such cases shall be stopped immediately, and the Licensing Authority shall be informed immediately. Further action in respect of stop marketing of drug shall be taken as per the directions of the Licensing Authority. In such cases, action equivalent to that taken with reference to the concerned drug(s) in the country of origin or in the country of marketing will be followed in India also, in consultation with the Licensing Authority. The Licensing Authority may direct any further modification to this course of action, including the withdrawal of the drug from Indian market within 48 hours'

time period.

3.7 We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the rules made there under.

3.8 We shall allow the Licensing Authority and/or any person authorized by him in that behalf to enter and inspect the manufacturing premises and to examine the process/procedure and documents in respect of any drug manufactured by us for which the application for Registration Certificate has been made.

3.9 We shall allow the Licensing Authority or any person authorized by him in that behalf to take samples of the drugs concerned for test, analysis or examination, if considered necessary by the Licensing Authority.

Place: . . . . . .

Date: . . . . . .

.....

Signature of the manufacturer

[or his authorized agent]

Seal/ Stamp

5.4 ANNEXURE- IV SCHEDULE D(II)

SCHEDULE D(II)

(See rule 21(d) and rule 24A)

INFORMATION REQUIRED TO BE SUBMITTED BY THE MANUFACTURER OR HIS AUTHORISED AGENT WITH THE APPLICATION FORM FOR THE REGISTRATION OF A BULK DRUG/FORMULATION/SPECIAL PRODUCT FOR ITS IMPORT INTO INDIA

(The format shall be properly filled in and the detailed information, secret in nature, may be furnished on a Computer Floppy)

1. General

1.1 Name of the drug/formulation/special product, a brief description and the therapeutic class to which it belongs.

1.2 Regulatory status of the drug. Free Sale Certificate and/or Certificate of Pharmaceutical Products (CPP) issued by the Regulatory Authority of the country of origin. Free sale approval issued by the Regulatory Authorities of other major countries.

1.3 Drugs Master File (DMF) for the drug to be registered (duly notarized).

1.4 GMP certificate as per WHO - GMP format, or Certificate of Pharmaceutical Products (CPP), or written confirmation for active substances exported to the European Union which is equivalent to GMP certificate issued as per WHO - GMP guidelines, by the National Regulatory Authority of the country of origin or a duly notarized copy of the certificate equivalent to GMP certificate as per WHO-GMP guidelines issued by United States of America or Japan or Australia or Canada or the European Union for the purpose of marketing of the drug in their country.

1.5 List of countries where marketing authorization or import permission for the said drug is granted with date (respective authorization shall be enclosed).

1.6 List of countries where marketing authorization or import permission for the said drug is cancelled /withdrawn with date.

1.7 List of countries where marketing authorization or import permission for the said drug is pending since (date).

1.8 Domestic price of the drug in the currency followed in the country of origin.

1.9 List of countries where the said drug is patented.

2. Chemical and Pharmaceutical information of Drugs

2.1 Chemical name Code name or number, if any Non-proprietary or generic name, if any Structure Physio-chemical properties.

2.2 Dosage form and its composition, Qualitative and Quantitative composition in terms of the active substance(s) and excipient(s). List of active substance(s) separately from the constituent(s) of excipient(s).

2.3 Specification of active and inactive ingredient(s) including pharmacopoeia references.

2.4 Sources of active ingredient(s), name and address.

2.5 Test for identification of active ingredient(s), Method of its assays and tests for impurity profile with reference standards for the impurities (Protocol to be submitted along with reference standards for the impurities) relative substances.

2.6 Outline method and flow chart of manufacture of the bulk drug or finished formulation or special product.

2.7 Detailed test protocol for the drug with pharmacopoeia reference or in-house specification as approved by the registration authority, in the country of origin.

2.8 Stability date including accelerated stability and real time stability analysis.

2.9 Documentation on pack size

2.10 Numerical expression or EAN bar code on the labels and cartons.

2.11 Safety documents on containers and closer.

2.12 Documentation on storage conditions.

2.13 Three samples of medical products/drug and outer packaging are to be submitted with batch certificates. Additional samples as well as reference substances with batch certificates including date of manufacture, and shelf-life storage conditions of reference substance may be required both during registration procedure and during validity of registration decision.

2.14 Batch test reports/certificates of five consecutive production batches in details of the medicinal product are to be submitted for every site of manufacturing premises.

2.15 Manner of labelling as per Rule 96 and 97 (as applicable) of the Drugs Rules, 1945.

2.16 Packages insert.

2.17 Details of safety handling procedure of the drug

2.18 Detailed of PMS study report for marketing period not exceeding five years.

3. Biological and Biopharmaceutical Information of Drugs

Not applicable

4. Pharmacological and Toxicological Information of Drugs

Executive summary of the product is to be submitted mentioning the specific and general pharmacological actions of the drug and pharmacokinetic studies on absorption, metabolism, distribution and excretion. A separate note is to be given on acute and sub- acute toxicity studies and long-term toxicity studies. Specific studies on reproductive toxicity, local toxicity and carcinogenic activity of the drug are to be elaborated, as far as possible.

5. Clinical Documentation

A new drug as defined under Rule 122E of the Drugs Rules, 1945 and/or Rule 2 (w) of NDCT Rules, 2019 is required to be permitted separately by the Licensing Authority under Rule 122A/Rule 76 of the said rules prior to its registration. Such a new drug requires a brief summary on clinical documentation, along with permission under 122A/ Rule 76 of the said rules for its Registration Certificate.

6. Labelling and Packaging Information of Drugs

6.1 Labels should conform as per the specifications under the Drugs and Cosmetics Rules, 1945.

6.2 Package insert should be in English and shall indicate the following therapeutic indications: —

- Posology and method of administration. Contra-indications.
- Special warnings and special precautions for use, if any.
- Interaction with other medicaments and oilier forms of intention.
- Pregnancy and lactation, if contra-indicated.
- Undesirable effects/side effects.
- Undesirable effects/side effects.
- Antidote for overdosing.

6.3 Package insert should indicate the following pharmaceutical information:

- List of excipients
- Incompatibilities
- Shelf life in the medical product as packaged for sale.
- Shelf life after dilution or reconstitution according to direction.
- Shelf life after first opening the container.
- Special precautions for storage.
- Nature and specification of the container.

- Instructions for use/handling.

7. Specific Information Required for the Special Products (to be supplied, separately in annexure, as 'A', ' B' and 'C')

The information submitted above is true to the best of my knowledge and belief.

Place.....

Date.....

Signature of the manufacturer
[or his authorized agent]
Seal/Stamp

NB.—1. Any change in the process of manufacture, method of testing, labelling, packaging, designing of the sale pack, medical literature and documentation is to be intimated to the Licensing Authority forthwith and permission to be obtained from him within 30 days' time period.

2 Information relating to Serial No. 4 and Serial No. 5 are not applicable for drugs figuring in Indian Pharmacopoeia and also for the drugs figuring in United States of Pharmacopoeia, European Pharmacopoeia, and British Pharmacopoeia. Provided such drugs have already been approved for marketing in India for the applicant under rules 122A, 122B, 122C or 122D of the Drugs and Cosmetics Rules, 1945.

5.5 ANNEXURE-V FORM 8

FORM 8

(*See* rule 24)

Application for license to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945

I/We* ..... (full address with telephone number, fax number and e-mail address) hereby apply for a license to import drugs specified below manufactured by M/s .....(full address with telephone no, fax and e- mail no.).

2. Names of the drugs to be imported:
   (1)
   (2)
   (3)
3. I/We*.....enclose herewith an undertaking in Form 9 dated.....signed by the manufacturer or his authorized agent as required by Rule 24 of the Drugs and Cosmetics Rules, 1945.
4. I/We* ..... enclose herewith a copy of Registration Certificate concerning the drugs to be imported in India, issued under Form-41 of the rules, vide Registration Certificate No ..... Dated ..... issued through M/s.....(name and full address) .....valid up to .....
5. I/We* ..... hold a valid wholesale license for sale or distribution of drugs or valid license to manufacture drugs, under the provisions of the Act and rules made thereunder. A copy of the said license is enclosed.
6. A fee of .....has been credited to Government under the Head of Account "0210- Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945 - Central *vide* Challan No..... dated.....(attached in original)

Signature .....
Name.....
Designation .....
Seal/Stamp of Manufacturer's agent in India.

Place:.....
Date: .....
* Delete whichever is not applicable.

5.6 ANNEXURE-VI FORM 8A

FORM 8A
(See rule 24)

Application for license to import drugs specified in Schedule X) to the Drugs and Cosmetics Rules, 1945

I/We* ..... (full address with telephone number, fax number and e-mail address) hereby apply for a license to import drugs specified below manufactured by M/s.....(full address with telephone no, fax and e- mail no.).

2. Names of the drugs to be imported:
   (1)
   (2)
   (3)
3. I/We*.....enclose herewith an undertaking in Form 9 dated .....signed by the manufacturer or his authorized agent as required by Rule 24 of the Drugs and Cosmetics Rules, 1945.
4. I/We* .....enclose herewith a copy of Registration Certificate concerning the drugs to be imported in India, issued under Form-41 of the rules, vide Registration Certificate No dated ..... issued through M/s..... (name and full address) .....valid up to .....
5. I/We* ..... hold a valid wholesale license for sale or distribution of drugs or valid license to manufacture drugs, under the provisions of the Act and rules made thereunder. A copy of the said license is enclosed.
6. A fee of .....has been credited to Government under the Head of Account "0210- Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945 - Central vide Challan No... dated.....(attached in original).

Signature .....

Name.....

Designation .....

Seal/Stamp of Manufacturer's agent in India

Place: .....

Date: .....

* Delete whichever is not applicable.

5.7 ANNEXURE-VII - FORM 9

FORM 9

(See rule 24)

FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR AN IMPORT LICENSE

Whereas ..... of..... intends to apply for a license under the Drugs and Cosmetics Rules, 1945, for the import into India, of the drugs specified below manufactured by us, we .....of.....hereby give this undertaking that for the duration of the said license--

1. the said applicant shall be our agent for the import of drugs into India;
2. we shall comply with the conditions imposed on a license by [rules 74 and 78] of the Drugs and Cosmetics Rules, 1945;
3. we declare that we are carrying on the manufacture of the drugs mentioned in this undertaking at the premises specified below, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories;
4. we shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945;
5. every drug manufactured by us for import under license into India shall as regards strength, quality and purity conform with the provisions of Chapter III of the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945;
6. we shall comply with such further requirements, if any, as may be specified by Rules, by the Central Government under the Act and of which the Licensing Authority has given to the licensee not less than four months' notice.

Names of drugs and classes of drugs

Particulars of premises where manufacture is carried on.

Dated.....

Signature .....
Name.....
Designation .....

Seal/Stamp of manufacturer or on behalf of the manufacturer.

Feedback/Suggestions, if any, in this regard, may be submitted to:

Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India FDA Bhawan, ITO, Kotla Road, New Delhi -110002 Email: import.regist@cdsco.nic.in

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