Central drugs standard control organisation

Directorate general of health services, Ministry of Health and Family Welfare
Government of India
(Import & Registration Division)

Pre-screening Checklist for FreshRegistration Certificate in Form 41 for Drug Product (s)/Drug Substance (s)

A. Name of Applicant :

B. Date of Application:

C. Name of Drug (s) :

SL. No.	CONTENTS/PARTICULARS	YES	NO
1.	Covering Letter indicating type of application.		
2.	**Application in Form-40, date, sign and Seal/Stamped of Indian agent or Manufacturer.**		
	• Name & Address of Authorized Agent in India.(having valid wholesale license as per Rule 24A)		
	• Names & Address of Manufacturer & its Factory Premises.		
	• Name of the drugs to be registered. • Specify No. of sites involved in the manufacturing of the drug (s).		
3.	**Original Power of Attorney**		
	• Executed & 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 (original copy).		
	• Name of the manufacturer & its manufacturing site as per Form-40 along with the name of the drugs		
	• Name and address of the Indian Agent. (having valid wholesale license as per Rule 24A)		
	• Name of the Proposed Products		
	• Duly signed, dated with name & designation of the signatory by both Indian agent & the manufacturer		
4.	TR-6 Challan of fees paid (1500USD for one site or its equivalent in Indian currency and 1000USD for one drug or its equivalent in Indian currency).		
	• Bank's Stamp.		
	• Name of drugs		
	• Address of manufacturing site and Indian agent • Head to Fees Deposited ("0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines)		
	• Products comprising of same API but different strengths & will be considered as separate product & require submission of fees accordingly.		
5.	Copy of Import permission for new drug (s) in Form-45 (formulation) or in Form-45A (new bulk drug substances)		
6.	Copy of Valid Whole sale Licence (20B/21C) or Manufacturing Licence of the Indian agent/Corporate office address.		
7.	Company's authorization letter (in original) for the bearer to submission and collect letter.		
8.	Schedule D (I) and Undertaking duly signed, dated and seal/stamped with name and designation of the authorised signatory of the manufacturer or his authorised Indian agent.		
9.	Schedule D (II) and Undertaking duly signed, dated and seal/stamped with name and designation of the authorised signatory of the manufacturer or his authorised Indian agent.		
10.	**Notarised copy of Plant Master File (PMF).**		
11.	**Notarised copy of Drug (s) Master File (DMF)**		
12.	Original Notarised Copy of **Manufacturing Licence, FSC, GMP, COPP (For finished products).**		
13.	Attested/Appostilled copy of Product Registration Certificate (CFDA) From China /certificate of suitability from (EDQM).		
14.	Original label /specimen label complying with Rule 96 and indicating name of the subject drug with pharmacopoeial specification, the importer name &address as per Wholesale license and Import License number. If proposed draft label/package insert whereever applicable, then duly attested either by the authorised Indian Agent or by the manufacturer is required to be submitted along with the application.		

Signature of the reviewer with date.

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Pre-screening Checklist for Re- Registration Certificate in Form 41 for Drug Product (s)/Drug Substance (s)

A. Name of Applicant :

B. Date of Application:

C. Name of Drug (s) :

SL. No.	CONTENTS/PARTICULARS	YES	NO
1.	Covering Letter indicating type of application.		
2.	**Application in Form-40, date, sign and Seal/Stamped of Indian agent or Manufacturer.**		
	• Name & Address of Authorized Agent in India (having valid wholesale license as per Rule 24A)		
	• Names & Address of Manufacturer & its Factory Premises.		
	• Name of the drugs to be registered. • Specify No. of sites involved in the manufacturing of the drug (s).		
3.	**Original Power of Attorney**		
	• Executed & 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 (original copy).		
	• Name of the manufacturer & its manufacturing site as per Form-40 along with the name of the drugs		
4	• Name and address of the Indian Agent (having valid wholesale license as per Rule 24A)		
	• Name of the Proposed Products		
	• Duly signed, dated with name & designation of the signatory by both Indian agent & the manufacturer		
4.	TR-6 Challan of fees paid (1500USD for one site or its equivalent in Indian currency and 1000USD for one drug or its equivalent in Indian currency).		
	• Bank's Stamp.		
	• Name of drugs		
	• Address of manufacturing site and Indian agent • Head to Fees Deposited ("0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines) • Products comprising of same API but different strengths & will be considered as separate product & require submission of fees accordingly.		
5.	Copy of Import permission for new drug (s) in Form-45 (formulation) or in Form-45A (new bulk drug substances)		
6.	Copy of Valid Whole sale Licence (20B/21C) or Manufacturing Licence of the Indian agent/Corporate office address.		
7.	Company's authorization letter (in original) for the bearer to submission and collect letter.		
8.	Schedule D (I) and Undertaking duly signed, dated and seal/stamped with name and designation of the authorised signatory of the manufacturer or his authorised Indian agent.		
9.	Schedule D (II) and Undertaking duly signed, dated and seal/stamped with name and designation of the authorised signatory of the manufacturer or his authorised Indian agent.		
10.	Original Notarised Copy of **Manufacturing Licence, FSC, GMP, COPP(For finished products)**		
11.	Attested/Appostilled copy of Product Registration Certificate (SFDA) /certificate of suitability from (EDQM).		
12.	Original RC.		
13.	Statement and or undertaking regarding pertaining to quality of the drug in the country of origin or regulatory Authority of any other country where the drug is marketed /distributed		
14.	Details regarding any administrative action taken by the regulatory authority due to ADR ,MARKET WITHDRAWL, CANCELLATION OF AUTHORISATION ETC.		
15.	Statements/undertakings regarding any change in manufacturing process/packaging/labelling/testing/ or documentation undertaken during last three years **(Drugs Master File)**		
16.	Statements/undertakings regarding any change in the constitution of the firm /address of registered office (**Site Master File)**		
17.	Total Quantity of drugs exported to India during last three years		
18.	Original label /specimen label complying with Rule 96 and indicating name of the subject drug with pharmacopoeial specification, the importer name & address as per Wholesale license and Import License number. If proposed draft label/package insert whereever applicable, then duly attested either by the authorised Indian Agent or by the manufacturer is required to be submitted along with the		

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	application.		

Signature of the reviewer with date.

Checklist for Form 10 (Drugs)
(Import & Registration Div.)

A. Name of applicant:

B. Date of application:

C. Name of Drug(s):

S. No.	Checklist for Form 10	Closed Response	
1.	Covering Letter	Yes	No
2.	Fees of Rs.1000/- for single drug and 100/- for each additional drug		
3.	Application in Form 8 duly signed and stamped by the applicant with name and designation for licence to import drugs		
4.	Original Form 9 duly filled & issued by the manufacturer/Indian agent. In case the Form 9 is issued by the manufacturer- a) Attested by the Indian embassy. b) Authenticated letter issued by the Indian Agent.		
5.	Copy of Valid RC duly attested by the Indian Agent/ manufacturer.		
6.	Copy of wholesale Licence/ Manufacturing Licence with list of products approved.		
7.	Copy of permission under rule 122A in case of New Drug in the name of importer.		
8.	If any condition is mentioned in RC, it should be fulfilled before making application for Form -10.		
9.	Original Labels/Specimen label attested by the importer for bulk drugs/ finished formulation as per Rule 96 & 97 of the Drugs and Cosmetics Act 1945 to be imported in the country		

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Signature of the reviewer with date

Checklist for the application of shelf-life extension for Export purpose only

(Import & Registration Div)

A. Name of applicant:

B. Date of application:

C. Name of Drug(s):

SL. No.	Documents required	Yes	No
1.	Covering letter clearly stating the purpose, name of drugs, country where exported.		
2.	Copy of manufacturing license with approved products list.		
3.	Copy of Real time and Accelerated stability data for the applied drugs to be exported		
4.	Certificate of Analysis (COA) from three consecutive batches of the product to be exported.		
5.	Original Purchase order from overseas buyer for the applied products to be exported.		
6.	Shelf-life approval of the products from National Regulatory Authority in the importing country		
7.	An undertaking from overseas buyer that they will accept the product with proposed shelf-life		
8.	Original Labels of the product to be exported.		

Signature of the reviewer with date

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Checklist for Rule 37

Sl. No	Documents required	Yes	No
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 period/transport duration/temperature excursions		

Signature of the reviewer with date