

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 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) :

S. 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.		
	<ul style="list-style-type: none"> • Name & Address of Authorized Agent in India. • 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		
	<ul style="list-style-type: none"> • 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. • 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).		
	<ul style="list-style-type: none"> • 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) 		
5.	Copy of Import permission for new drug (s) in Form-45 (formulation) or in Form-45A (new bulk drug substances)		
6.	Copy of 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) duly sign, 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.	Copy of Manufacturing Licence /GMP/COPP/FSC for bulk drugs or formulation /special products.		
13.	Attested/Appostilled copy of Product Registration Certificate (SFDA) /certificate of suitability from (EDQM).		

Signature of the reviewer with date.

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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	
		Yes	No
1.	Covering Letter	<input type="checkbox"/>	<input type="checkbox"/>
2.	Fees of Rs. 1000/- for single drug and 100/- for each additional drug	<input type="checkbox"/>	<input type="checkbox"/>
3.	Application in Form 8 duly signed and stamped by the applicant with name and designation for licence to import drugs	<input type="checkbox"/>	<input type="checkbox"/>
4.	Original Form 9 duly filled & issued by the manufacturer/Indian agent.	<input type="checkbox"/>	<input type="checkbox"/>
	In case the Form 9 is issued by the manufacturer-		
	a) Attested by the Indian embassy.	<input type="checkbox"/>	<input type="checkbox"/>
	b) Authenticated letter issued by the Indian Agent.	<input type="checkbox"/>	<input type="checkbox"/>
5.	Copy of Valid RC duly attested by the Indian Agent/ manufacturer.	<input type="checkbox"/>	<input type="checkbox"/>
6.	Copy of wholesale Licence / Manufacturing Licence with list of products approved.	<input type="checkbox"/>	<input type="checkbox"/>
7.	Copy of permission under rule 122A in case of New Drug in the name of importer.	<input type="checkbox"/>	<input type="checkbox"/>
8.	If any condition is mentioned in RC, it should be fulfilled before making application for Form -10.	<input type="checkbox"/>	<input type="checkbox"/>

Signature of the reviewer with date