

**Central Drug Standard Control Organization  
Directorate General of Health Services  
Office of Drugs Controller General (India)  
(Biological Division)**

**Checklist for Registration Certificate (Form -41)**

<b>S.No</b>	<b>CONTENTS</b>	<b>YES</b>	<b>NO</b>
1.	Covering Letter		
2.	TR-6 Challan of required amount; Bank's Stamp for Cheque realization		
3.	Power of Attorney; sign/ stamp of both parties & Indian Embassy or Appostile		
4.	Application in Form-40, sign, date, stamp		
5.	Copy of the import Permission on Form-45 (Formulation) and / or Form-45A (Bulk).		
6.	Notarized copy of Whole sale/Manufacturing license.		
7.	Company's Authorization letter (in original) for the bearer to submit application and collect letter		
8.	SCHEDULE D (I) & SCHEDULE D (II) Sign, Date, Stamp by the overseas manufacturer.		
9.	Plant Master File (PMF), Notarised in foreign country		
10.	GMP certificate, Notarized in country of origin		
11.	Certificate of Pharmaceutical Products (COPP) Notarized in country of origin		
12.	Regulatory status of the drug in the country of origin. Table with registration, Launching, Withdrawal status.		
13.	Regulatory status of the drug worldwide. Table with registration, Launching, Withdrawal status.		
14.	Free Sale Certificate (FSC); Notarized in country of origin		
15.	Drugs Master File (DMF) Notarized in country of origin		
16.	Annexures -- A / C of Sch-D-II. Annx A: For Blood Products Annx C: For r-DNA product and Vaccines		