Indian Manufacture of Blood Products:

S. No.	Indian Manufacturer	Products manufactured
1.	M/s Reliance Life Sciences Pvt. Ltd. Plant 4A,4B,TTC Area of MIDC, Rable Navi Mumbai	Albumin, IVIG, Anti D Immunoglobulin, fibrin sealant kit, factor VIII, Hep B Immunoglobulin, Tetanus Immunoglobulin, Rabies Immunoglobulin. Thrombin concentrate.
	M/s Reliance Life Sciences Pvt. Ltd. Plant No. 1, Worli, Mumbai	
3..	M/s Virchow Biotech Ltd. Hyderabad	Human serum Albumin, Factor VIII, IV Immunoglobulin
4.	M/s Hemarus Therapeutics Ltd. Hyderabad	Human Albumin .IV Immunoglobulin, Factor IX, Factor VIII, and Fibrin Sealant Kit.
5.	Bharat Serum and Vaccine Ltd.	IVIG, IMIG, tetanus Immunoglobulin ,
6.	Intas Pharmaceutical Ahmedabad	Albumin, IV Immunoglobulin , Factor VIII and Factor IX

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Checklist for Registration Certificate (Form -41)

S.No	CONTENTS	YES	NO
1.	Covering Letter		
2.	TR-6 Challan of required amount; Bank's Stamp for Cheque reallization		
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		

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Check List for Import License (Form-10)

S.no	CONTENTS	YES	NO
1	Covering letter		
2	TR-6 Challan of required amount, Banks Stamp for Cheque realization		
3	Application in Form-8, Sign, Date, Stamp		
4	Copy of the import permission on Form-45 (Formulation) and /or Form-45 A (Bulk)		
5	Notarized copy of whole sale/manufacturing License		
6	Company's Authorization letter (in original) for the bearer to submit application and collect letter		
7	Copy of valid Registration certificate		
8	Undertaking in Form-9, attested by Indian Embassy/Appostiled (If issued by the manufacturer		
9	Signed stamped by the Indian Agent		
10	Labels of the applied product		

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Check List for NOC for manufacturing of test batches for test and analysis under Form-29

S.no	CONTENTS	YES	NO
1	Name of the Manufacturer		
2	Name of the Drug/Drugs		
3	Source of Plasma a) Imported b) Blood banks		
4	Process flow		
5	Site plan for manufacture of subject drug		
6	List of equipments and testing facility		
7	If technology transfer, details thereof		
8	Name, qualification, experience of personal responsible for manufacturing of trial batches		

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Checklist for Test Licence to Import of Vaccine under Form-11

S.No	Check List for Form 12:	Closed Responses
1	Name of Applicant	☐ Yes ☐ No
2	Drug	☐ Yes ☐ No
3	Dosage Form and Composition	☐ Yes ☐ No
4	Application in Form 12	☐ Yes ☐ No
5	Fees	☐ Yes ☐ No
6	Justification and utilization breakup of the drug detailing the test parameters visà-vis quantities of the drugs, batch manufacturing plan	☐ Yes ☐ No

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Check List for NOC for collection of Plasma from blood banks for fractionation

S.no	CONTENTS	YES	NO
1	Covering letter		
2	20B/21B whole sale License		
3	Concerned SOPs		
4	Contract Agreement with Fractionators		
5	Contract Agreement with blood banks		
6	Labels		

Annexure #1

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Checklist for Pre Screening of Applications for variations under Post approval changes as per CDSCO Guidance for Industry.

Name of the firm: _____ **Date:** _____

TR-6 challan (if applicable) no:_____ **Date:**_____ **Ref.no:**_____

S.no.	Information and Documents	Status	
		Yes	No
1	Covering Letter-Purpose should be clearly mentioned with page number and Index.		
2	Whether change in Drug Substance or Drug Product along with **Description of change.**		
3	Change category: Supplement/Notifiable/Annual notification as per CDSCO Guidance for Industry.		
4	Copy of Market Authorization and other permissions/approvals for subject's product.		
5	Undertaking or satisfactory statement to fulfill conditions of proposed change as per CDSCO Guidance for industry.		
6	Side by side comparison of previously approved and changed information and declaration that other information is not changed or no change as a result of variation if applicable.		
7	Whether information as per CDSCO Guidance for industry for proposed variation is submitted.		
8	For imported products certified copy of approval from NRA of country of origin and from EMEA, USFDA etc. along with list of countries where proposed variation is approved.		
9	In case of annual notification declaration stating that supporting data for Level III change should be submitted on annual basis or within 15days whenever required by DCGI.		
10	Statements & evidences about effect of change on quality, stability, validation, animal toxicity & clinical (safety & efficacy) status of the product.		
11	For label change, Package insert change, extension in shelf life or change in specifications not mentioned in Indian pharmacopoeia one additional set of literature (hard & soft copy).		

Accepted/Returned due to incomplete application

Signature of the Reviewer

Signature of firm representative