CHECKLIST FOR FORM-5

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S. NO.	PARAMETER	YES	NO
1.	Product Profile i. Brand Name ii. Formulation and evidence of competitor availability in the local or international market iii. List of Ingredient with strength iv. In case of herbal drugs the scientific name and species name of plant along with following:- a) State part used, nature of ingredient i.e. powder drugs, extracts (aqueous, alcoholic or any other solvent used for extraction) b) In case of standardized extracts state the percentage of active ingredient(s) case may be. v. In case of extracts state Drug Extract Ratio if the extract is not standardized. vi. Common name of ingredient vii. Recommended use viii. Pack size ix. Maximum retail price		
2.	Master Formula stating batch size mentioning quantities of active and inactive ingredients		
3.	Manufacturing process		
4.	In-process controls		
5.	Testing specifications of starting materials and finished products,		
6.	Validation data		
7.	Certificates of analysis		
8.	Shelf life and storage		
9.	Evidence of long term and accelerated Stability data		
10.	Recommended Conditions for use i. Dosage form ii. Recommended route of administration; iii. Recommended dose; iv. Recommended duration of use, if any; and v. Risk information, including any cautions, warnings, contraindications or known adverse reactions associated with its use (With evidence of quality, safety and efficacy data).		
11.	Evidence of clinical safety and efficacy based on Pre-clinical and clinical studies along with data.		
12.	Packaging and labeling. i. Type of packing material used ii. Primary and secondary labels iii. Patient information leaflet / summary of product characteristics approved in the country of origin.		

13.	Import documents as under duly originated by the regulatory authority in the country origin, legalized by notary public and attested from the embassy or consulate of Pakistan in the country of origin. a) Approval of product registration or marketing authorization in the country of origin. b) Certificate of pharmaceutical product on WHO Format (Medicinal Products) or free sale certificate (OTC Health) and marketing authorization. c) Certification with any Organization or Authority. d) Certificate of Analysis of active ingredients and finished products from the (preferably from). Public Sector Laboratory or Independent Accredited Lab		
14.	G.M.P Certificate of Principal Manufacturer by the local regulatory Authority.		
15.	Form-6 about enlistment as importer		
16.	Last inspection report by the local regulatory Authority. Applicable for new products after the expiry of current GMP (GMP Certificate submitted for enlistment as importer).		
17.	State countries with evidence where product is approved/available/submitted for approval/rejected and approved recommended conditions for use (attach evidence).		
18.	Fee deposit receipt		
19.	Undertaking on stamp paper		