CHECKLIST FOR FORM-4

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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 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 i. Batch size ii. Quantity of each active used in the batch iii. Quantity of excipients used		
3	Manufacturing process i. Steps and procedure for batch manufacturing. ii. Critical steps required to be taken in to account.		
4	In-process controls		
5	Testing specifications for raw material i. Identity, Purity and strength ii. Acceptable limits, ranges and criteria iii. Testing procedures and methodology. iv. Certificate of analysis		
6	Testing specifications for finished products. i. Identity, Purity and strength ii. Acceptable limits, ranges and criteria iii. Testing procedures and methodology. iv. Certificate of analysis		
7	Shelf life and storage (shelf life shall base on stability data) In case data not available then letter of commitment for submission of data be submitted.		

8	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; (evidence for therapeutic or disease reduction claims as per standards of evidence		
9	Packaging and labeling. i. Type of packing material used ii. Primary and secondary labels Patient information leaflet		
10	Maximum Retail price.		
11	Fee deposit receipt		
12	Undertaking on stamp paper (notarized)		