

CHECKLIST FOR FORM-3

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S NO.	PARAMETER	YES	NO
1	<p>Product Profile</p> <ul style="list-style-type: none"> 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:- <ul style="list-style-type: none"> 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	<p>Testing specifications of Raw Material and Finished Products</p> <ul style="list-style-type: none"> i. Identity, Purity and strength ii. Acceptable limits, ranges and criteria iii. Testing procedures and methodology. iv. Certificate of Analysis (COA) 		
5	Shelf life and storage.		
6	<p>Recommended Conditions for use</p> <ul style="list-style-type: none"> 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 		
7	<p>Packaging and labeling.</p> <ul style="list-style-type: none"> i. Type of packing material used ii. Primary and secondary labels iii. Patient information leaflet 		
8	Fee deposit receipt		
9	Undertaking on stamp paper (notarized)		