Checklist for Grant/Renewal of Manufacturing Licence of Drug Products

Part A: Firm/Facility Related Details

Checklists No	Item Description
1	Covering letter
2	Specific Power of Attorney in favour of authorized signatory for submitting application on behalf of the company
3	Site Plan and layout of the building with the name, address, scale, measurements of the area as per Schedule M Requirement *Plan and layout of the premises showing the installation of Machinery and Equipment. preferably a Blue Print duly signed by the applicant who signed in the statutory form.*
4	Self-attested copies of documents pertaining to the possession of premises such as Registered ownership/rent/lease/allotment letter/Possession Letter, Tax Receipt (Documents should be registered with appropriate Authority) *Declaration of the ownership of the premises if premises owned by the applicant firm or company, with the documentary evidence of ownership like Registered sale deed and/or proof of allotment of the site along with the latest property tax receipt.*
5	Consent to Establish and Consent to Operate from State Pollution Control Board
6	List of Directors, Partners, Trustees, along with **ROC Copy**, **Registered Partnership deed, Trust deed**
7	List of Competent Technical Staff with their qualification, Registration, Experience, previous FDA Approvals, etc.
8	Appointment/Acceptance Letter of Competent Technical staff of **Manufacturing** Section *Application for approval of Technical Staff in the prescribed format with enclosures of consent letter, copies of qualification certificates, experience certificates of proposed technical staff along with earlier approvals, if any, appointment order of the Technical staff.*
9	Appointment/Acceptance Letter of Competent Technical staff of **Testing** Section *Application for approval of Technical Staff in the prescribed format with enclosures of consent letter, copies of qualification certificates, experience certificates of proposed technical staff along with earlier approvals, if any, appointment order of the Technical staff.*
10	Section-wise List of plant and Machineries *Detailed list of Manufacturing and Analytical Equipment.*
11	NOC of Department of Industrial Safety & Health : *Permission obtained from the Municipal Authorities/ Panchayat authorities/ Industrial Local Authority, Certificate in conformity with **Factories** Act for construction and starting the Unit & Permission from **Fire Safety** Department regarding the manufacturing facility.*

12	HVAC installation and validation Certificate
13	Water System installation and validation Certificate
14	Site Master File
15	Constitution details of firms
16	List of SOPs/STPs
17	Self-declaration of technical person
18	Self-declaration of Directors/Partners/Proprietor *Declaration of the Directors/Partners/Proprietor in Affidavit (as per format) & List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of company).* *Self attested Copy of Aadhar card/Passport/Electoral card as proof of residential address of the responsible person as mentioned in the Affidavit*

Part B: Product Specific Details

Checklists No	Item Description
19	Copy of valid Test license in Form 29
20	Source of bulk drugs along with current regulatory status with copy of Form 46A/45A/CT-19/CT-22 (if obtained)
21	Certificate of Analysis of the bulk drugs/drug substance
22	Master Manufacturing Formula
23	Manufacturing Procedure of each product applied *Flow Chart with structural Formula of reactions (for bulk drugs)*
24	Product Development report with Excipient compatibility and forced degradation study
25	Process validation report
26	Finished product specification including impurity profile *Copies of monographs for formulations with pharmacopoeial specifications other than IP.*
27	Finished Product Method of Analysis
28	Finished product Analytical method validation report
29	Finished Product Certificate of Analysis for three consecutive batches/three validation batches
30	Stability study data report as per requirements mentioning batch size (should be presented in tabular form with details of Batch No., Batch size, Date of Manufacturing, Date of initiation, Packaging details) *Evidence and data justifying that the applied drugs:* *(i) contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful.* *(ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulation and under the conditions in which the formulation for administration and use are recommended;*

	(iii) are stable under the conditions of storage recommended; (adequate evidence and data regarding stability has to be submitted) *(iv) contain such ingredients and in such quantities for which there is therapeutic justification. (as per amendment to the Drugs and Cosmetics Rules, 1945 vide G.S.R. 360(E) dated: 10th April, 2018)*
31	Comparative Dissolution Release Profile with the approved formulation (in case of oral dosage form)
32	Comparative evaluation of pharmaceutical equivalence with international brand(s) or approved Indian brands, if applicable
33	Draft specimen of the label and carton
34	Bioequivalence protocol and report *Biopharmaceutical Classification System (BCS) class of the constituent API in case of Oral Dosage Forms and the results of bioequivalence study referred to in Schedule Y for Oral Dosage Forms containing drugs specified under category II and category IV of the Biopharmaceutical Classification System. (Results has to be submitted as per Annexure-I) (as per amendment to the Drugs and Cosmetics Rules, 1945 vide G.S.R. 327(E) dated: 03-04-2017)* *Results of bioequivalence study referred to in Schedule Y - Bioequivalence protocol and report should give the complete documentation of its study protocol, conduct and evaluation.*
35	Justification on Bioequivalence study waiver, if requested
36	Details of the approval of the New Drug in the country. In case of new drugs, copy of approval of new drug from CLAs in favour of the applicant in Form 46/CT-23 ***For New Drugs:*** *Form CT-22 (for APIs) / Form CT-23 (for Formulations) in case of 'New Drugs' as defined as per New Drugs & Clinical Trial Rules, 2019 (for New Drugs for Human Use) (or) Form 46/ Form 46-A in case of 'New Drugs' under Rule 122E of Drugs and Cosmetics Act and Rules made thereunder (for New Drugs for Veterinary Use) (or) NOC for specific quantity export of New Drugs.* ***Note:*** *Definition for 'New Drugs' for Human Use has to be referred as per Clause (w) of Rule 2 (1) of New Drugs & Clinical Trial Rules, 2019*
37	Form 10 issued by CDSCO where required
38	Form 51 Undertaking *Undertaking in Form 51 of Drugs and Cosmetics Rules to the licensing authority regarding Brand Names.* *Declaration regarding the Brand Names of the Product. (in case of Formulations ONLY for Export).*
39	Challan of Fees Paid to be uploaded
40	Any Other Document
41	Application in prescribed legal form (e.g., Form 24, Form 27, Form 27-D, 27DA, etc.) *duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution.*

Note:

1. For obtaining permission for **additional items** on approved category, the applicant will be required to submit details as mentioned at serial no. 19 to 41 only.

2. If applicant is submitting "Not Applicable (NA)" against any above-mentioned documents, the same needs to be justified adequately.