

## CHECKLIST

Form Name: Form-27

Fresh

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter	Yes
2.0	Specific Power of Attorney in favour authorized signatory for submitting application on behalf of the company	Yes
3.0	Site Plan and layout of the building with the name, address, scale, measurements of the area as per Schedule –M Requirement	Yes
4.0	Self attested copies of documents pertaining to the possession of premises such as, Register ownership /rent /lease/allotment letter /Possession Letter, Tax Receipt,(Documents should be Registered with appropriate Authority )	Yes
5.0	Consent to establish from State Pollution Control Board	Yes
6.0	List of Directors, Partners, Trustees, along with ROC Copy Registered Partnership deed,Trust deed	Yes
7.0	List of Competent Technical Staff, with their qualification, Registration , Experience, previous FDA Approvals,Etc.	Yes
8.0	Appointment/Acceptance Letter of Competent Technical staff of manufacturing Section.	Yes
9.0	Appointment/Acceptance Letter of Competent Technical staff of Testing Section.	Yes
10.0	Section wise List of plant and Machineries	Yes
11.0	NOC of department of industrial safety & Health	Yes
12.0	HVAC installation and validation Certificate(s)	Yes
13.0	Water System installation and validation Certificate(s)	Yes
14.0	Site Master File	Yes
15.0	Constitution details of firms	Yes
16.0	List of SOPs/STPs	Yes
17.0	Self declaration of technical person	Yes

18.0	self declaration of directors	Yes
19.0	Copy of valid Test license in Form 29	Yes
20.0	Source of bulk drugs along with current regulatory status with copy of Form 46A/ 45A/CT-19/CT-22 (if obtained)	Yes
21.0	Certificate of Analysis of the bulk drugs/drug substance	Yes
22.0	Master Manufacturing Formula	Yes
23.0	Manufacturing Procedure	Yes
24.0	Product Development report with Excipient compatibility and forced degradation study	Yes
25.0	Process validation report	Yes
26.0	Finished product specification including impurity profile	Yes
27.0	Finished Product Method of Analysis	Yes
28.0	Finished product Analytical method validation report	Yes
28.0	Finished product Analytical method validation report	Yes
29.0	Finished Product Certificate of Analysis for three consecutive batches/three validation batches	Yes
30.0	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)	Yes
31.0	Comparative Dissolution Release Profile with the Approved formulation (in case of oral dosage form)	Yes
32.0	Comparative evaluation of pharmaceutical equivalence with international brand(s) or approved Indian brands, if applicable	Yes
33.0	Draft specimen of the label and carton	Yes
34.0	Bio Equivalence protocol and report	Yes
35.0	Justification on Bio equivalence study waiver, if requested	Yes
36.0	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	Yes
37.0	Form 10 Issued by CDSCO where required	Yes
38.0	Form 51 Undertaking	Yes

39.0	Challan of Fees Paid To Be Upload	Yes
40.0	Any Other Document	No
41.0	Application in prescribed legal(Form 27)	Yes