

Checklist for Approval of Additional Product (Endorsement) Under Drug License Granted

- A.** Covering Letter
B. Consolidated list of Products / Formulations with packing particulars under each licence separately category wise viz. Tablets, Capsules, Injectables etc.

C.Product Specific Details

Checklists No	Item Description
1.	Copy of valid Test license in Form 29
2.	Source of bulk drugs along with current regulatory status with copy of Form 46A/45A/CT-19/CT-22 (if obtained)
3.	Certificate of Analysis of the bulk drugs/drug substance
4.	Master Manufacturing Formula
5.	Manufacturing Procedure of each product applied <i>Flow Chart with structural Formula of reactions (for bulk drugs)</i>
6.	Product Development report with Excipient compatibility and forced degradation study
7.	Process validation report
8.	Finished product specification including impurity profile <i>Copies of monographs for formulations with pharmacopoeial specifications other than IP.</i>
9.	Finished Product Method of Analysis
10.	Finished product Analytical method validation report
11.	Finished Product Certificate of Analysis for three consecutive batches/three validation batches
12.	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) <i>Evidence and data justifying that the applied drugs:</i> <i>(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.</i> <i>(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;</i> <i>(iii) are stable under the conditions of storage recommended;</i> <i>(adequate evidence and data regarding stability has to be submitted)</i> <i>(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)</i>
13.	Comparative Dissolution Release Profile with the approved formulation (in case of oral dosage form)
14.	Comparative evaluation of pharmaceutical equivalence with international

	brand(s) or approved Indian brands, if applicable
15.	Draft specimen of the label and carton
16.	<p>Bioequivalence protocol and report</p> <p><i>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)</i></p> <p><i>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.</i></p>
17.	Justification on Bioequivalence study waiver, if requested
18.	<p>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</p> <p>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.</p> <p>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</p>
19.	Form 10 issued by CDSCO where required
20.	<p>Form 51 Undertaking</p> <p><i>Undertaking in Form 51 of Drugs and Cosmetics Rules to the licensing authority regarding Brand Names.</i></p> <p><i>Declaration regarding the Brand Names of the Product. (in case of Formulations ONLY for Export).</i></p>
21.	Challan of Fees Paid to be uploaded
22.	Any Other Document
23.	<p>Application in prescribed legal form (e.g., Form 24, Form 27, Form 27-D, 27DA, etc.)</p> <p><i>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.</i></p>

Note:

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