

F. No. DC-DT-15011(11)/20/2026
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(DCC-DTAB Division)

Dated: 25 FEB 2026

To,
All State/UTs Licensing Authority

Subject: Guidance Document on Dossier based licensing of Drugs - Regarding

Sir/Madam,

This is with reference to the Guidance Document on "Dossier based licensing of Drugs for submission of application for obtaining Manufacturing License by the Applicant" forwarded by this office vide email dated 12.02.2024 for necessary action for uniform product licensing across the country.

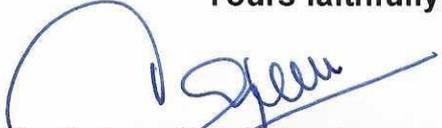
In this regard, it is to mention that the guidance document was presented in the meeting of State Regulatory Authorities held on 29th August, 2023 at CDSCO (HQ) under the chairmanship of Secretary, HFW, and all the States/UTs in principle agreed with the said Guidance document.

The guidance document contains the checklist in two Section/Parts i.e. Part A is w.r.t. submission for various administrative information about the company & Part B is w.r.t. submission of various technical information about the applied drug products. The same checklist has already been introduced in the Online National Drugs licensing system (ONDLS) portal for issuing of manufacturing licenses.

Accordingly, it is once again reiterated to adopt the guidance document for uniform product licensing across the country.

You are requested to kindly acknowledge the receipt and update the action taken in the matter.

Yours faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Encl.: Guidance document

Copy to: CDSCO Zonal and Sub Zonal office

Guidance Document

Title: Guidance Document for submission of application for obtaining Manufacturing License by the Applicant based on Dossier based licensing of Drugs

Document No. CDSCO/DBA/V.01



**Central Drugs Standard Control Organisation
Directorate General of Health Services,
Ministry of Health and Family Welfare
Government of India**

GUIDANCE DOCUMENT FOR GRANT OF MANUFACTURING LICENCE

Purpose:

To provide guidance to Indian manufacturer for submission of application to concerned State Licensing Authority and CDSCO Zonal/Sub-Zonal Offices for grant/renewal of manufacturing License, as the case may be.

Scope:

The guidance document is applicable to the manufacturer for the submission of application for grant of license and also to the regulatory authorities for reviewing the submitted application as per provided checklist. It is not applicable for AYUSH drugs, cosmetics and medical devices.

Introduction:

Dossier based approval is a process commonly used to assess and approve application. Instead of making decision based on the individual evaluation, a dossier based approach allows for more structured and comprehensive evaluation of relevant information contained in a dossier submitted by the applicant.

This includes application Form, supportive documents, test reports, certificates and any other required materials. Once the dossier is received, it is reviewed by the concerned authorities for making decision. The evaluation criteria is based on the various provisions provided under Drugs and Cosmetics Act and Rules thereunder. Based on the review, a decision is to be made, whether to approve, reject or request for further clarification from the applicant.

The dossier based approval process promotes the transparency and ensures fairness in the decision making process. The dossier based approach is more efficient than the individual evaluation as it streamlines the process and reduces the need for redundant assessment. The dossier based approach is very helpful when objective and consistent evaluation is required.

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Background:

An applicant is required to apply in prescribed form as provided under Drugs and Cosmetics Rules 1945 for obtaining manufacturing license for manufacturing drug products including APIs. The applicant is expected to submit various statutory documents along with application for ensuring that the drug products so manufactured are safe and effective.

As per Drugs Rules, an applicant shall:-

1. Provide adequate space, plant and equipment for the manufacturing operations; the space, plant and equipment recommended for various operations are given in Schedule M.
2. Provide and maintain adequate staff, premises and laboratory equipment for carrying out tests of the strength, quality and purity of the substances at the testing unit which shall be separate from the manufacturing unit and head of the testing unit shall be independent of the head of the manufacturing unit:
3. Make adequate arrangements for the storage of drugs manufactured by him
4. While applying a license to manufacture a new drug in the form of active pharmaceutical ingredient or pharmaceutical formulation, as the case may be, for sale or distribution, shall make an application for grant of permission to the Central Licencing Authority in applicable Form along with a fee as specified in the Sixth Schedule in New Drugs and Clinical Trials Rules 2019.
5. Comply with the requirements of 'Good Manufacturing Practices' as laid down in Schedule M.
6. In case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

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7. Shall submit the result of bioequivalence study along with the application for grant of a licence of oral dosage form of drugs specified under category II and category IV of the biopharmaceutical classification system.

Discussion held in 61st DCC meeting:

The matter was also discussed in 61st DCC meeting. DCC was apprised that concerns have been raised from time to time regarding Quality, Safety and Efficacy of the drugs and uniform implementation of the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder, including safety of the excipients used in the formulations.

Further, Committee was informed about the need to take measures for uniform implementation of document/ dossier based approval for licensing of drugs to ensure quality, safety and efficacy of drugs in the country.

It was deliberated that uniform implementation of document based licensing will be able to address many issues relating the quality of drugs manufactured in the country. It was also deliberated that a specified checklist / format may be developed which can be adopted uniformly across the country. The checklist presently being used for approval of subsequent new drug in CDSCO may be used after appropriate modification required as per the Drugs rules, 1945.

The committee after detailed deliberation recommended that the dossier / document based licensing of the drugs should be implemented uniformly across the country and the checklist for submission of documents by the applicant may be prepared based on the checklist of subsequent new drugs followed at CDSCO. The draft Checklist should be circulated to all the members for their comments within seven days. The committee also recommended that a letter should be issued by DCG (I) advising the State Licensing Authorities to implement the documents based licensing uniformly across the country.

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Discussion held in the meeting of Drug Regulatory Authorities held on 29th August, 2023 at CDSCO (HQ):

The Guidance Document as one of the agenda during the meeting was presented for submission of application for obtaining Manufacturing License by the Applicant based on Dossier based licensing of Drugs.

The purpose of guidance document is to provide guidance to Indian manufacturer for submission of application to concerned State Licensing Authority and CDSCO Zonal/Sub-Zonal Offices for grant/renewal of manufacturing License so that uniformity could be achieved across the country in seeking the data from the applicant.

The guidance document contains the checklist in two Section/Parts i.e. Part A is w.r.t. submission for various administrative information about the company & Part B is w.r.t. submission of various technical information about the applied drug products. The State Drugs Controller, H.P. has raised the concern regarding the requirement of Form-29 in case of technology transfer from R&D to commercial manufacturing plant or from one manufacturing plant of same company to another manufacturing plant. It was clarified that in such case, firm need to submit proper technology transfer documents for the consideration by the licensing authority.

After discussion, all the states in principle agreed with the proposed Guidance document for Uniform product licensing.

Guidance:

In order to achieve the objective as discussed in 61st DCC for uniform implementation of dossier based approval for licensing of drugs to ensure quality, safety and efficacy of drugs in the country, a checklist has been developed considering all the requirements which need to be complied by the applicants before obtaining the license.

The checklist has been developed in two Section/Parts:

Part A is w.r.t. submission for various administrative information about the company like Certificate of Incorporation (ROC), Constitution of firm, land ownership/lease

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agreement/MIDC approval, approval of other Government Authorities and other facility related information.

Part B is w.r.t submission of various technical information about the applied drug products like Stability data, process validation data, analytical method validation/verification data etc.

The checklist so developed will help the applicant to submit the dossier in the uniform manner across the country and will bring the credibility and predictability in the regulatory system.

All the State regulatory authorities are expected to implement the checklist in their respective States in order to achieve the objective of uniform submission of documents for obtaining the license which is as under:

Checklist for grant/renewal of manufacturing license of drug products:

Checklists No	Item Description
	Part A – Firm/facility related details
1	Covering letter
2	Specific Power of Attorney in favour 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
4	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)
5	Consent to establish from State pollution control Board.
6	List of Directors, Partners, Trustees, alongwith 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

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	manufacturing Section.
9	Appointment/Acceptance Letter of Competent Technical staff of Testing Section.
10	Section wise List of plant and Machineries
11	NOC of department of industrial safety & Health
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
	Part B - Product specific details
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
24	Product Development report with Excipient compatibility and forced degradation study
25	Process validation report
26	Finished product specification including impurity profile
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)

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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	Bio Equivalence protocol and report
35	Justification on Bio equivalence 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
37	Form 10 Issued by CDSCO where required
38	Form 51 Undertaking
39	Challan of Fees Paid To Be Upload
40	Any Other Document
41	Application in prescribed legal form (e.g. Form 24, Form 27, Form 27-D, 27DA, etc.)

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.