File No. DCG (I)/MISC/2026 (4)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
O/o Drugs Controller General (I)

FDA Bhawan,
New Delhi - 110002 (India)

Dated: 23rd Feb, 2026

CIRCULAR

Subject: Testing of Drugs for Grant of Permissions for Import/Manufacture of New Drug for sale or for distribution and Issuance of Registration Certificate for Import of Drugs etc.-regarding.

The Central Drugs Standard Control Organization (CDSCO) receives applications for Grant of Permissions for Import/Manufacture of New Drug for sale or for distribution and Issuance of Registration Certificate for Import of Drugs etc. At present, the specifications submitted by applicants are examined by CDSCO and a No Objection Certificate (NOC) for testing is issued considering the following:

i. Type of formulation, dosage form, Critical Quality Attributes (CQAs), and general characteristics of the product.
ii. Product development reports, forced degradation studies, and other relevant data, in accordance with applicable guidelines.
iii. Compliance with relevant Pharmacopoeial Monographs.
iv. Provisions of General Chapters of the Indian Pharmacopoeia (IP) or other pharmacopoeias specified in the Second Schedule of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

As a pre-requisite for approval, testing of the product to be approved is carried out by the designated laboratories, namely Indian Pharmacopoeia Commission (IPC), Ghaziabad; Central Drugs Testing Laboratory (CDTL), Mumbai; CDL at CRI, Kasauli or National Institute of Biologicals (NIB), Noida. These laboratories conduct testing as per the submitted specifications and the test reports are submitted to CDSCO for consideration of approval of the applied products.

In order to expedite the processing of applications, it has been decided that No Objection Certificate (NOC) for testing of drug samples at the designated laboratories (IPC, Ghaziabad; CDTL, Mumbai; CDL at CRI, Kasauli; or NIB, Noida) shall be issued immediately upon receipt of applications in the concerned division. As part of the filing document, applicants shall submit their finalized regulatory specifications based on:

a. Prevailing Pharmacopoeia standards and relevant general chapters of the Pharmacopoeia, as specified in the Second Schedule of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.
b. Product Specific Quality Management System (QMS).

In cases where specifications are revised or updated after review or comments by CDSCO, a fresh NOC for testing shall be issued for re-testing at the designated laboratory as per the revised specifications.

This circular will be effective from 1st June, 2026.

This is issued for information and necessary action.

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

Copy for information and necessary action to:

1. All Divisions of CDSCO, HQ.
2. The Secretary-cum-Scientific Director Indian Pharmacopoeia Commission, Ministry of Health &Family Welfare, Govt. of India, CIPL Campus, Sector-23, Raj Nagar, Ghaziabad-201 002.
3. The Director, CDTL, Mumbai.
4. The Director, NIB Noida, UP
5. The Director CDL at CRI Kasauli, Himachal Pradesh.
6. All stake holders though CDSCO website.
7. CDAC at CDSCO.