F. No. ND-11012(17)/1/2026-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

24 JUN 2026

Circular

Subject: Regulation of Formulation intermediates such as Directly Compressible granules, Taste masked granules, Modified release granules / Pellets-regarding

Various representations have been received by this office regarding regulation of formulation intermediates such as Directly Compressible granules, Taste masked granules, Modified release granules / Pellets direct compression/capsule filling to facilitate the industries.

The concerns raised by stakeholders were examined through internal technical discussions with respect to uniformity in licensing system for formulation intermediates across the country and there after the matter was placed before the 68th Meeting of the Drugs Consultative Committee (DCC) held on 20.03.2026 through Hybrid mode.

After deliberation, DCC recommended CDSCO to issue clarification, on the following:-

1. For New Drugs including SR/ER/PR/DR formulations and bulk intermediates, for formulation manufacturing. CDSCO marketing permission under NDCT Rules 2019 will be required.
2. For drugs other than New Drugs such as directly compressible granules, the manufacturers may approach SLA. Further, in case of use of new/novel excipients, CDSCO approval will be required.

In view of the above, it is hereby informed as follows:

a) As per Rule 2 (1) (w) of the New Drugs and Clinical Trials Rules, 2019 modified or sustained release form of a drug including Gastro-resistant Tablets/Capsules /Delayed release Tablets/Capsules (Enteric Coated Tablets/Capsules) shall always be deemed to be new drug as per the provisions of New Drugs and Clinical Trials Rules, 2019. Accordingly, it is clarified that all modified release dosage forms (SR/ER/PR/DR) including formulation intermediates intended to be used in such formulations i.e bulk SR, ER, PR, DR Pellets, granules will require CDSCO approval. Manufacturers of such formulation are required to submit application of pharmaceutical formulation accompanied with that of application for formulation intermediate for grant of permission to manufacture for sale or distribution in accordance with the provisions of New Drug and Clinical Trial Rules 2019 to CDSCO

b) All formulation intermediate other than those mentioned in Sr. No. "a" and not classified as new drugs, in such cases, the applicant shall submit application along with requisite data to the concerned State Licensing Authority for license to manufacture for sale or distribution for such formulation intermediate. However, if such formulation or formulation intermediate contains any new or novel excipient, approval from the CDSCO shall be required.

Accordingly, the applicant shall submit the application of formulation intermediates to CDSCO or to the SLA as the case may be for import/manufacturing and marketing.

Yours faithfully,

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

To,
1- All State/UT Drugs Controllers
2- All Zonal/Sub-Zonal/Port Offices CDSCO

Copy to:
All Stakeholders through CDSCO website