June 24, 2026

CDSCO

Modified-release pellets and granules need CDSCO approval

CDSCO's circular of June 24, 2026 says modified-release pellets and granules need its approval, while other intermediates go to State Licensing Authorities.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), New Drugs Division, under the Directorate General of Health Services, issued a circular under F. No. ND-11012(17)/1/2026-eoffice. It is stamped June 24, 2026 and signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India). Its subject is the regulation of formulation intermediates such as directly compressible granules, taste masked granules and modified release granules or pellets. It is addressed to all State/UT Drugs Controllers and all CDSCO Zonal, Sub-Zonal and Port Offices, with a copy to all stakeholders through the CDSCO website. CDSCO listed it among its circulars on June 24, 2026.

KEY FACTS

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CDSCO

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Circular, F. No. ND-11012(17)/1/2026-eoffice

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The circular says CDSCO received various representations on how these intermediates are regulated. CDSCO examined them in internal technical discussions on uniformity in licensing for formulation intermediates across the country. It then placed the matter before the 68th meeting of the Drugs Consultative Committee (DCC), held on March 20, 2026 in hybrid mode. The DCC recommended two clarifications. For new drugs, including SR/ER/PR/DR formulations and bulk intermediates for formulation manufacturing, CDSCO marketing permission under the New Drugs and Clinical Trials Rules, 2019 will be required. For drugs other than new drugs, such as directly compressible granules, manufacturers may approach the State Licensing Authority (SLA), and CDSCO approval will be required where new or novel excipients are used.

Point (a) of the circular cites rule 2(1)(w) of the New Drugs and Clinical Trials Rules, 2019. Under it, a modified or sustained release form of a drug, including gastro-resistant and delayed release (enteric coated) tablets and capsules, is always deemed a new drug. So all modified release dosage forms (SR/ER/PR/DR), including formulation intermediates intended for them, "i.e bulk SR, ER, PR, DR Pellets, granules", will require CDSCO approval. Manufacturers of such formulations must submit the application for the pharmaceutical formulation together with the application for the formulation intermediate to CDSCO, for permission to manufacture for sale or distribution under those Rules.

Point (b) covers every other formulation intermediate not classified as a new drug. The applicant applies, with the requisite data, to the concerned SLA for a licence to manufacture it for sale or distribution. If the formulation or the formulation intermediate contains any new or novel excipient, CDSCO approval is required. The circular ends by saying applicants are to submit the application for formulation intermediates to CDSCO or to the SLA, as the case may be, "for import/manufacturing and marketing".

Points (a) and (b) speak of permission or a licence to manufacture; only the last sentence mentions import, and the circular gives no separate procedure for it. It names no form or fee, does not define a new or novel excipient, and does not spell out SR, ER, PR or DR. It does not say how a firm that makes only the pellets or granules, and not the finished formulation, is to apply. It

says nothing about intermediates already licensed by a State, and sets no date from which it applies.

Issued by	Central Drugs Standard Control Organization, New Drugs Division (Directorate General of Health Services)
Document	Circular, F. No. ND-11012(17)/1/2026-eoffice
Dated	June 24, 2026 (date stamp)
Addressed to	All State/UT Drugs Controllers; all CDSCO Zonal, Sub-Zonal and Port Offices; copy to all stakeholders through the CDSCO website
Applies to	Applicants for import or manufacture and marketing of formulation intermediates, such as pellets and granules
CDSCO approval	Modified release (SR/ER/PR/DR) dosage forms and the intermediates intended for them, "i.e bulk SR, ER, PR, DR Pellets, granules"; any formulation or intermediate containing a new or novel excipient
How to apply to CDSCO	The application for the pharmaceutical formulation, with the application for the formulation intermediate, under the New Drugs and Clinical Trials Rules, 2019
State Licensing Authority	Other formulation intermediates not classified as new drugs, such as directly compressible granules: a licence to manufacture for sale or distribution
Basis	Rule 2(1)(w), New Drugs and Clinical Trials Rules, 2019; recommendation of the 68th meeting of the Drugs Consultative Committee, March 20, 2026
Takes effect	No date stated
Listed	CDSCO circulars, June 24, 2026
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India)

Who approves which formulation intermediate

Formulation intermediate	Who approves
Intermediates intended for modified release (SR/ER/PR/DR) dosage forms: bulk SR, ER, PR and DR pellets and granules	CDSCO, under the New Drugs and Clinical Trials Rules, 2019, applied for with the finished formulation
Other intermediates not classified as new drugs, such as directly compressible granules	The concerned State Licensing Authority

Any formulation or formulation intermediate containing a new or novel excipient	CDSCO

The circular (PDF, 757 KB)

Source: CDSCO's own copy.

Checked against the official copy on October 28, 2026.

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