

File No. ND-13020/2/2024-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization (HQ)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi -110002

Dated **24 FEB 2025**

To,

All State/UT Drugs Controllers

Subject:- Gastro Resistant Tablets/Capsules, Delayed Release Tablets/Capsules as "New Drugs" as per Rule 2, (1)(w) of the New Drugs and Clinical Trials Rules, 2019-Reg.

Sir/Madam,

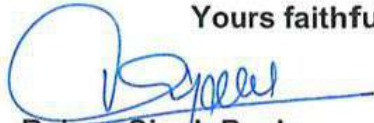
As per the definition of "New Drug" specified in Rule 2(1)(w) of the New Drugs and Clinical Trials Rules, 2019, a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licensing Authority shall always be deemed to be a new drug.

The issues relating to uniform implementation of this rule regarding Gastro-resistant Dosage forms / Delayed-release Dosage forms (Enteric Coated Tablets/Capsules) across the country was deliberated in 64th meeting of the Drugs Consultative Committee (DCC) held on 19-06-2024.

After detailed deliberation, the committee recommended to issue a Circular to all the States/UTs regarding the interpretation of Gastro-resistant Tablets/Capsules /Delayed release Tablets/Capsules (Enteric Coated tablets/ capsules) as "New Drug" as per Rule 2 (1) (w) of the New Drugs and Clinical Trials Rules, 2019, for uniform implementation across the country.

Accordingly, all the State/UT Drugs Controllers are requested to ensure uniform implementation of the Rule 2 (1) (w) of the New Drugs and Clinical Trials Rules, 2019 that modified or sustained release form of a drug including Gastro-resistant Tablets/Capsules /Delayed release Tablets/Capsules (Enteric Coated Tablets/Capsules) or novel drug delivery system shall always be deemed to be new drug as per the provisions of New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Yours faithfully,


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

Copy to:

1. All Stakeholder through CDSCO website.
2. All Zonal/ Sub-Zonal Offices of CDSCO.
3. CRU Section of CDSCO (HQ)