C-217

File No.: DCGI/Misc./2025-09

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(O/o DCG(I))

To,
All State Drugs Controllers/UTs

11 SEP 2025

Subject: Withdrawal / cancellation of product permission for not Implementing of GSR 327 (E) dated 03.04.2017 for obtaining result of bio-equivalence study before grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System-Reg.

Sir/Madam,

This is to inform that as per the provisions of the GSR 327 (E) dated 03.04.2017, the applicant is required to submit the result of bioequivalence study along with the application before grant of a license of oral dosage form of drugs specified in category II and IV of the BCS. There is no provision of accepting an undertaking from the manufacturers that none of the applied solid oral dosage form falls under the category II and IV of notification No. GSR 327 dated 03-04-2017, as per the said Rules.

Further, approval in absence of BE study data for BCS Class II & IV category products is in violation of Rule 74(q), 74 B (8), 76(10) 78(r), 78A (9) of the Drug & Cosmetics Act 1940 & Rules made there under and a risk to public health.

In view of the above facts and circumstances, you are requested to cancel / withdrawal the product permission of solid oral dosage form falling under the BCS category II and IV whose BE studies were not submitted by the manufacturer at the time of submission of the application.

This may be accorded TOP PRIORITY.

Yours faithfully

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