



No.F.2-6/2024 DD (RRR)
Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drugs Regulatory Authority of Pakistan
(Division of Pharmaceutical Evaluation & Registration)

Islamabad, the 11th September ,2026

NOTIFICATION

SUBJECT: Evaluation of Iron Content and Quality Compliance of Non-Pharmacopeial Iron-Containing Preparations

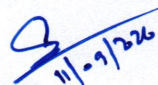
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Drug Regulatory Authority of Pakistan (DRAP) in line with its mission, ensures availability of affordable quality assured, safe and efficacious therapeutic goods. The DRAP Act, 2012 mandates the adoption of best international practices in the regulation of therapeutic goods.

2. Iron-containing formulations are intended for use in high-risk patient populations, including pregnant women and elderly patients suffering from iron-deficiency anaemia. A significant number of such formulations available in the market are non-pharmacopeial and are currently evaluated using manufacturer-specific analytical methods, including titrimetric methods.
3. Considering the critical therapeutic use of these products and the limitations associated with titrimetric methods, including comparatively lower precision, susceptibility to analyst-dependent errors, and potential variability in endpoint interpretation, reliance on different manufacturer-specific methods may result in inconsistency in the assessment of iron content.
4. Accordingly, a uniform, validated and scientifically robust analytical method for determination of iron content in such formulations shall be established and adopted to ensure consistency, accuracy, reliability and reproducibility of analytical results and to safeguard the quality and safety of these products.

Resultantly, the Registration Board, in its **358th meeting held on 12th May, 2026**, considered and deliberated upon the regulatory and analytical concerns associated with iron-containing formulations, particularly non-pharmacopeial preparations, including Ferric Carboxymaltose and Iron (III) Hydroxide Polymaltose Complex.

5. The Board has advised all registration holders, DTLs and CDL, to employ duly validated and scientifically appropriate analytical methods for the determination of iron content in iron-containing preparations. The testing and assessment of iron content not to be carried out solely based on analytical methods submitted or proposed by the manufacturers. Any analytical method employed for such determination shall be appropriately validated and demonstrably suitable for its intended purpose, particularly where no specific pharmacopeial method is available.
6. Accordingly, above decision of Registration Board is hereby circulated for information and compliance for all relevant stakeholders.


11/07/22

(Sana Kanwal)

Deputy Director, PE&R
For Secretary Registration Board

Distribution:

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