



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

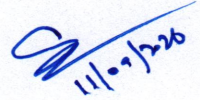
SUBJECT: ADOPTION OF HPLC METHOD FOR ANALYSIS OF MECOBALAMIN (METHYLCOBALAMIN) INJECTION PRODUCTS

I am directed to refer to the subject captioned above.

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. The Mecobalamin injections manufactured in Pakistan are currently being tested in accordance with the respective manufacturers' approved specifications. However, technical concerns have been raised regarding the analytical techniques and identification methodologies being employed for the testing of these products. The adequacy and reliability of the existing analytical procedures, and their potential impact on the assessment of product quality, safety, and efficacy, warrant consideration by the Registration Board.
3. Resultantly, the Registration Board in its **358th meeting held on 12th May, 2026** deliberated on suitability and standardization of analytical methods for testing Mecobalamin injections. In view of the capability of HPLC to detect relevant impurities, including hydroxocobalamin and cyanocobalamin, the Board decided that all manufacturers/Marketing Authorization Holders of Mecobalamin injections shall adopt the HPLC method for analysis of their finished product.
4. In the light of above-mentioned decision, all manufacturers'/MA holders holding registrations for Mecobalamin/Methylcobalamin Injection are directed to submit applications for the change of specifications/analytical method if they are not employing HPLC based method of testing for Mecobalamin, to the relevant section of PE&R Division within Six months of issuance of this notification i.e 11-09-2026.

5. Accordingly, above decision of Registration Board is hereby circulated for information and compliance for all relevant stakeholders.



(Sana Kanwal)
Deputy Director, PE&R
For Secretary Registration Board

Distribution:

Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
Executive Director, Pharma Bureau, Karachi.
Executive Director, Pakistan Chemist and Druggist Association, Karachi.

Through E-office:

PS to CEO, DRAP, Islamabad
Director (MIS), DRAP for uploading on DRAPs website.
Additional Director / Office In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective area of jurisdiction