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 22nd October, 2025

NOTIFICATION

SUBJECT: PRODUCT SPECIFICATION OF MECOBALAMIN / METHYCOBALAMIN TABLET

I am directed to refer to the subject captioned above. PQCB Punjab sought advice on product specification of tablet containing Mecobalamin / Methylcobalamin. Registration Board in its 348th meeting held on 1st & 2nd July, 2025, deliberated on the subject matter and decided that the Mecobalamin / Methylcobalamin Tablet monograph is available as drug product in Japanese Pharmacopoeia. Hence, all the registration holders should follow JP monograph of Mecobalamin/ Methylcobalamin Tablet.

- 2. In the light of above-mentioned decision all manufacturers / MA holders having registration of the tablet containing Mecobalamin / Methylcobalamin are advised to apply for change of specifications in relevant section of PE&R Division within Six months of issuance of this notification.
- 3. Accordingly, above decision of Registration Board is hereby circulated for information and compliance for all relevant stakeholders.

(SANA KANWAL)
Deputy Director, PE&R

Distribution:

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

Through E-office:

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