



No.F.14-1/2022-PEC  
Government of Pakistan  
Ministry of National Health Services, Regulation and Coordination  
(Drug Regulatory Authority of Pakistan)  
TF Complex Sector G-9/4

\*\*\*\*\*

"SAY NO TO CORRUPTION"

Islamabad, the 14<sup>th</sup> March, 2022

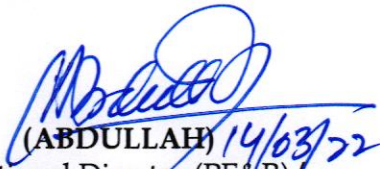
Subject: - **Mecobalamin manufacturing and testing.**

I am directed to refer to the subject captioned above. Registration Board in its 313<sup>rd</sup> meeting held on 16<sup>th</sup> - 18<sup>th</sup> November, 2021 discussed the subject matter and decided as under:

*Registration Board discussed the matter in detail and deliberated regarding the light sensitive nature of mecobalamin and thoroughly reviewed the monograph of mecobalamin drug substance and mecobalamin tablet in Japanese Pharmacopeia 17<sup>th</sup> Edition. Registration Board observed that mecobalamin is a light sensitive drug and it decomposes on exposure to light. Thus, keeping in view photolabile nature of the mecobalamin and pharmacopoeial recommendations, the Board advised the manufacturers of mecobalamin containing drug products to protect the drug substance from light during all manufacturing and testing stages taking appropriate measures including use of light-resistant vessels.*

*The Board further advised all pharmaceutical manufacturers/importers having registration of mecobalamin and all other light sensitive/photolabile drug substance containing drug products to comply the directions of the Board.*

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

  
(ABDULLAH) 14/03/22  
Additional Director (PE&R)/  
Secretary, Registration Board

**Distribution:**

- i. Director (MIS), DRAP for uploading on DRAP's website.
- ii. Director, Central Drugs Laboratory, Karachi.
- iii. Chief, Drug Control and Traditional Medicine Division, National Institute of Health, Islamabad.
- iv. Director, Drug Testing Laboratories of the Punjab (Lahore, Faisalabad, Multan, Bahawalpur, Rawalpindi), Sindh, Khyber Pakhtunkhwa, Balochistan, AJ&K and Gilgit Baltistan.
- v. The Chief Drugs Controller/Inspector, Punjab / KPK / Sindh / Balochistan / ICT / AJ&K / Gilgit Baltistan.
- vi. Additional Director / Officer In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective area of jurisdiction
- vii. Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
- viii. Executive Director, Pharma Bureau, Karachi.
- ix. Executive Director, PCDA, Karachi.