No. 8-6/2019-I&V-I(Vet)
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
TF Complex Sector G-9/4
****

Islamabad, 6th February, 2023

ADVISORY

Subject: - **Compliance to Pharmacopoeial Specifications for Dissolution Test.**

I am directed to refer to the subject captioned above. Registration Board in its 323rd meeting observed that various USP monographs for drug products prescribe more than 1 type of dissolution tests and that the pharmacopoeia in such cases recommends that *"When more than one Dissolution Test is given, the labeling states the Dissolution Test used only if Test 1 is not used."*

2. Keeping in the USP labeling requirements narrated above and to comply to the Pharmacopoeial specifications, the Board decided as under:

"The manufacturer shall mention the dissolution test Number on the secondary packing/unit carton of product for dissolution tests No 2,3 or 4 as per requirement of USP otherwise it would be presumed that dissolution test No.1 shall be performed on the finished product."

3. Accordingly, above decision of Registration Board is hereby circulated for information and compliance by relevant stakeholders / manufacturers.

6/2/2023

(Ch. Zeeshan Nazir Bajar)
Additional Director (PE&R)/
Secretary, Registration Board

Distribution:

i. Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
ii. Executive Director, Pharma Bureau, Karachi.
iii. Executive Director, PCDA, Karachi.

Through E-Office:

i. Director (PE&R)/Chairman, Registration Board.
ii. Director (MIS), DRAP for uploading on DRAP's website.
iv. Additional Director / Officer In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective area of jurisdiction.

Additional Director (PE&R)/
Secretary, Registration Board