



Islamabad, the 08th December, 2020.

[Medical Product Alert]

“Pantopep Tablets”

M/s Hassan Pharmaceuticals,
(Pvt.) Ltd., 96/102-C Kohat Road,
Peshawar.

Subject: **DRUG RECALL OF SUBSTANDARD PANTOPEP TABLETS, BATCH NO. 911, REG. NO. 064137, MANUFACTURED BY M/S HASSAN PHARMACEUTICALS (PVT.) LTD., PESHAWAR.**

I am directed to refer to the subject cited above and CDL, Karachi report vide No.IP.100/2020 dated 26th November, 2020 wherein your product “PANTOPEP TABLETS, BATCH NO. 911, REG. NO. 064137, MANUFACTURING DATE 10-2019, EXPIRY DATE 09-2021 has been declared of Substandard quality. Details of CDL reports are as under;

S.No.	Test	Acceptance Criteria	Results	Reference
1	Description	Light brown biconvex enteric coated tablets having word “Hassan” on one side	Complies.	Mfg. Specs
2	Identification	The identification test must identify Pantoprazole Sodium.	Complies.	USP 43
3	Dissolution	Each unit is not less than 75% (Q)	Does not Comply	USP 43
4	Uniformity of dose units by weight variation	Acceptance value should be less than or equal to L1 (L1 is 15)	14.73. Complies.	USP 43
5	Assay Pantoprazole Label claim is 40mg/tablet.	90% to 110%	107.1%. Complies.	USP 43

02. You are therefore directed to recall all the stock of above-mentioned batch of product “PANTOPEP TABLETS, BATCH NO. 911, REG. NO. 064137,” from market, alert your sales officers/suppliers/ distributors to issue instructions to the pharmacies/hospitals, point of sales/purchase/use for the return of suspected stocks of product in question. Furthermore, you are directed to submit a compliance report of recall to this division within seven (07) days positively.


-/sd-
(Shahid Nawaz)
Assistant Director (QC-II)

Copy for information and necessary action – with request to issue necessary directions to points of use/sale (Hospitals Pharmacies, Medical stores, Distributors, Whole sellers, etc) under administrative control/ fall under area of jurisdiction, please.

1. The Secretary (SHC&ME) Health Department (Government of Punjab).
2. The Secretary Primary and Secondary Health Department (Government of Punjab).
3. The Secretary Health Department (Government of Sindh).
4. The Secretary (SHC&ME) Health Department (Government of KPK).
5. The Secretary (SHC&ME) Health Department (Government of Baluchistan).
6. The Secretary (SHC&ME) Health Department (Government of AJ&K).
7. The Director General Health, M/o NHR&C, Islamabad.
8. The Director General Health, Government of Punjab.
9. The Director General Health, Government of Sindh.
10. The Director General Health, Government of KPK.
11. The Director General Health, Government of Baluchistan.
12. The Director General Health, Government of AJ&K.
13. The Additional Director / Office In-charge, DRAP, Lahore, Karachi, Islamabad, Peshawar, and Quetta.
14. The Chief Drug Controller / Inspector Punjab, Sindh, KPK, Baluchistan, AJ&K, GB and ICT.

Copy to:-

- i. The Director, QA<, DRAP, Islamabad.
- ✓ ii. The Additional Director MIS **with request to upload it on official website in the larger interest of public.**
- iii. FID-I/III, DRAP, Peshawar for information record and necessary action, if any, please.
- iv. Area FID, DRAP, Quetta.
- v. PS to CEO, DRAP, Islamabad.
- vi. Assistant Director, QC-I, DRAP, Islamabad.
- vii. Office copy.


08-12-2020
(Assistant Director QC-II)