



F. No.03-48/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulation & Coordination

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 27th October, 2020.

[Medical Product Alert]

“Aqua-Nov Injection”

M/s. Novartana Pharmaceuticals (Pvt.) Ltd.,
7-B Sundar Industrial Estate,
Lahore.

Subject: **DRUG RECALL OF AQUA-NOV INJECTION B# W-214 MFG. BY M/S. NOVARTANA PHARMACEUTICALS (PVT.) LTD., 7-B SUNДАР INDUSTRIAL ESTATE, LAHORE.**

I am directed to refer to the subject cited above and reports of Central Drugs Laboratory, Karachi vide No. R.IP.89/2020 (Initial) wherein Central Drugs Laboratory Karachi has declared subject mentioned batch of Aqua-Nov Injection manufactured by your firm present in the combo pack of product “Oxiphin 1g Injection” (Mfg. by M/s. Kannel Pharmaceuticals, Islamabad) as “**Adulterated and Sub-Standard**”. Details of CDL reports are as under;

SPECIFICATIONS FOR FINISHED PRODUCT (AQUA-NOV INJECTION)

S. No.	Test	Specifications	Result	Reference
1.	Description	Clear water, free from visible particles, preserved in single dose glass or plastic container.	Water preserved in single dose glass ampoules, containing visible glass particles. Does not comply.	USP 43

02. You are therefore directed to recall all the stocks of mentioned batches of product “Aqua-Nov Injection” 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.

(Hafiz Saqaulah Babar)
Assistant Director QC-III

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 NHSR&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. The Additional Director, DRAP, Lahore.
- iv. Area FID Islamabad for information record and necessary action please.
- v. Area FID Lahore for necessary action please.
- vi. PS to CEO, DRAP, Islamabad.
- vii. Assistant Director QC-I for information and record.
- viii. Office copy.


(Assistant Director QC-III)