OFFICE OF THE CONTROLLER DRUG & FOOD CONTROL ORGANIZATION Drug Testing Laboratory Complex Dalgate Srinagar (J&K)

Most Urgent/Immediate Action/Drug Alert Notice Out by email

The Deputy Controller Drug & Food Control Organization Jammu / Kashmir

No.: DFO/D-T/1545/2007 - 10 Dated: 10 - 07 2017

Subject: Drug Samples Declared to be Not of Standard Quality.

Madam.

This office has received copies of test reports from Drug Analyst - Drug Testing Laboratory Dalgate Srinagar as per following details regarding Drug Samples declared to be "Not of Standard Quality".

S.N o	Name of the Drug	Manufactured By	Sample Lifted By	B.No. & MD/ED	Test Report No. & Date	Reasons
1.	OXCIN-Z	M/s Oscar Remedies Johron, Adjoining Industrial Area , Kala Amb – 173030 (H.P) Mrk. By: MAK Pharmaceuticals, Tirath Nagar , Baddi Majra , Yamuna Nagar - 135001	DI Zone Khag / Magam / Beerwah	T-160457 MD: 07/2016 ED: 06/2018	L/DA/2017-18/562 Dt: 07-07-2017	1. The sample doesnot conform the claim in respect to assay of Ofloxacin and Ornidazole. 2. The sample doesnot comply the test Uniformity of weight of tablets.
2	AMZOLE- DSR	M/s Oscar Remedies Johron, Adjoining Industrial Area , Kala Amb – 173030 (H.P) Mrk. By: MAK Pharmaceuticals, Tirath Nagar , Baddi Majra , Yamuna Nagar - 135001	DI Zone Khag / Magam / Beerwah	C-160088 M/D: 07 /2016 E/D: 06 /2018	L/DA/2017-18/563 Dt: 07-07-2017	The sample fails in Disintegration test for capsule shells
		M/s Oscar Remedies Johron, Adjoining Industrial Area , Kala Amb – 173030 (H.P) Mrk. By: MAK Pharmaceuticals, Tirath Nagar , Baddi Majra , Yamuna Nagar - 135001	DI Zone Khag / Magam / Beerwah	T-160458 M/D: 07 /2016 E/D: 06 /2018	L/DA/2017-18/564 Dt: 07-07-2017	The drug Pantoprazole Sodium is not shown official on the label. Hence Misbranded.

You are hereby requested to alert the field staff working under your control to keep a strict vigil over the movement of the above Drugs & take further appropriate action to ensure that un-utilised stocks of the said batches of the Drugs are not put to use at the level of end users.

It is further requested that procedure of the Act is got completed at the Inspectorate level & Recommendations of Screening Committee are provided to this office at an early date.

(Lotika Khajuria)

Controller Orug & Food Control Organization

cc:

1. The Commissioner / Secretary to Government, Health & Medical Education Department, Civil Secretariat,

2. Drugs Controller General (India), Directorate General of Health Services, FDA Bhawan, Kotla Road, I.T.O. New Delhi-110002 for favour of information & n/a.