



PUNJAB HEALTH SYSTEMS CORPORATION

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No. PHSC/Proc/Med/2022/ 2953

Dated: 25.11.2022

To

All the Rate Contract holders
for supply of medicines to PHSC

Subject: Notice regarding meeting to be held on 06.12.2022 at 11:00 am in the Committee Room of PHSC with the manufacturers whose samples have failed on testing as well as the other R.C holders for ensuring compliance of medicines to the quality standards as per concerned Pharmacopeia.

Please refer to the subject cited above:

As per test reports received from the State Drug Testing Laboratory, samples of various drugs supplied by different manufacturers have failed on testing during last six months. Samples of some of the drugs have failed on quality parameters regarding assay, dissolution, disintegration etc., while samples of some of the drugs failed due to labelling problems (Misbranded). Failure of any drug after supply (even if it is minor defect) not only reflects poorly on the manufacturer and the procurement entity, it also adversely affects the supply chain planning and availability of drugs at Public health facilities. Therefore it is imminent to ensure that the supplied drugs complies with the relevant standards and the failure rate is reduced down to the negligible by ensuring strict compliance to the relevant pharmacopeia standards during manufacturing and Internal Q.C process.

As per the terms and conditions of the contract, notices have been issued from time to time to the concerned manufacturers whose samples have failed on testing over the period of last few months. Replies from some of the manufacturers have been received while replies are awaited from some of the manufacturers. **To discuss the issue regarding failed samples and replies/submissions of the concerned manufacturers w.r.t failed samples as well as to decide on the further course of action in each case of failed sample, a meeting has been scheduled to be held under the chairmanship of Managing Director, PHSC in the committee room of PHSC on 06.12.2022 at 11:00 am.** The above meeting will also be attended by the committee comprising of experts from State Drug testing Laboratory as well as State Drug Control Authority. **The meeting is mandatorily to be attended in person by the senior authorised representatives of the principal manufacturers who are well acquainted/ conversant with the manufacturing process and internal Q.C management of the concerned manufacturers whose samples have failed on testing (List attached).** Please note that liaisoning agents or distributors will not be allowed to attend the above meeting. Further this communication shall be treated as a notice for personal hearing for explaining position on failed drugs and accordingly further action will be initiated by this office.

In addition to discussions/ hearings on the failed samples a general session will also be carried out in the above meeting with all the manufacturers with whom the PHSC is having Rate Contract arrangements to sensitize the respective manufacturers on how to ensure the adherence to the Quality Parameters. All the Rate Contract holders of the drugs in the PHSC are therefore requested to attend the meeting even if no batch of the material supplied by them has failed on testing over the period of last two years. However the manufacturers whose medicines have not failed over the period of last two years may attend the meeting thorough V.C for which link will be shared with such manufacturers.

Preed
25.11.22
Director (Procurement)
PHSC, S.A.S.Nagar

S.No	Name of Firm	Name of Item	Batch No	Report No/Date	Brief Reason of Failure & Category	Notice issued vide No/Date
1	M/s Maxmed Life Sciences Pvt. Ltd.,	Cefuroxime Axetil tab 500mg	22CT064	3318/02.09.2022	Not of standard quality & Description	2055/ 14.09.22
2	M/s Nestor Pharmaceuticals Ltd.	Iron and Folic Acid large (red)-Dried Ferrous Sulphate IP-60mg eq to ferrous iron folic 0.5 mg sugar coated	IQTZ-271	3321/ 02.09.2022	Not of standard quality & Description	2056/ 14.09.22
3	M/s Navkar Lifesciences	Ciprofloxacin 500 mg	TH2004A	3059/13.08.2022	Not of Standard quality. The dissolution found to be 77.89% against Limit of NLT 80% of labeled claim, also the four (04) units are less than D-25% (as per IP standards of test).	2076/ 16.09.22
4	M/s Medipol Pharmaceutical India Pvt Ltd	Tamsulosin HCl Tab 0.4 mg	TMLS-004	796/28.02.2022	Not of Standard Quality as defined in the Drugs & Cosmetics Act, 1940. The contents of Tamsulosin Hydrochloride found to be 0.4545 mg (113.12%) per uncoated tablet against labelled claim of 0.4 mg per uncoated tablet.	2138/ 20.09.22
5	M/s Apple Formulations Private Limited	Albendazole Tab IP 400mg	ABN-2201	3433/ 12.09.22	Not of Standard Quality and dissolution of Albendazole found to be 61.27% against Limit of NLT 80% of labelled claim of Albendazole.	2565/ 18.10.22

6	M/s Unimark Healthcare Ltd(UHL)	Clonazepam Mouth Dissolving Tab 0.5mg	UGT22918	3495/ 08.09.22	Not of standard quality & Description	2563/ 18.10.22
7	M/s Zenith Drugs Pvt Ltd	Oral Rehydration Salts IP	P-21054	3382/ 08.09.22	Not of standard quality & The contents of Chloride and Citrate found to be 73.337mOsmol/L(112.83%) & 8.723mOsmol/L(87.23%) respectively against respective label claim of 65.) mOsmol/L and 10.0mOsmo	2564/ 18.10.22
8	M/s Modern Laboratories	Zinc Sulphate dispersible Tab IP 20mg	ZET3212	2235/ 22.06.22	Not of standard quality & Description	2534/ 17.10.22
9	M/s Rusan Pharma Limited	Buprisan-N tablet	29132202	1591/ 03.05.2022	Not of standard quality & Dissolution test for Buprenorphine found to be 72.63% against the IP Limits (Not less than 80% of the Claim).	2237/ 06.10.22
10	M/s J.Duncan Healthcare Pvt. Ltd	Lovofloxacin Tab 500 mg	JDWF206	3018/ 10.08.2022	Not of standard quality & label	1924/ 10.08.22
11	M/s J.Duncan Healthcare Pvt.ltd	Ivermectin 6 mg tab	JDJS201	3019/ 10.08.2022	Standard Quality with remarks label on container shall indicate common name of the color which is not mentioned on the strips of the referred sample	1924/ 10.08.22
12	M/s Zee Laboratories	Ornidazole Tab IP 500 mg	Z-20132	2851/ 02.08.2022	Not of standard quality & failed in description	2569/18.10.2 022

13	M/s Bengal Chemicals & Pharmaceuticals Ltd,	Norfloxacin Tab IP 400mg	2605001		Not of standard quality & dissolution of Norfloxacin found to be 62.16% against Limit of NLT 70% of labeled claim of Norfloxacin	
14	M/s Healer's Lab (Unit -II)	Telmisartan 40mg)	TLP-502 TLP-513 TLP-514 TLP-515		Not of Standard Quality	
15	M/s Verve Humancare Laboratories	Tab. Buprenorphine 0.4 mg + Naloxone 0.1mg	P2292105			
16	M/s Hindustan Laboratories Limited	Vitamin A Paediatric Oral Solution I.P	LPA2020 AL	3324/02.09.2022	Standard quality but as per I.P monograph, labelling should state the name of retinol ester or esters present which is not mentioned on the label of cited sample.	2644/21.10.2022