

Recalls, Market Withdrawals, & Safety Alerts

SFDA has issued a recall of the following Products:

Trade Name	Batch number	Recall reason	MAH*
Lipoplus 20% Emulsion for infusion 100 ML	243918081	Droplet-like agglomerates have been observed in some batches at later points of shelf life at 25 C° storage in stability studies	Mediserv
Fasenra 30MG/ML AI	YK0060	Remote Sterility Assurance Risk	Saudi International Trading Company LTD (SITCO)
Tegalax gel 15 g	All batches	Non-compliance with the requirements of the Law of Pharmaceutical Products and Establishments and its Implementing Regulations.	مستودع تيجان الصحة للأدوية Cigalah Group
NECTAR مستحضرات مصنع LIFE SCIENCES LIMITED	Annex 1	Non-compliance with Good Manufacturing Practices (GMP)	ZIMMO TRADING ESTABLISHMENT and Med city Tabuk Pharmaceutical Manufacturing Company
Septiva hand sanitizer spray 120 ml & 250 ml & 500 ml	All batches	Non-compliance with the requirements of the Law of Pharmaceutical Products and Establishments and its Implementing Regulations.	شركة مصنع العناية الوحيدة للصناعات للأدوية
Prazosin Hydrochloride 5 mg capsules	3010404A 3010403A 3010405A 3010510A	Due to the presence of Nitrosamine impurities exceeding acceptable limits.	Spectropharma



Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Saudi Drug Updates (SDU)

SFDA urges healthcare Professional to avoid using the above-listed products