F. No.03-35/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulation & Coordination
****

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, *the 18th August,* 2020.

[Medical Product Alert]

"Hydryllin Sugar Free Syrup"

(Aminophylline 35mg/5ml, Diphenhydramine HCl 8mg/5ml, Ammonium Chloride 30mg/5ml)

M/s. The Searle Company Limited,
32Km Multan Road,
Lahore.

Subject: **DRUG RECALL OF HYDRYLLIN SUGAR FREE SYRUP BATCH NO. B0003, B0009, B0243, A0013, A0014, A0015, A0016 AND A0017 REG. NO. 058021, MANUFACTURED BY M/S THE SEARLE COMPANY LIMITED, 32KM MULTAN ROAD, LAHORE.**

I am directed to refer to the subject cited above and reports of Central Drugs Laboratory, Karachi vide Nos. R.LHR.121/2020 R.LHR.122/2020, R.LHR.115/2020, R.LHR.116/2020, R.LHR.117/2020, R.LHR.118/2020, R.LHR.119/2020 and R.LHR.120/2020 wherein Central Drugs Laboratory Karachi has declared subject mentioned batches of your product "Hydryllin Sugar Free Syrup" as **"Sub-standard and Adulterated"**. Details of CDL reports are as under;

Sr. #	Product Name	Batch No.	Mfg. Date	Exp. Date	Test Report No.	Results	Remarks
01	Hydryllin Sugar Free syrup	B0003	03-2020	03-2022	R.LHR.121/2020	**Does not comply (Numerous visible black particles were observed in the sample)**	The sample is **"Adulterated and Sub-Standard"** under the Drugs Act, 1976.
02	-do-	B0009	05-2020	05-2022	R.LHR.122/2020	-do-	-do-
03	-do-	B0243	07-2020	07-2022	R.LHR.115/2020	-do-	-do-
04	-do-	A0013	12-2019	12-2021	R.LHR.116/2020	-do-	-do-

05	-do-	A0014	12-2019	12-2021	R.LHR.117/2020	-do-	-do-
06	-do-	A0015	12-2019	12-2021	R.LHR.118/2020	-do-	-do-
07	-do-	A0016	12-2019	12-2021	R.LHR.119/2020	-do-	-do-
08	-do-	A0017	12-2019	12-2021	R.LHR.120/2020	-do-	-do-

02. You are therefore directed to recall all the stocks of mentioned batches of product "Hydryllin Sugar Free Syrup" 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-
(Hafiz Sanaullah 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&LT, DRAP, Islamabad.
ii. The Additional Director MIS **with request to upload it on official website in the larger interest of public.**
iii. FID VIII Lahore for information record and necessary action please.
iv. PS to CEO, DRAP, Islamabad.
v. Office copy.

(Assistant Director QC-III)