



Circular No. 22 / 2025

29 -07-1446 H
29 -01-2025

بتقدم بثقة
Moving Forward
with Confidence



Recall of Oral Dispensing Syringe White Plunger with Tip Cap from Alshifa Medical Products Co.(CJS).

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/260
Product	Oral Dispensing Syringe White Plunger with Tip Cap.
Manufacturer	Alshifa Medical Products Co.(CJS).
Local agent	Salalah Medical Supplies Manufacturing. Co.LLC.
The affected products	Model: F32300000330 Affected Lot number: 20619.
Reason	A manufacturing defect has caused a change in the color of the syringes.
Action	1. Stop using the affected products. 2. Return the affected products to the manufacturer. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General





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To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 32/2025 dated 29/1/2025 Regarding SFDA Recall of Oral Dispensing Syringe White Plunger with Tip Cap from (mfr: Alshifa Medical Products Co.(CJS)).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



DSC
مركز سلامة الدواء
Drug Safety Center



URGENT FIELD SAFETY NOTICE

FSN #: SA-21-01-25-753

Date

21-01-2025

Product Name	Oral Dispensing Syringe White Plunger with Tip Cap
Attention to User	

1. Purpose of FSN:

To inform the client about color discrepancy of the oral syringe

1.1. Affected Product Description

Manufacturer	Alshifa Medical product Co.	Brand	Ramy
Model	Oral syringe	Lot.No	20619
Type	3ml	Ref.No/ CAT. No	F32300000330
Mfg. Date		Exp.Date	

2. Description of the problem

لون الحقنة غامق يعيق تحديد قياس الجرعة ،

The color of the syringe was dark, which hindered the determination of the dose measurement.

3. Root Cause for this Issue

The root cause was traced to the introduction of an experimental color during production, leading to dark-colored syringes instead of the required transparent amber. The experimental color was not explicitly flagged or approved for production.

4. Corrective Action

ALSHIFA ONLY TO PRODUCE AMBER TRANSPARENT COLOR ONLY FOR THE ORAL SYRINGE.

ALSHIFA MEDICAL PRODUCTS CO.
Closed Joint Stock Co.

1st. Industrial City , P.O.Box 7917, Road 22, Cross II,
Dammam 31472 Kingdom of Saudi Arabia
Tel. : +966 13 84 74 284
Fax : +966 13 84 74 033
C.R. 2050008936
www.alshifa.com

شركة منتجات الشفاء الطبية
مساهمة مقفلة

المدينة الصناعية الأولى - ص.ب. ٧٩١٧ - طريق ٢٢ - تقاطع ١١
الدمام ٣١٤٧٢ المملكة العربية السعودية
تلفون : +٩٦٦ ١٣ ٨٤٧ ٤٢٨٤
فاكس : +٩٦٦ ١٣ ٨٤٧ ٤٠٣٣
ص.ت. : ٢٠٥٠٠٠٨٩٣٦
www.alshifa.com

5. Preventive Action

Update the Bill of Materials (BOM) and Production Request for the 3ml oral syringe to specify transparent amber color clearly.

Enhanced Inspection:

Implement a color verification step in quality control to confirm that all syringes meet the specified color requirement.

6. Risk On Health

6.1. For Patient

Inaccurate dose

6.2. For the User

Not easy to give correct dose

7. Action to be taken by the END USER

To return the remaining balance with the hospital of the same lot.

8. Action to be taken by the MANUFACTURER

To replace all the 3ml oral syringe with dark color from the customer lot#20619

9. Authorized Representative Contact Information

Name	Wed Alshaalan	Email	wedas@alshifa.com qad@alshifa.com
Phone No.	013 8474284 ext. 104 / 303	Address	Dammam, KSA

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