



URGENT: DRUG RECALL

Hindy Schiff
Vice President Regulatory Affairs and Compliance
Ascend Laboratories, LLC
135 US Highway 202-206, Suite 15
Bedminster, NJ, 07921

Dear Customer:

This is to inform you of a product recall involving Cephalexin FOS, 125 mg/5 mL. Please reference lot-specific information included below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed (in bottles)
1	Cephalexin FOS, 125 mg/5 mL	23141828	125 mg/5 mL	May 2025	100 mL	67877-544-88	September 20, 2023	7,008
2	Cephalexin FOS, 125 mg/5 mL	23141829	125 mg/5 mL	May 2025	100 mL	67877-544-88	October 4, 2023	7,008
3	Cephalexin FOS, 125 mg/5 mL	23142342	125 mg/5 mL	June 2025	100 mL	67877-544-88	October 16, 2023	6,984
4	Cephalexin FOS, 125 mg/5 mL	23142343	125 mg/5 mL	June 2025	100 mL	67877-544-88	September 1, 2023	3,372
5	Cephalexin FOS, 125 mg/5 mL	23142708	125 mg/5 mL	July 2025	100 mL	67877-544-88	November 9, 2023	7,008
6	Cephalexin FOS, 125 mg/5 mL	23143526	125 mg/5 mL	September 2025	200 mL	67877-544-68	December 1, 2023	3,360
7	Cephalexin FOS, 125 mg/5 mL	23144035	125 mg/5 mL	October 2025	100 mL	67877-544-88	May 1, 2024	7,032
8	Cephalexin FOS, 125 mg/5 mL	23144036	125 mg/5 mL	October 2025	200 mL	67877-544-68	February 2, 2024	3,060

9	Cephalexin FOS, 125 mg/5 mL	23144269	125 mg/5 mL	November 2025	200 mL	67877-544-68	September 23, 2024	564
10	Cephalexin FOS, 125 mg/5 mL	23144270	125 mg/5 mL	November 2025	100 mL	67877-544-88	April 25, 2024	7,032
11	Cephalexin FOS, 125 mg/5 mL	24140026	125 mg/5 mL	December 2025	100 mL	67877-544-88	June 7, 2024	6,864
12	Cephalexin FOS, 125 mg/5 mL	24140027	125 mg/5 mL	December 2025	200 mL	67877-544-68	August 28, 2024	252
13	Cephalexin FOS, 125 mg/5 mL	24144282	125 mg/5 mL	October 2026	200 mL	67877-544-68	March 5, 2025	12
Total Distributed								59,556

See enclosed product labels for ease in identifying the product at the WHOLESALE level.

An out-of-specification (OOS) result was observed in the related substance test at the sixth month of stability analysis (with conditions set at 25°C± 2°C/60%±5%RH) of Cephalexin for Oral Suspension USP 125 mg/5 mL. The individual impurity was identified to be Cephalexin Glucose Adduct. As a precautionary measure, all non-expired batches are being recalled from the market.

Cephalexin is used to treat infections caused by bacteria such as pneumonia and other respiratory infections as well as infections of the bones, skin, ears, genitalia, and urinary tract. Cephalexin is considered a cephalosporin and works by killing infection-inducing bacteria. This medicine is only available by prescription and can only be used to treat patients 15 years of age and older. To date, there have been no adverse events reported by patients who have ingested Cephalexin containing the impurity.

Our firm began shipping this product on September 1, 2023. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above.

Please perform the following activities:

- Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above. Please follow the directions in the attached recall stock response to return the affected product.
- Promptly complete the attached recall stock response form even if you have no product to return.
- The completed Recall Response Form can be submitted by any of the following methods:

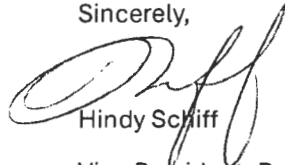
Fax: 817-868-5362 or E-mail: rxrecalls@inmar.com

This recall is being carried out to the WHOLESALE level. Your assistance is appreciated and necessary to prevent consumer harm.

If you have any questions related to customer service, please contact product inquiries—available 24 hours a day, 7 days a week—at 877-272-7901. If you have any questions about the return of the product, please contact Inmar toll free at 855-243-9132—available 9:00 AM to 5:00 PM ET Monday through Friday.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Hindy Schiff', is written over the printed name.

Hindy Schiff

Vice President, Regulatory Affairs and Compliance

Ascend Laboratories, LLC

135 US Highway 202-206, Suite 15

Bedminster, NJ, 07921

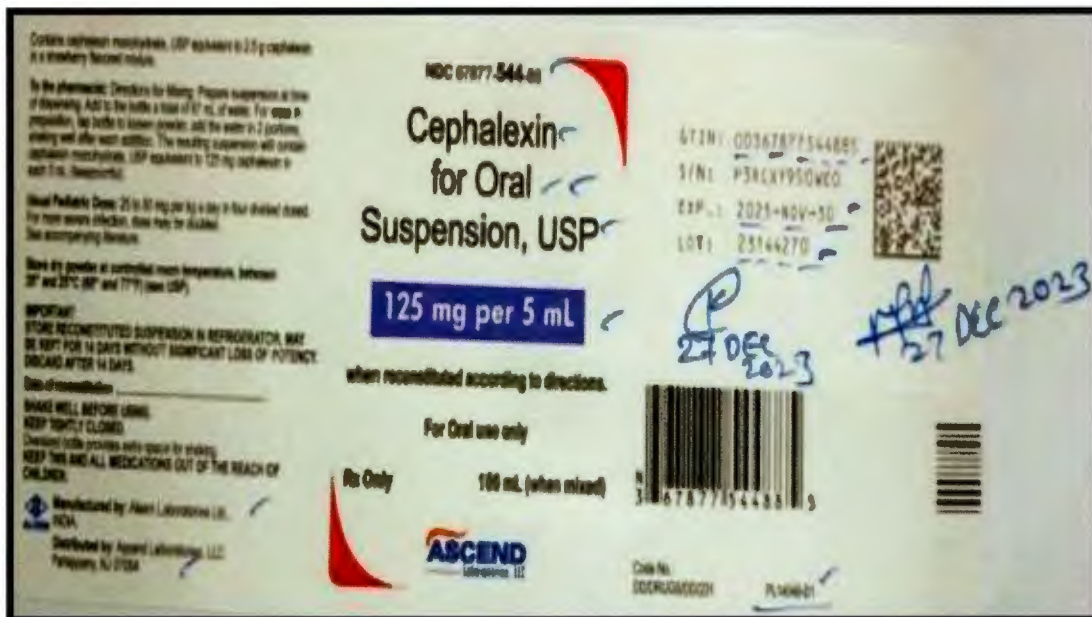
ANNEXURE-I

PRODUCT IMAGE

Batch # 24144282

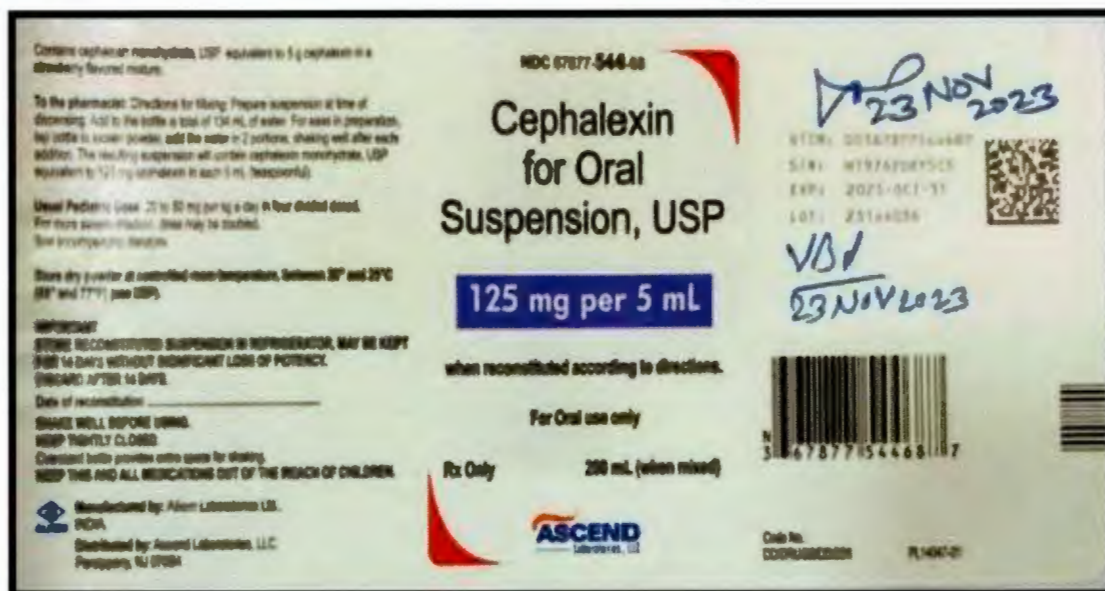


Batch # 23144270





Batch # 23144269





ANNEXURE-I

Batch # 23144035

Contains cephalexin monohydrate, USP equivalent to 2.5 g cephalexin in a strawberry flavored mixture.

To the pharmacist: Directions for Mixing: Prepare suspension at time of dispensing. Add to the bottle a total of 10 mL of water. For ease in preparation, tap bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate, USP equivalent to 125 mg cephalexin in each 5 mL (suspension).

Usual Pediatric Dose: 25 to 50 mg per kg a day in four divided doses. For more severe infection, dose may be doubled. See accompanying literature.

Store dry powder at controlled room temperature, between 20° and 25°C (68° and 77°F) (see USP).

IMPORTANT: STORE RECONSTITUTED SUSPENSION IN REFRIGERATOR, MAY BE KEPT FOR 14 DAYS WITHOUT SIGNIFICANT LOSS OF POTENCY. DISCARD AFTER 14 DAYS.

Date of reconstitution _____

SHAKE WELL BEFORE USING.
KEEP TIGHTLY CLOSED.
Overhead bottle provides extra space for shaking.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured by: Alkem Laboratories Ltd.,
PUNE.

Distributed by: Ascend Laboratories, LLC
Parsippany, NJ 07054

NDC 67877-544-48

**Cephalexin
for Oral
Suspension, USP**

125 mg per 5 mL

when reconstituted according to directions.

For Oral use only

Rx Only 100 mL (when mixed)

ASCEND
Laboratories, LLC

GTIN: 00567877544885
S/N: ZP89C5322P67
EXP: 2025-01-31
LOT: 23144035

24 NOV 2023

24 NOV 2023

3 67877 54488 5

Code No:
D0DRUG000001 PL1005-01

Batch # 23143526

Contains cephalexin monohydrate, USP equivalent to 5 g cephalexin in a strawberry flavored mixture.

To the pharmacist: Directions for Mixing: Prepare suspension at time of dispensing. Add to the bottle a total of 134 mL of water. For ease in preparation, tap bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate, USP equivalent to 125 mg cephalexin in each 5 mL (suspension).

Usual Pediatric Dose: 25 to 50 mg per kg a day in four divided doses. For more severe infection, dose may be doubled. See accompanying literature.

Store dry powder at controlled room temperature, between 20° and 25°C (68° and 77°F) (see USP).

IMPORTANT: STORE RECONSTITUTED SUSPENSION IN REFRIGERATOR, MAY BE KEPT FOR 14 DAYS WITHOUT SIGNIFICANT LOSS OF POTENCY. DISCARD AFTER 14 DAYS.

Date of reconstitution _____

SHAKE WELL BEFORE USING.
KEEP TIGHTLY CLOSED.
Overhead bottle provides extra space for shaking.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured by: Alkem Laboratories Ltd.,
PUNE.

Distributed by: Ascend Laboratories, LLC
Parsippany, NJ 07054

NDC 67877-544-08

**Cephalexin
for Oral
Suspension, USP**

125 mg per 5 mL

when reconstituted according to directions.

For Oral use only

Rx Only 200 mL (when mixed)

ASCEND
Laboratories, LLC

GTIN: 00567877544687
S/N: R25GR1195RAF
EXP: 2025-SEP-30
LOT: 23143526

12 OCT 2023

17 OCT 2023

3 67877 54468 7

Code No:
D0DRUG000023 PL1005-01



ANNEXURE-I

Batch # 23141828

Contains cephalexin monohydrate, USP equivalent to 2.5 g cephalexin in a strawberry flavored mixture.

To the pharmacist: Directions for Mixing: Prepare suspension at time of dispensing. Add to the bottle a total of 57 mL of water. For each 5 mL of suspension, tap bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate, USP equivalent to 125 mg cephalexin in each 5 mL (suspension).

Usual Pediatric Dose: 25 to 50 mg per kg a day in four divided doses. For more severe infection, dose may be doubled. See accompanying literature.

Store dry powder at controlled room temperature, between 20° and 25°C (68° and 77°F) (see USP).

IMPORTANT: STORE RECONSTITUTED SUSPENSION IN REFRIGERATOR. MAY BE KEPT FOR 14 DAYS WITHOUT SIGNIFICANT LOSS OF POTENCY. DISCARD AFTER 14 DAYS.

Date of reconstitution _____

SHAKE WELL BEFORE USING.
KEEP TIGHTLY CLOSED.
Overused bottle provides extra space for shaking.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured by: Alkem Laboratories Ltd., INDIA.
Distributed by: Ascend Laboratories, LLC
Parappully, NJ 07654

NDC 67877-544-88

**Cephalexin
for Oral
Suspension, USP**

125 mg per 5 mL

when reconstituted according to directions.

For Oral use only

Rx Only 100 mL (when mixed)

ASCEND
Laboratories, LLC

GTIN: 00367877544885
S/N: KAATFNDV132A
EXP.: MAY 2025
LOT: 23141828

Code No: 800RU0600031 PL1405-01

12 JUN 2023

Batch # 23142342

Contains cephalexin monohydrate, USP equivalent to 2.5 g cephalexin in a strawberry flavored mixture.

To the pharmacist: Directions for Mixing: Prepare suspension at time of dispensing. Add to the bottle a total of 57 mL of water. For each 5 mL of suspension, tap bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate, USP equivalent to 125 mg cephalexin in each 5 mL (suspension).

Usual Pediatric Dose: 25 to 50 mg per kg a day in four divided doses. For more severe infection, dose may be doubled. See accompanying literature.

Store dry powder at controlled room temperature, between 20° and 25°C (68° and 77°F) (see USP).

IMPORTANT: STORE RECONSTITUTED SUSPENSION IN REFRIGERATOR. MAY BE KEPT FOR 14 DAYS WITHOUT SIGNIFICANT LOSS OF POTENCY. DISCARD AFTER 14 DAYS.

Date of reconstitution _____

SHAKE WELL BEFORE USING.
KEEP TIGHTLY CLOSED.
Overused bottle provides extra space for shaking.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured by: Alkem Laboratories Ltd., INDIA.
Distributed by: Ascend Laboratories, LLC
Parappully, NJ 07654

NDC 67877-544-88

**Cephalexin
for Oral
Suspension, USP**

125 mg per 5 mL

when reconstituted according to directions.

For Oral use only

Rx Only 100 mL (when mixed)

ASCEND
Laboratories, LLC

GTIN: 00367877544885
S/N: 278164864HPR
EXP.: JUN 2025
LOT: 23142342

Code No: 800RU0600031 PL1405-01

15 JUL 2023



ANNEXURE-I

Batch # 23141829

Contains cephalexin monohydrate, USP equivalent to 2.5 g cephalexin in a sweetened flavored mixture.

To the pharmacist: Directions for Mixing: Prepare suspension at time of dispensing. Add to the bottle a total of 67 mL of water. For ease in preparation, tip bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate, USP equivalent to 125 mg cephalexin in each 5 mL (disposable).

Usual Pediatric Dose: 25 to 50 mg per kg a day in four divided doses. For severe infection, dose may be doubled. See accompanying literature.

Store dry powder at controlled room temperature, between 20° and 25°C (68° and 77°F) (see USP).

IMPORTANT: STORE RECONSTITUTED SUSPENSION IN REFRIGERATOR. MAY BE KEPT FOR 14 DAYS WITHOUT SIGNIFICANT LOSS OF POTENCY. DISCARD AFTER 14 DAYS.

Date of reconstitution: _____

SHAKE WELL BEFORE USING.
KEEP TIGHTLY CLOSED.
Unopened bottle provides ample space for shaking.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured by: Alkem Laboratories Ltd.
INDIA.
Distributed by: Ascend Laboratories, LLC
Paripatnam, NJ 07054

NDC 67877-544-88

**Cephalexin
for Oral
Suspension, USP**

125 mg per 5 mL

when reconstituted according to directions.

For Oral use only

Rx Only 100 mL (when mixed)

ASCEND
Laboratories, LLC

Code No. 000RU000001 PL1802-01

GTIN: 00567877544885
S/N: PEWHENK31129
EXP.: MAY 2021
LOT: 23141829

213 JUN 2023
13 JUN 2023

Batch # 23140027

Contains cephalexin monohydrate, USP equivalent to 5 g cephalexin in a sweetened flavored mixture.

To the pharmacist: Directions for Mixing: Prepare suspension at time of dispensing. Add to the bottle a total of 125 mL of water. For ease in preparation, tip bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate, USP equivalent to 125 mg cephalexin in each 5 mL (disposable).

Usual Pediatric Dose: 25 to 50 mg per kg a day in four divided doses. For severe infection, dose may be doubled. See accompanying literature.

Store dry powder at controlled room temperature, between 20° and 25°C (68° and 77°F) (see USP).

IMPORTANT: STORE RECONSTITUTED SUSPENSION IN REFRIGERATOR. MAY BE KEPT FOR 14 DAYS WITHOUT SIGNIFICANT LOSS OF POTENCY. DISCARD AFTER 14 DAYS.

Date of reconstitution: _____

SHAKE WELL BEFORE USING.
KEEP TIGHTLY CLOSED.
Unopened bottle provides ample space for shaking.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured by: Alkem Laboratories Ltd.
INDIA.
Distributed by: Ascend Laboratories, LLC
Paripatnam, NJ 07054

NDC 67877-544-88

**Cephalexin
for Oral
Suspension, USP**

125 mg per 5 mL

when reconstituted according to directions.

For Oral use only

Rx Only 200 mL (when mixed)

ASCEND
Laboratories, LLC

Code No. 000RU000001 PL1802-01

GTIN: 00567877544887
S/N: 809248WKEWH
EXP.: 2023-DEC-31
LOT: 23140027

26 JAN 2024
20 JAN 2024



ANNEXURE-I

Batch # 23140026

Contains cephalexin monohydrate, USP equivalent to 2.5 g cephalexin in a strawberry flavored mixture.

To the pharmacist: Directions for Mixing: Prepare suspension at time of dispensing. Add to the bottle a total of 67 mL of water. For ease in preparation, tap bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate, USP equivalent to 125 mg cephalexin in each 5 mL (teaspoonful).

Usual Pediatric Dose: 25 to 50 mg per kg a day in four divided doses. For more severe infection, dose may be doubled. See accompanying literature.

Store dry powder at controlled room temperature, between 20° and 25°C (68° and 77°F) (see USP).

IMPORTANT
STORE RECONSTITUTED SUSPENSION IN REFRIGERATOR. MAY BE KEPT FOR 14 DAYS WITHOUT SIGNIFICANT LOSS OF POTENCY. DISCARD AFTER 14 DAYS.

Date of reconstitution _____

SHAKE WELL BEFORE USING.
KEEP TIGHTLY CLOSED.
Over-sized bottle provides extra space for shaking.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured by: Alkem Laboratories Ltd.,
PADA,
Distributed by: Ascend Laboratories, LLC
Parsippany, NJ 07054

NDC 67877-544-88

**Cephalexin
for Oral
Suspension, USP**

125 mg per 5 mL

when reconstituted according to directions.

For Oral use only

Rx Only 100 mL (when mixed)

GTIN: 00367877544885
S/N: CC2ADC1FC4K8
EXP.: 2025-DEC-31
LOT: 24140026

28 JAN 2024

Code No: 00367877544885
PL14046-01

Prepared By Recall Coordinator
(Sign & Date)

Nitish K.
Pandey

Digitally signed by Nitish K.
Pandey
Date: 2025.05.15 11:55:39
+05'30'

RECALL STOCK RESPONSE FORM

Recall: Cephalexin FOS, 125 mg/5mL

Lots: 23141828, 23141829, 23142342, 23142343, 23142708, 23143526, 23144035, 23144036, 23144269, 23144270, 24140026, 24140027, 24144282

Customer Name: _____ DEA #: _____

***Please note that DEA # is required. If it is not provided, the processing of your form will be delayed. ***

Address: _____

City: _____ State: _____ Zip Code: _____

Contact Name (please print): _____ Telephone #: _____

Contact Signature: _____ Date: _____

Wholesaler Information if not directly purchased from Ascend:

Wholesaler Name: _____ Wholesaler DEA#: _____

Wholesaler City: _____ Wholesaler State: _____ Wholesaler Zip: _____

Please check and fill out each section accordingly.

- ☐ I have read and understand the recall instructions provided in the Recall Letter.
- ☐ I have checked my stock for the quarantined inventory indicated in the table below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Quantity on Hand (in Bottles)
1	Cephalexin FOS, 125 mg/5 mL	23141828	125 mg/ 5mL	May 2025	100 mL	67877-544-88	
2	Cephalexin FOS, 125 mg/5 mL	23141829	125 mg/ 5 mL	May 2025	100 mL	67877-544-88	
3	Cephalexin FOS, 125 mg/5 mL	23142342	125 mg/ 5 mL	June 2025	100 mL	67877-544-88	
4	Cephalexin FOS, 125 mg/5 mL	23142343	125 mg/ 5 mL	June 2025	100 mL	67877-544-88	

5	Cephalexin FOS, 125 mg/5 mL	23142708	125 mg/ 5 mL	July 2025	100 mL	67877- 544-88	
6	Cephalexin FOS, 125 mg/5 mL	23143526	125 mg/ 5 mL	September 2025	200 mL	67877- 544-68	
7	Cephalexin FOS, 125 mg/5 mL	23144035	125 mg/ 5 mL	October 2025	100 mL	67877- 544-88	
8	Cephalexin FOS, 125 mg/5 mL	23144036	125 mg/ 5 mL	October 2025	200 mL	67877- 544-68	
9	Cephalexin FOS, 125 mg/5 mL	23144269	125 mg/ 5 mL	November 2025	200 mL	67877- 544-68	
10	Cephalexin FOS, 125 mg/5 mL	23144270	125 mg/ 5 mL	November 2025	100 mL	67877- 544-88	
11	Cephalexin FOS, 125 mg/5 mL	24140026	125 mg/ 5 mL	December 2025	100 mL	67877- 544-88	
12	Cephalexin FOS, 125 mg/5 mL	23141828	125 mg/ 5mL	December 2025	200 mL	67877- 544-68	
13	Cephalexin FOS, 125 mg/5 mL	23141829	125 mg/ 5 mL	October 2026	200 mL	67877- 544-68	
Total Product							

☐ Indicate disposition of recall product:

☐ Returned/Held for Return (Yes / No)

- Quantity: _____
- Date: _____
- Method: _____

OR

☐ No recall product on hand (Yes / No)

- ☐ I have identified and notified my customers that this product was shipped/received or may have been shipped by:
- o Date: _____
 - o Method of Notification: _____

Were there any adverse events associated with the recalled product?

- ☐ Yes
☐ No

If yes, please explain: _____

If you have any questions regarding this form or product return, please contact Inmar at 1-855-243-9132. Office Hours: 9:00 AM to 5:00 PM EST Monday through Friday.

Please return this form by fax to 1-817-868-5362 or E-mail rxrecalls@inmar.com.

After receipt of this response form, a return kit will be provided for affected product return to:

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX, 75050

Inmar Recall Event ID: RCL108-2025