

Enforcement Report - Week of April 8, 2026

Class II Drugs Event

Event ID:

98533

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

03/03/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/31/2026

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

K.C. Pharmaceuticals, Inc
3420 Pomona Blvd
Pomona, CA 91768-3236
United States

Distribution Pattern:

Nationwide in the US

Associated Products

Product Description:

Sterile EYE DROPS AC (tetrahydrozoline HCl 0.05%, zinc sulfate 0.25%), 0.5 fl. oz. (15 mL) bottles; a) Best Choice, PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO., 5000 KANSAS AVE, KANSAS CITY, KS 66106, UPC 0 70038 47010 6; b) QC-Quality Choice, Sterile Eye drops Irritation Relief, Distributed by: CDMA, Inc., Novi, MI 48375, NDC 83324-190-14; c) Discount drug mart, Eye Drops A.C., Discount Drug Mart Food Fair, Medina, OH 44256, UPC 0 93351 01158 0; d) Good Sense Sterile Eye Drops, Distributed By: Perrigo Direct, Inc., Peachtree City, GA 30269, www.PerrigoDirect.com, NDC 50804-160-01; e) Walgreens, Eye Drops, DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015, UPC 3 11917 17954 4; f) CAREONE, Itchy relief Eye drops, DISTRIBUTED BY: FOODHOLD U.S.A, LLC., LANDOVER, MD 20785; g) Equaline, DISTRIBUTED BY: UNFI, PROVIDENCE, RI 02908 UPC 0 41163 25114 4; h) TopCare health TM, DISTRIBUTED BY: TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007, UPC 0 36800 03640 6; i) meijer, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544, www.meijer.com, NDC 41250-598-01; j) H.E.B A.C. Eye Drops, MADE WITH PRIDE & CARE FOR H-E-B, SAN ANTONIO, TX 78204, UPC 0 41220 43746 7

Product Quantity:

182,424 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0409-2026

Code Information:

Lot: a) AC24E01, Exp.: 05/31/26; b) AC24E01, Exp.: 05/31/26; c) AC24E01, Exp.: 05/31/26; d) AC24E01, Exp.: 05/31/26; e) AC24E01, Exp.: 05/31/26; f) AC24E01, Exp.: 05/31/26; g) AC24E01, Exp.: 05/31/26; h) AC24E01, Exp.: 05/31/26; i) AC24E01, Exp.: 05/31/26; j) AC24E01, Exp.: 05/31/26;

Product Description:

EYE DROPS Advanced Relief, (dextran 70 0.1%, polyethylene glycol 400 1% and tetrahydrozoline HCl 0.05%), 0.5 FL OZ (15 mL) bottles, Sterile; a) Walgreens, DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015; UPC 3 11917 20074 3; b) Kroger, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202; c) CVS Health, Distributed by :CVS Pharmacy, Inc., Woonsocket, RI 02895, UPC 0 50428 43544 1; d) QC-Quality Choice, Distributed by: CDMA, Inc., Novi, MI 48375, NDC 83324-191-14; e) Discount drug mart, Discount Drug Mart Food Fair, Medina, OH 44256, UPC 0 93351 01155 9; f) Foster & Thrive, Distributed by: McKesson Corp., via SSSL, Memphis, TN 38141, NDC 70677-1158-1; g) GoodSense, Distributed By: Perrigo Direct Inc., Peachtree City, GA 30269, www.PerrigoDirect.com, NDC 50804-130-01; h) TopCare health, DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELKGROVE VILLAGE, IL 60007, UPC 0 36800 03641 3; I) DG health Sterile, DISTRIBUTED BY OLD EAST MAIN CO., 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072, UPC 0 95072 02556 3; j) Fast Acting, CODE RED Eye Drops, Sterile, Distributed by: 4 Trees, LLC, NDC 83817-963-01.

Product Quantity:

303,216 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0410-2026

Code Information:

Lot: a) AR24D01, Exp.: 04/30/26; AR24G01, AR24G02, Exp.: 07/31/26; AR24M01, Exp.: 10/31/26; b) AR24D01, Exp.: 04/30/26; AR24G01, Exp.: 07/31/26; AR24M01, Exp.: 10/31/26; c) AR24D01, Exp.: 04/30/26; AR24G02, Exp.: 07/31/26; AR24M01, Exp.: 10/31/26; d) AR24G02, Exp.: 07/31/26; e) AR24G02, Exp.: 07/31/26; f) AR24G02, Exp.: 07/31/26; g) AR24M01, Exp.: 10/31/26; h) AR24G01, Exp.: 07/31/26; AR24M01, Exp.: 10/31/26; i) AR24M01, Exp.: 10/31/26; j) AR24D01, Exp.: 04/30/26.

Product Description:

Dry Eye Relief Eye Drops, (glycerin 0.2%, hypromellose 0.2% and polyethylene glycol 400 1%) 0.5 FL OZ (15 mL) bottles; a) GERI CARE, Distributed by: Gericare Pharmaceuticals Corp., Lakewood, NJ 08701, NDC 57896-181-05; b) TopCare health, DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELKGROVE VILLAGE, IL 60007, UPC 0 36800 36100 3; c) Rite Aid, DISTRIBUTEDBY: RITE AID, Camp Hill, PA 17011, NDC 11822-1067-2; d) LEADER DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017, www.myleader.com, NDC 70000-0502-1; e) Discount drug mart, Discount Drug Mart Food Fair, Medina, OH 44256, UPC 0 93351 01156 6; f) H-E-B, MADE WITH PRIDE & CARE FOR H-E-B, SAN ANTONIO, TX 78204, UPC 0 41220 43741 2; g) Foster & Thrive, Distributed by: McKesson Corp., via Strategic Sourcing Services LLC, Memphis, TN 38141, www.fosterandthrive.com, NDC 70677-1158-1; h) meijer, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544, www.meijer.com, NDC 41250-718-01; i) DG health Sterile, DISTRIBUTED BY OLD EAST MAIN CO., GOODLETTSVILLE, TN 37072, UPC 0 95072 02656 0; j) Harris Teeter, Eye Drops, Artificial Tears, PROUDLY DISTRIBUTED BY: HARRIS TEETER, LLC, MATHEWS, NC 28105, UPC 0 72036 71303 2; k) exchange select, Manufactured for your Military Exchanges by: KC Pharmaceuticals, Inc., Pomona, CA 91768, UPC 6 14299 05620 6; l) Good Neighbor Pharmacy, Distributed By AmerisourceBergen, Conshohocken, PA 19428, NDC 46122-605-05

Product Quantity:

1,023,096 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0411-2026

Code Information:

Lot: a) LT24E01, LT24E02, LT24E03, Exp.: 05/31/26; LT24F01, Exp.: 06/30/26; LT24G01, Exp.: 07/31/26; LT24M01, LT24M02, Exp.: 10/31/26; b) LT24E03, Exp.: 05/31/26; LT24F01, Exp.: 06/30/26; LT24G01, Exp.: 07/31/26; LT24M02, Exp.: 10/31/26; c) LT24F01, Exp.: 06/30/26; d) LT24F01, Exp.: 06/30/26; LT24G01, Exp.: 07/31/26; e) LT24F01, Exp.: 06/30/26; f) LT24F01, Exp.: 06/30/26; LT24G01, Exp.: 07/31/26; g) LT24F01, Exp.: 06/30/26; LT24G01, Exp.: 07/31/26; h) LT24F01, Exp.: 06/30/26; i) LT24F01, Exp.: 06/30/26; LT24G01, Exp.: 07/31/26; j) LT24F01, Exp.: 06/30/26; k) LT24G01, Exp.: 07/31/26; l) LT24F01, Exp.: 06/30/26; m)

Product Description:

Ultra Lubricating Eye Drops (polyethylene glycol 400 0.4%, propylene glycol 0.3%), Sterile, 0.5 FL OZ (15mL) bottles; a) LEADER, DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017, www.myleader.com, NDC 70000-0457-1; b) Harris Teeter, Eye Drops, Ultra Lubricant, PROUDLY DISTRIBUTED BY: HARRIS TEETER, LLC, MATHEWS, NC 28105, UPC 0 72036 73588 1; c) Foster & Thrive, Lubricating Eye Drops, Distributed by: McKesson Corp., via Strategic Sourcing Services LLC, Memphis, TN 38141, www.fosterandthrive.com, NDC 70677-1160-1; d) Walgreens Lubricant Eye Drops, DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015, UPC 3 11917 20167 2; e) P high performance Eye drops, DISTRIBUTED BY PUBLIX SUPER MARKETS, INC, LAKELAND, FL 33811, UPC 0 41415 09876 3; f) Kroger high performance lubricant eye drops, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202; g) Good Sense Ultra Lubricant Eye Drops, Distributed By: Perrigo Direct, Inc., Peachtree City, GA 30269, www.PerrigoDirect.com, NDC 50804-160-01; h) meijer Ultra Lubricant, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544, www.meijer.com, NDC 41250-937-01; i) CVS Health, Fast Acting Lubricant Eye Drops, Distributed by: CVS Pharmacy, Inc., Woonsocket, RI 02895, UPC 0 50428 39690 2; j) CVS Health, Fast Acting Lubricant Eye Drops, Twin pack, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 44738 3; k) QC-Quality Choice, Lubricant Eye Drops, Distributed by: CDMA, Inc., Novi, MI 48375, NDC 83324-029-15; l) AVENOVA LUBRICANT EYE DROPS, Twin pack, Distributed by: NovaBay Pharmaceuticals, Inc., CA 94608, UPC 8 57005 00411 9.

Product Quantity:

245,184 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0412-2026

Code Information:

Lot: a) SU24E01, SU24E02, Exp.: 5/31/26; SU24K01, Exp.: 9/30/26; b) SU24E01, Exp.: 5/31/26; c) SU24E01, SU24E02, Exp.: 5/31/26; SU24K01, Exp.: 9/30/26; d) SU24E01, SU24E02, Exp.: 5/31/26; e) SU24E01, SU24E02, Exp.: 5/31/26; SU24K01, Exp.: 9/30/26; f) SU24E01, SU24E02, Exp.:

5/31/26; SU24K01, Exp.: 9/30/26; g) SU24E01, SU24E02, SU24E03, Exp.: 5/31/26; h) SU24E01, Exp.: 5/31/26; i) SU24E01, SU24E02, SU24E03, Exp.: 5/31/26; j) SU24E03, Exp.: 5/31/26; k) SU24E02, Exp.: 5/31/26; SU24K01, Exp.: 9/30/26; L) SU24K01, Exp.: 9/30/26.

Product Description:

Sterile Eye Drops ORIGINAL FORMULA (tetrahydrozoline HCl 0.05%), 0.5 FL OZ (15mL) bottles; a) Good Sense Sterile Eye Drops, Distributed By: Perrigo Direct, Inc., Peachtree City, GA 30269, www.PerrigoDirect.com, NDC 50804-141-01; b) Walgreens, Eye Drops, Original Formula, DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015, UPC 3 11917 20073 6; c) Walgreens, Eye Drops, Original Formula, 2 Bottles, DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015, UPC 3 11917 20076 7; d) Kroger Sterile eye drops, Original, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202, UPC 0 1110 38597 0; e) Sterile eye drops, Regular formula, Product manufactured for: Lil' Drug Store Products, Inc., Cedar Rapids, IA 52404, UPC 3 66715 68324 3; f) CVP Sterile EYE DROPS, Distributed by: Salado Sales. Inc., Temple, TX 76503; UPC 7 61606 16500 3; g) Harris Teeter, Eye Drops, Original, PROUDLY DISTRIBUTED BY: HARRIS TEETER, LLC, MATHEWS, NC 28105, UPC 0 72036 71302 5; h) H.E.B Original Eye Drops, MADE WITH PRIDE & CARE FOR H-E-B, SAN ANTONIO, TX 78204, UPC 0 41220 43747 4; i) Rugby tetrahydrozoline ophthalmic Solution, Distributed by: RUGBY LABORATORIES, IN 46268, NDC 0536-1217-94, j) Equaline, DISTRIBUTED BY UNFI, PROVIDENCE, RI 02908, UPC 0 41163 25110 6; k) Discount drug mart, EyeDrops ORIGINAL, Discount Drug Mart Food Fair, 211 Commerce Drive, Medina, OH 44256, UPC 0 93351 01156 3; L) LEADER Original Eye Drops, DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017, www.myleader.com, NDC 70000-0454-1; m) CAREone, DISTRIBUTED BY FOODHOLD U.S.A, LLC, LANDOVER, MD 20785, NDC 41520-431-05; n) Circle K sterile eye drops, Product manufactured for: Lil' Drug Store Products, Inc., Cedar Rapids, IA 52404, Proudly distributed by Circle K Stores Inc., UPC 1 94283 65185 8; o) DG health Original Formula, DISTRIBUTED BY OLD EAST MAIN CO., GOODLETTSVILLE, TN 37072, UPC 0 95072 00556 5; p) Good Neighbor Pharmacy Eye Drops, Original Formula, Distributed By AmerisourceBergen, Conshohocken, PA 19428, NDC 24385-075-05; q) TopCare health, Original Eye Drops, DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELKGROVE VILLAGE, IL 60007, UPC 0 36800 03639 0; r) Best Choice, Eye Drops, ORIGINAL, PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO., KANSAS CITY, KS 66106, UPC 0 70038 47011 3

Product Quantity:

378,144 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0413-2026

Code Information:

Lot: a) RG24E01, Exp.: 05/31/26; RG24G02, Exp.: 07/31/26; b) RG24E01, Exp.: 05/31/26; RG24G02, Exp.: 07/31/26; c) RG24G02, Exp.: 07/31/26; d) RG24E01, Exp.: 05/31/26; RG24G01, RG24G02; Exp.: 07/31/26; e) RG24E01, Exp.: 05/31/26; RG24G01, Exp.: 07/31/26; f) RG24E01, Exp.: 05/31/26; RG24G02; Exp.: 07/31/26; g) RG24E01, Exp.: 05/31/26; h) RG24E01, Exp.: 05/31/26; RG24G02, Exp.: 07/31/26; i) RG24E01, Exp.: 05/31/26; j) RG24E01, Exp.: 05/31/26; k) RG24E01, Exp.: 05/31/26; L) RG24E01, Exp.: 05/31/26; m) RG24E01, Exp.: 05/31/26; n) RG24G01, Exp.: 07/31/26; o) RG24G01, Exp.: 07/31/26; p) RG24G02, Exp.: 07/31/26; q)RG24E01, Exp.: 05/31/26; RG24G02, Exp.: 07/31/26; r) RG24G02, Exp.: 07/31/26

Product Description:

Sterile EYE DROPS REDNESS LUBRICANT (glycerin 0.25% and naphazoline HCl 0.012%), 0.5 fl oz (15 mL) bottles; a) Industrial Eye Relief, Distributed by: Cintas Corp., Mason, OH 45040, UPC 130209; b) Good Neighbor Pharmacy Eye Drops, Redness & Dry Eye Relief, Distributed By AmerisourceBergen, Conshohocken, PA 19428, NDC 46122-606-05; c) Colirio Ojo De Aguila Eye Drops, Distributed by: Grandall Distributing Co., Inc., Glendale, CA 91204-2707, UPC 3 48201 01615 5; d) Colirio OFTAL-MYCIN, Distributed by: Grandall Distributing Co., Inc., Glendale, CA 91204-2707, UPC 3 48201 01613 1; e) LEADER Redness Relief, DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017, www.myleader.com, NDC 70000-0010-1; f) Equaline, sterile redness relief, DISTRIBUTED BY UNFI, PROVIDENCE, RI 02908, UPC 0 41163 46151 2; g) Walgreens, Redness Relief Eye Drops, DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015, UPC 3 11917 17741 0; h) Foster & Thrive, Redness Relief Eye Drops, Sterile, Distributed by: McKesson Corp., via SSSL, Memphis, TN 38141, www.fosterandthrive.com, NDC 70677-1161-1; i) LUBRICANT EYE DROPS, Redness Relief, DISTRIBUTEDBY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011, NDC 11822-6453-4; j) Discount drug mart, Eye Drops Redness Relief, Distributed by: Discount Drug Mart, Medina, OH 44256, UPC 0 93351 03411 4

Product Quantity:

315,144 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0414-2026

Code Information:

Lot: a) RL24D01, Exp.: 04/30/26; RL24F01, RL24F02, Exp.:06/30/26; b) RL24F01, RL24F02, Exp.:06/30/26; c) RL24F01, Exp.:06/30/26; d) RL24F02, Exp.:06/30/26; e) RL24F01, RL24F02, Exp.:06/30/26; f) RL24F01, RL24F02, Exp.:06/30/26; g) RL24F01, RL24F02, Exp.:06/30/26; h) RL24F01, Exp.:06/30/26; i) RL24F01, Exp.:06/30/26; j) RL24F02, Exp.:06/30/26; k)

Product Description:

STERILE EYE DROPS SOOTHING TEARS (polyethylene glycol 400 0.4% and propylene glycol 0.3%), 0.5 OZ 0.5 fl oz (15 mL) bottles; a) Rugby

LUBRICATING EYE DROPS, Distributed by: Rugby Laboratories, Livonia, MI 48152, NDC 0536-1219-94; b) Walgreens, Lubricant Eye Drops, DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015, UPC 3 11917 20300 3

Product Quantity:

74,016 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0415-2026

Code Information:

Lot: a) SY24K01, SY24K02, Exp.: 09/30/26; b) SY24K01, SY24K02, Exp.: 09/30/26.

Product Description:

Artificial Tears Sterile Lubricant Eye Drops (polyvinyl alcohol 0.5%, povidone 0.6%), 0.5 FL OZ (15 mL) bottles; a) LEADER, DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017, www.myleader.com, NDC 70000-0011-1; b) Good Sense, Distributed By: Perrigo Direct, Inc., Peachtree City, GA 30269, www.PerrigoDirect.com, NDC 50804-110-01; c) Good Neighbor Pharmacy, Distributed By AmerisourceBergen, Conshohocken, PA 19428, NDC 24385-006-05; d) TopCare health, DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELKGROVE VILLAGE, IL 60007, UPC 0 36800 09331 7; e) Best Choice, PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO., KANSAS CITY, KS 66106, UPC 0 70038 47008 3; f) Kroger, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202, UPC 0 11110 38600 7; g) P, DISTRIBUTED BY PUBLIX SUPER MARKETS, INC, LAKELAND, FL 33811, UPC 0 41415 00976 9; h) Quality Choice, Distributed by CDMA Inc, Novi, MI NDC 83324-189-14

Product Quantity:

589,848 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0416-2026

Code Information:

Lot: a) AT24D01, Exp.: 04/30/26; AT24E01, Exp.: 05/31/26; AT24G01, Exp.: 07/31/26; b) AT24D01, Exp.: 04/30/26; AT24E01, AT24E02, Exp.: 05/31/26; AT24G01, Exp.: 07/31/26; c) AT24D01, Exp.: 04/30/26; AT24E01, Exp.: 05/31/26; AT24G01, Exp.: 07/31/26; d) AT24D01, Exp.: 04/30/26; AT24E01, AT24E02, Exp.: 05/31/26; AT24G01, Exp.: 07/31/26; e) AT24E01, Exp.: 05/31/26; AT24G01, Exp.: 07/31/26; f) AT24E01, AT24E02, Exp.: 05/31/26; AT24G01, Exp.: 07/31/26; g) AT24E02, Exp.: 05/31/26.

Class II Drugs Event

Event ID:

98623

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

03/19/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/30/2026

Initial Firm Notification of Consignee or Public:

N/A

Recalling Firm:

Amneal Pharmaceuticals, LLC
400 Crossing Blvd Fl 3
Bridgewater, NJ 08807-2863
United States

Distribution Pattern:

Nationwide within the USA

Associated Products

Product Description:

traMADol Hydrochloride Tablets, USP, 50 mg, 500-count bottles, Rx only, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd., Ahmedabad 382220, India, Distributed by: Amneal Pharmaceuticals LLC, Glasgow, KY 42141, NDC 60219-2348-5.

Product Quantity:

29,542 bottles

Reason for Recall:

Failed Impurities/Degradation Specifications: N-nitroso-desmethyl-tramadol impurity (NDSRI) was found out of the specification at 24-month stability interval during Long term stability (25°C/60%RH).

Recall Number:

D-0408-2026

Code Information:

Lot #: AM230987, Exp. Date 05/2026; AR232387, Exp. Date 12/2026.

Class II Drugs Event

Event ID:

98647

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

03/18/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/31/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

ALEMBIC PHARMACEUTICALS, INC.
550 Hills Dr Ste 104b
Bedminster, NJ 07921-1537
United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Bromfenac Ophthalmic Solution 0.07%, 3 ml, Rx only, Sterile, Manufactured for: Alembic Pharmaceuticals, Inc., Bedminster, NJ 07921, USA, Made in India, Manufactured by: Alembic Pharmaceuticals Limited, Karakhadi- 391 450, Gujarat, India NDC 62332-583-03.

Product Quantity:

N/A

Reason for Recall:

Failed Impurities/Degradation Specifications: out of specification at the time of testing i.e. 20th month stability testing.

Recall Number:

N/A

Code Information:

Lot # 7240184, 7240185, 7240186, 7240187, Exp Date: 3/31/2026; Lot # 7240278, Exp Date: 5/31/2026.

Class II Drugs Event

Event ID:

98658

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

03/27/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/31/2026

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Appco Pharma LLC
 262 Old New Brunswick Rd Ste N
 Piscataway, NJ 08854-3888
 United States

Distribution Pattern:

U.S.A. Nationwide

Associated Products

Product Description:

Prazosin Hydrochloride Capsules, USP, 1mg, 100-count bottle, Rx Only, Manufactured for: Biocon Pharma Inc., Iselin, NJ, Manufactured by: Appco Pharma LLC, Piscataway, NJ, NDC 70377-066-11.

Product Quantity:

88,008 bottles- 100's count

Reason for Recall:

cGMP deviation: detection of Nitrosamine Drug Substance-Related Impurities, N-nitroso-prazosin impurity C (NNP) above acceptable limits.

Recall Number:

D-0419-2026

Code Information:

Lot:2404160C, Exp.:2026/MAR; 2406253C, Exp.:2026/MAY; 2407311C, Exp.: 2026/JUL; 2407312C, Exp.:2026/JUL; 2408350C, Exp.:2026/JUL; 2505172C, Exp.:2027/MAY; 2506191C, Exp.: 2027/JUN.

Product Description:

Prazosin Hydrochloride Capsules, USP, 2mg, 100-count bottle, Rx Only, Manufactured for: Biocon Pharma Inc., Iselin, NJ, Manufactured by: Appco Pharma LLC, Piscataway, NJ, NDC 70377-067-11.

Product Quantity:

58,896 bottles- 100's count

Reason for Recall:

cGMP deviation: detection of Nitrosamine Drug Substance-Related Impurities, N-nitroso-prazosin impurity C (NNP) above acceptable limits.

Recall Number:

D-0420-2026

Code Information:

Lot:2404153UC, Exp.: 2026/MAR; 2404154UC, Exp.:2026/MAR; 2502055UC, Exp.: 2027/JAN; 2505173UC, Exp.: 2027/MAY; 2505175UC, Exp.: 2027/MAY.

Product Description:

Prazosin Hydrochloride Capsules, USP, 5mg, 100-count bottle, Rx Only, Manufactured for: Biocon Pharma Inc., Iselin, NJ, Manufactured by: Appco Pharma LLC, Piscataway, NJ, NDC 70377-068-11.

Product Quantity:

28,157 bottles- 100's count

Reason for Recall:

cGMP deviation: detection of Nitrosamine Drug Substance-Related Impurities, N-nitroso-prazosin impurity C (NNP) above acceptable limits.

Recall Number:

D-0421-2026

Code Information:

Lot:2406255UC, Exp.: 2026/MAY; 2406256UC, Exp.: 2026/JUL; 2407313UC Exp.: 2026/JUL; 2408351UC, Exp.: 2026/JUL; 2408352UC , Exp.: 2026/JUL; 2509311UC, Exp.: 2027/SEP. .

Not Yet Classified Drugs Event

Event ID:

98587

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:
03/18/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
N/A

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amneal Pharmaceuticals, LLC
400 Crossing Blvd Fl 3
Bridgewater, NJ 08807-2863
United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

<p>Product Description: Magnesium Sulfate in Water for Injection, 4g/100 mL (40mg/mL) IV bag, further packaged in cartons of 12 x 100 mL IV bags, Rx only, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd., Ahmedabad, 382110, India, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807, NDC 70121-1720-3.</p> <p>Product Quantity: 784 (12x100mL) cartons</p> <p>Reason for Recall: Product mix up: An IV bag, contained within a labeled Magnesium Sulfate in Water for Injection, 4 g/100 mL foil pouch, was identified as Tranexamic Acid</p> <p>Recall Number: N/A</p> <p>Code Information: Lot: AH250162, Exp 8/31/2027</p>
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