Enforcement Report - Week of March 8, 2023

Class II Drugs Event

Event ID:
91654

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/06/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/24/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alvogen, Inc
44 Whippany Rd Ste 107
Morristown NJ United States

Distribution Pattern:
Nationwide and Puerto Rico.

Associated Products

Product Description:
Levothyroxine Sodium Tablets, USP 112 mcg, 90 tablets per bottle, Rx Only, Manufactured by Lloyd Inc., Shenandoah, IA, 51601, Distributed by: Alvogen Inc, Pine Brook, NJ 07058, NDC 47781-654-90.

Product Quantity:
21,276 bottles

Reason for Recall:
Sub-Potent Drug: Out of specification for assay at the 24 month interval.

Recall Number:
D-0353-2023

Code Information:
Lot # HE02221, Exp. 05/2023

Class II Drugs Event

Event ID:
91657

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/07/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/02/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Accord Healthcare, Inc.
1009 Slater Rd Ste 210B
Durham NC United States

Distribution Pattern:
United States including Puerto Rico and Canada

Associated Products

Product Description:
Aripiprazole Tablets, USP 2 mg, Rx Only, Packaged as a) 30-count bottle, NDC 16729-278-10, UPC 3 16729 27810 2; b) 100-count bottle, NDC 16729-278-01, UPC 3 16729 27801 10 Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213. India

Product Quantity:
747,464 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0365-2023

Code Information:
Batches: a) P2005474, Exp 9/30/2023; P2100001, Exp 12/31/2023; P2100789, P2100790, Exp 1/31/2024; P2101319, Exp 2/28/2024; P2102147, P2102148, Exp 3/31/2024; P2104084, Exp 6/30/2024; P2105410, P2107233, P2105411, Exp 7/31/2024; P2106671, P2106673, P2106675, Exp 9/30/2024; P2200428, P2200429, P2200430, Exp 12/31/2024; P2203333, P2203334, Exp 5/31/2025; b) P2102940 Exp. 3/31/2023, P2105793, Exp. 7/31/2024;

Product Description:
Aripiprazole Tablets, USP 5 mg Rx Only, Packaged as a) 30-count bottle, NDC 16729-279-10, UPC 3 16729 27910 9; b) 100-count bottle, NDC 16729-279-01, UPC 3 16729 27901 7; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213. India

Product Quantity:
1,109,904 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0366-2023

Code Information:
Batches: a) P2004259, P2004260, P2004261, Exp. Date 7/31/2023; P2006799, P2101391, Exp. Date 11/30/2023; P2100826, Exp. Date 1/31/2024; P2101320, Exp. Date 2/28/2024; P2102510, P2102409, P2102407, Exp. Date 3/31/2024; P2102410, Exp. Date 3/31/2024; P2105251, P2105252, P2105253, Exp. Date 7/31/2024; P2107404, P2107029, Exp. Date 10/31/2024; P2200260, P2200265, Exp. Date 12/31/2024; P2202067, P2202068, Exp. Date 3/31/2025; P2204239, Exp. Date 7/31/2025; b) P2006800 Exp. Date 11/30/2023; P2102141, Exp. Date 3/31/2024; P2104085, Exp. Date 6/30/2024; P2107031, P2107466, Exp. Date 10/31/2024;

Product Description:
Aripiprazole Tablets, USP 10 mg Rx Only, Packaged as a) 30-count bottle, NDC 16729-280-10, UPC 3 16729 28010 5; b) 100-count bottle, NDC 16729-280-01, UPC 3 16729 28001 3; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213. India

Product Quantity:
539,004 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0367-2023

Code Information:
Batches: a)P2006421, P2004882, P2004939, P2004883, P2004940, P2004942, P2004943, P2004944, Exp. Date 8/31/2023; P2107593, P2106907, P2106906, P2106908, P2106909, Exp. Date 10/31/2024; b)P2102144, Exp. Date 3/31/2023; P2106903 Exp. Date 10/31/2023; P2204437, Exp. Date 7/31/2025;

Product Description:
Aripiprazole Tablets, USP 15 mg Rx Only, Packaged as: a) 30-count bottle NDC 16729-281-10, UPC 3 16729 28110 2; b) 100-count bottle NDC 16729-281-01, UPC 3 16729 28101 0; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213. India

Product Quantity:
312,864 bottles

Reason for Recall:

CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0368-2023

Code Information:
Batches: a) P2004997, P2004998, P2004999, Exp. Date 8/31/2023; P2101206, Exp. Date 1/31/2024 , P2102486, Exp. Date 4/30/2024; P2106247, P2105375, Exp. Date 7/31/2024; P2107239, P2107240, Exp. Date 10/31/2024; b) P2204222 Exp. Date 7/31/2025, P2105374 Exp. 7/31/2024, P2203449 Exp. 5/31/2025

Product Description:
Aripiprazole Tablets, USP 20 mg Rx Only, packaged as, a) 30-count bottle, NDC 16729-282-10, UPC 3 16729 28210 9; b) 100-count bottle, NDC 16729-282-01, UPC 3 16729 28201 7; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213. India

Product Quantity:
170,448 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0369-2023

Code Information:
Batches: a) P2100787, P2100788, Exp. Date 1/31/2024; P2104736, Exp. Date 6/30/2024; P2105492, Exp. Date 8/31/2024; P2107172, P2107175, Exp. Date 10/31/2024; P2203043, Exp. Date 5/31/2025; b) P2104086 Exp. Date 6/30/2024, P2205370 Exp. 8/31/2025;

Product Description:
Aripiprazole Tablets, USP 30 mg Rx Only, a) 30-count bottle, NDC 16729-283-10, UPC 3 16729 28310 6; b) 100-count bottle, NDC 16729-283-01, UPC 3 16729 28301 4; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213. India

Product Quantity:
88,728 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0370-2023

Code Information:
Batches: a) P2005477, Exp. Date 9/30/2023; P2100002, Exp. Date 12/31/2023; P2101359 Exp. Date 2/28/2024; P2105409, Exp. Date 7/31/2024; P2107447, Exp. Date 10/31/2024; P2203388 Exp. Date 5/31/2025; b) P2101859 Exp. Date 2/28/2023; P2107056, Exp. Date 10/31/2023; P2203066, Exp. Date 5/31/2024; P2206130, Exp. Date 8/31/2024;

Product Description:
Atorvastatin Calcium Tablets USP, 10 mg* Rx Only, Packaged as a) 90 Tablets NDC 16729-044-15 UPC 3 16729 04415 8; b) 1,000 Tablets NDC 16729-044-17 UPC 3 16729 04417 2; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA.

Product Quantity:
256,106 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0371-2023

Code Information:
Batches: a)R2100455, Exp. Date 3/31/2023; R2200274, Exp. Date 1/31/2024; R2200700, Exp. Date 5/31/2024; b) R2101342, R2101343, R2101476, Exp. Date 9/30/2023; R2101364, R2101365, R2101366, R2101367, Exp. Date 10/31/2023; R2101612, R2101613, R2101614, Exp. Date 11/30/2023; R2200222, R2200221, R2200223, Exp. Date 1/31/2024; R2200795, R2200713, R2200701, R2200711, R2200712, R2200756, R2200757, R2200754, R2200755, Exp. Date 5/31/2024; R2200945, R2200943, Exp. Date 6/30/2024;

Product Description:
Atorvastatin Calcium Tablets USP 20 mg* Rx Only, Packaged as a) 90 Tablets NDC 16729-045-15 UPC 3 16729 04515 5; b) 1,000 Tablets NDC

16729-045-17 UPC 3 16729 04517 9, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
241,585 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0372-2023

Code Information:
Batches: a)R2100305, Exp. Date 2/28/2023; R2200227, Exp. Date 1/31/2024; R2200797, Exp. Date 6/30/2024; b) R2101423, R2101438, R2101447, R2101446, Exp. Date 10/31/2023; R2200040, R2200041, R2200052, R2200043, R2200044, R2200051, R2200060, R2200061, R2200062, R2200077, R2200078, Exp. Date 12/31/2023; R2200228, R2200480, Exp. Date 1/31/2024; R2200266, R2200267, R2200265, R2200268, Exp. Date 2/29/2024; R2200370, Exp. Date 3/31/2024; R2201038, Exp. Date 6/30/2024;

Product Description:
Atorvastatin Calcium Tablets USP 40 mg* Rx Only, Packaged as a) 90 Tablets NDC 16729-046-15 UPC 3 16729 04615 2; b) 1,000 Tablets NDC 16729-046-17 UPC 3 16729 04617 6, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
147,736 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0373-2023

Code Information:
Batches: a)R2100552, R2100553, Exp. Date 4/30/2023; R2200253, Exp. Date 2/29/2024; R2200627, Exp. Date 4/30/2024; R2201113, Exp. Date 6/30/2024; R2201184, Exp. Date 8/31/2024; R2201366, Exp. Date 9/30/2024; b) R2200280, Exp. Date 2/29/2024; R2200385, R2200386, R2200491, R2200490, R2200494, R2200496, R2200495, Exp. Date 3/31/2024; R2200510, R2200520, R2200521, R2200517, R2200511, R2200632, R2200631, R2200637, R2200635, R2200648, R2200638, R2200639, R2200647, Exp. Date 4/30/2024; R2200727, Exp. Date 5/31/2024;

Product Description:
Atorvastatin Calcium Tablets USP 80 mg* Rx Only, Packaged as a) 90 Tablets NDC 16729-047-15 UPC 3 16729 04715 9; b) 500 Tablets NDC 16729-047-16 UPC 3 16729 04716 6; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
72,376 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0374-2023

Code Information:
Batches: a)R2100283, R2100288, R2100289, Exp. Date 2/28/2023; R2200235, Exp. Date 1/31/2024; R2201037, R2200952, Exp. Date 6/30/2024; b) R2100291, R2100281, R2100282, R2100292, R2100293, R2100294, R2100290, R2100306, R2100348, R2100349, R2100347, R2100350, R2100356, R2100355, Exp. Date 2/28/2023; R2100461, R2100463, R2100464, Exp. Date 3/31/2023; R2101214, R2101215, R2101216, Exp. Date 9/30/2023; R2101572, R2101573, R2101577, R2101578, R2101585, R2101579, R2101584, R2101587, R2101597, Exp. Date 11/30/2023; R2200801, Exp. Date 6/30/2024;

Product Description:
BusPIRone Hydrochloride Tablets USP 7.5 mg, 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA, NDC 16729-201-01

Product Quantity:
23,784 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0375-2023

Code Information:
Batches: P2105532, Exp. Date 6/30/2024; P2200348, Exp. Date 12/31/2024;

Product Description:
BusPIRone Hydrochloride Tablets USP, 5 mg, Rx Only, Packaged as: a) 100 Tablets NDC 16729-200-01 UPC 3 16729 20001 1; b) 500 Tablets NDC 16729-200-16 UPC 3 16729 20016 5; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
24,408 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0376-2023

Code Information:
Batches: a) P2200530, Exp. Date 12/31/2024; b) P2105583, Exp. Date 6/30/2024;

Product Description:
BusPIRone Hydrochloride Tablets USP 15 mg, Rx Only, 100-count bottle, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA, NDC 16729-203-01, UPC 3 16729 20301 2;

Product Quantity:
10992 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0377-2023

Code Information:
Batches: P2105483, Exp. Date 7/31/2024;

Product Description:
BusPIRone Hydrochloride Tablets USP, 10 mg 500-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA, NDC 16729-202-16 UPC 3 16729 20216 9

Product Quantity:
3,784 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0378-2023

Code Information:
Batches: P2105472, Exp. Date 4/30/2024;

Product Description:
BusPIRone Hydrochloride Tablets USP 30 mg, 60-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA, NDC 16729-289-12 UPC 3 16729 28912 2

Product Quantity:
25,812 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0379-2023

Code Information:
Batches: P2105551, Exp. Date 7/31/2024;

Product Description:
Clopidogrel Tablets USP, 75 mg, Rx Only, Packaged in a) 30-count bottles NDC 16729-218-10 UPC 3 16729 21810 8; b) 90-count bottles NDC 16729-218-15 UPC 3 16729 21815 3; c) 500-count bottles, NDC 16729-218-16, UPC 3 16729 21816 0; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
1,420,988 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0380-2023

Code Information:
Batches: a) P2001925, Exp. Date 3/31/2023; P2003532, Exp. Date 6/30/2023; P2004847, Exp. Date 7/31/2023; R2000856, Exp. Date 11/30/2023; P2100452, Exp. Date 12/31/2023; P2100898, Exp. Date 1/31/2024; P2106273, Exp. Date 9/30/2024; b) R2000578, Exp. Date 7/31/2023; R2000653, Exp. Date 9/30/2023; R2000652, Exp. Date 9/30/2023; R2000826, Exp. Date 10/31/2023; R2000852, Exp. Date 10/31/2023; R2000853, Exp. Date 10/31/2023; R2000827, Exp. Date 11/30/2023; P2100102, Exp. Date,12/31/2023; P2100004, Exp. Date 12/31/2023; P2100450, Exp. Date 12/31/2023; P2100449, Exp. Date 12/31/2023; c)P2001392, P2001393, P2001395, P2001396, P2001397, P2001492, P2001493, P2001494, P2001495, Exp. Date 2/28/2023; P2001863, P2001864, P2001865, P2001924, P2001866, P2001926, P2001927, P2002072, P2002073, P2002071, P2002074, P2002075, P2002392, Exp. Date 3/31/2023; P2002230, P2002233, P2002234, P2002235, P2002274, P2002400, P2002399, P2002398, P2002479, P2002478, P2002481, P2002480, P2002482, P2002483, Exp. Date 4/30/2023; P2002759, P2002758, P2002755, P2002756, P2003058, P2003059, P2003061, P2003060, P2003062, P2003055, Exp. Date 5/31/2023; P2003533, P2003534, P2003535, P2003675, P2003537, P2003536, P2003676, P2003677, P2003678, P2003679, P2003680, P2003909, P2003910, Exp. Date 6/30/2023; P2004010, P2004008, P2004009, P2004232, P2004233, P2004234, Exp. Date 7/31/2023; P2004576, P2004838, R2000614, R2000624, R2000623, R2000615, R2000638, R2000637, R2000642, R2000640, Exp. Date 8/31/2023; R2000644, R2000662, R2000664, R2000643, R2000667, R2000666, R2000670, R2000671, R2000672, P2005692, P2005656, P2005693, P2005691, P2005694, Exp. Date 9/30/2023; P2005840, P2005841, P2005842, P2005843, P2005844, P2005870, P2005925, P2005923, P2005924, P2006007, P2006009, P2006010, P2005845, P2006008, P2006065, Exp. Date 10/31/2023; R2100003, R2100008, R2100010, R2100015, R2100016, R2100017, R2100018, R2100031, R2100022, R2100024, R2100069, R2100070, R2100071, R2100084, R2100080, R2100083, R2100078, R2100082, R2100093, Exp. Date 11/30/2023; P2100109, P2100304, P2100107, P2100103, P2100106, P2100108, P2100305, Exp. Date 12/31/2023; P2100718, P2100721, P2100720, P2100748, Exp. Date 1/31/2024; P2104140, Exp. Date 6/30/2024; P2104861, P2104860, P2104859, P2104866, Exp. Date 7/31/2024;

Product Description:
Daptomycin for Injection 350 mg/vial, Rx only, Packaged as: a) Single-dose vial NDC 16729-434-05 UPC 3 16729 43405 8; b) 10 Single-dose vials NDC 16729-434-45 UPC 3 16729 43445 4 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
65,233 vials

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0381-2023

Code Information:
Batches: a) R2101274, Exp. Date 9/30/2023; R2200161, Exp. Date 1/31/2025; R2200506, Exp. Date 1/31/2025; R2200697, Exp. Date 4/30/2025; R2201107, Exp. Date 7/31/2025; b) R2101471, Exp. Date 9/30/2023; R2200588, Exp. Date 4/30/2025; R2201333, Exp. Date 7/31/2025; R2201361, Exp. Date 8/31/2025;

Product Description:
Daptomycin for Injection 500 mg per vial, Single-dose vial, Rx only, Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA. NDC 16729-435-05 UPC 3 16729 43505 5.

Product Quantity:
228,760 vials

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0382-2023

Code Information:
Batches: R2101282, Exp. Date 9/30/2023; R2101600,Exp. Date 11/30/2024; R2200002, R2200028, R2200116, R2200142, R2200152, Exp. Date

12/31/2024; R2200165, R2200190, Exp. Date 1/31/2025; R2201042, Exp. Date 7/31/2025;

Product Description:
Dofetilide Capsules, 125 mcg (0.125 mg), 60-count bottle, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA, NDC 16729-490-12 UPC 3 16729 49012 2

Product Quantity:
37,790 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0383-2023

Code Information:
Batches: P2101480, Exp. Date 2/28/2023; P2102579, P2102596, Exp. Date 4/30/2023; P2104711, P2104707, Exp. Date 6/30/2023; P2200771, P2200829, P2200795, Exp. Date 12/31/2023; P2202608, Exp. Date 4/30/2025; P2203492, P2203463, Exp. Date 5/31/2025; P2205373, P2205412, Exp. Date 8/31/2025;

Product Description:
Dofetilide Capsules 250 mcg (0.25 mg) 60-count bottle, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA NDC 16729-491-12 UPC 3 16729 49112 9

Product Quantity:
113,571 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0384-2023

Code Information:
Batches: P2101481 Exp. Date 2/28/2023; P2101985, P2101958, P2102019, Exp. Date 3/31/2023; P2102580, P2102597, Exp. Date 4/30/2023; P2104708, P2104712, Exp. Date 6/30/2023; P2107154, P2107187, Exp. Date 10/31/2023; P2107874, Exp. Date 11/30/2023; P2200772, P2200796, P2200830, Exp. Date 12/31/2023; P2201196, P2201198, Exp. Date 1/31/2024; P2200817, Exp. Date 12/31/2024; P2202610, Exp. Date 4/30/2025; P2203466, Exp. Date 5/31/2025;

Product Description:
Dofetilide Capsules 500 mcg (0.5 mg), 60-count bottle, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA NDC 16729-492-12 UPC 3 16729 49212 6

Product Quantity:
113,003 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0385-2023

Code Information:
Batches: P2101582, P2101661, P2101482, P2101686, Exp. Date 2/28/2023; P2102581, P2102598, Exp. Date 4/30/2023; P2103623, P2103653, P2103670, Exp. Date 5/31/2023; P2104463, P2104385, P2104386, P2104472, P2104709, P2104714, Exp. Date 6/30/2023; P2200797, P2200773, P2200831, Exp. Date 12/31/2023; P2201017, P2201081, P2201056, Exp. Date 1/31/2024; P2200819, Exp. Date 12/31/2024; P2202611, P2202616, Exp. Date 4/30/2025, P2203467, Exp. Date 5/31/2025

Product Description:
Doxazosin Tablets USP 1 mg, Rx Only, Packaged as: a) 100-count bottle NDC 16729-211-01 UPC 3 16729 21101 7; b) 1,000-count bottle NDC 16729-211-17 UPC 3 16729 21117 8; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
44,068 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:

D-0386-2023

Code Information:
Batches: a) R2200402, Exp. Date 5/31/2024; R2200642, Exp. Date 5/31/2024; R2200643 Exp. Date 8/31/2024; R2201300 Exp. Date 8/31/2024; b) R2200403, Exp. Date 5/31/2024;

Product Description:
Doxazosin Tablets USP, 2 mg, Rx Only, Packaged as: a) 100-count bottle NDC 16729-414-01 UPC 3 16729 41401 2; b) 1,000-count NDC 16729-414-17 UPC 3 16729 41417 3; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
69,122 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0387-2023

Code Information:
Batches: a) R2200401, Exp. Date 5/31/2024; R2200675, Exp. Date 5/31/2024; R2200676 Exp. Date 11/30/2024; R2201070, Exp. Date 7/31/2025; b) R2200680, Exp. Date 9/30/2024;

Product Description:
Doxazosin Tablets USP, 4 mg, Rx Only, Packaged as: a) 100-count bottle NDC 16729-213-01 UPC 3 16729 21301 1; b) 1,000-count bottle NDC 16729-213-17 UPC 3 16729 21317 2; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
75,190 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0388-2023

Code Information:
Batches: a) R2200352, Exp. Date 5/31/2024; R2200356, Exp. Date 8/31/2024; R2200357, Exp. Date 8/31/2024; R2200633, Exp. Date 4/30/2025; R2200634, Exp. Date 4/30/2025; b) R2200677,Exp. Date 8/31/2024; R2200572,Exp. Date 4/30/2025; R2200571, Exp. Date 4/30/2025; R2200646, Exp. Date 4/30/2025;

Product Description:
Doxazosin Tablets USP, 8 mg, Rx Only, Packaged in: a) 100 Tablets NDC 16729-415-01 UPC 3 16729 41501 9; b) 1,000 Tablets NDC 16729-415-17 UPC 3 16729 41517 0; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
31,116 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0389-2023

Code Information:
Batches: a) R2200672, Exp. Date 5/31/2024; R2200673, Exp. Date 9/30/2024; R2201097, Exp. Date 7/31/2025; b) R2200678, Exp. Date 10/31/2024;

Product Description:
Finasteride Tablets USP, 1 mg, Rx Only, Packaged as: a) 30-count bottle NDC 16729-089-10 UPC 3 16729 08910 4; b) 90-count bottle NDC 16729-089-15 UPC 3 16729 08915 9; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
325,356 bottles

Reason for Recall:

CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0390-2023

Code Information:
Batches: a) P2005979, Exp. Date 10/31/2023; P2100252, Exp. Date 12/31/2023; P2101710, Exp. Date 2/29/2024; b) P2100253, Exp. Date 12/31/2023; P2103035, Exp. Date 4/30/2024; P2103036, Exp. Date 4/30/2024;

Product Description:
Finasteride Tablets USP 1 mg, 90-count bottle, Keeps, Rx Only, Manufactured for: Thirty Madison, Inc. New York, NY 10016 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA, NDC 71713-096-90 UPC 3 71713 09690 2

Product Quantity:
1,440,652 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0391-2023

Code Information:
Batches: P2005583, P2005584, P2005585, P2005527, P2005528, P2005586, Exp. Date 9/30/2023; P2005980, Exp. Date 10/31/2023; P2100396, P2100264, P2100263, Exp. Date 12/31/2023; P2101583, P2101711, P2101708, P2101584, Exp. Date 2/29/2024; P2102852, P2102851, P2102853, P2102854, P2102855, Exp. Date 4/30/2024; P2103993, P2103998, P2103997, P2103999, P2104205, P2104206, P2105631, P2105632, P2105546, P2105547, P2105548 Exp. Date 8/31/2024;

Product Description:
Finasteride Tablets USP, 5 mg, Rx Only, Packaged as: a) 30-count bottles NDC 16729-090-10 UPC 3 16729 09010 0; b) 90-count bottles NDC 16729-090-15 UPC 3 16729 09015 5; c) 100-count bottles NDC 16729-090-01 UPC 3 16729 09001 8; d) 500-count bottles NDC 16729-090-16 UPC 3 16729 09016 2; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
2,731,365 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0392-2023

Code Information:
Batches: a) P2001383, Exp. Date 2/28/2023; P2004886, Exp. Date 8/31/2023; P2100853, Exp. Date 11/30/2023; P2101652, Exp. Date 2/29/2024; P2101821, Exp. Date 2/29/2024; P2102146, Exp. Date 3/31/2024; P2107270, Exp. Date 10/31/2024; P2107939, Exp. Date 10/31/2024; P2201491, Exp. Date 2/28/2025; b) P2001377, Exp. Date 2/28/2023; P2005673, Exp. Date 9/30/2023; P2005911, Exp. Date 10/31/2023; P2005878, Exp. Date 10/31/2023; P2006076, Exp. Date 10/31/2023; P2006110,Exp. Date 10/31/2023; P2006830, Exp. Date 11/30/2023; P2100639, Exp. Date 1/31/2024; P2100640, Exp. Date 1/31/2024; P2104208, Exp. Date 6/30/2024; P2105388, Exp. Date 7/31/2024; P2105387, Exp. Date 7/31/2024; P2200316, Exp. Date 12/31/2024; P2200318, Exp. Date 12/31/2024; P2200317, Exp. Date 12/31/2024; P2200319, Exp. Date 12/31/2024; P2200820, Exp. Date 1/31/2025; P2200822, Exp. Date 1/31/2025; P2201492, Exp. Date 2/28/2025; P2201493, Exp. Date 2/28/2025; P2201758, Exp. Date 2/28/2025; P2201759, Exp. Date 2/28/2025; P2202107, Exp. Date 3/31/2025; c) P2001375, Exp. Date 2/28/2023; P2003258, Exp. Date 5/31/2023; P2005402, Exp. Date 9/30/2023; P2005497, Exp. Date 9/30/2023; P2100511, Exp. Date 12/31/2023; P2101047, Exp. Date 1/31/2024; P2104753, Exp. Date 6/30/2024; P2105389, Exp. Date 7/31/2024; P2107273, Exp. Date 10/31/2024; P2107276, Exp. Date 10/31/2024; P2107419, Exp. Date 10/31/2024; P2201757, Exp. Date 2/28/2025; d)P2001376, Exp. Date 2/28/2023; P2002182, Exp. Date 3/31/2023; P2002184, Exp. Date 3/31/2023; P2003254, Exp. Date 5/31/2023; P2003255, Exp. Date 5/31/2023; P2003256, Exp. Date 5/31/2023; P2003257, Exp. Date 5/31/2023; P2004403, Exp. Date 7/31/2023; P2004404, Exp. Date 7/31/2023; P2004416, Exp. Date 7/31/2023; P2004417, Exp. Date 7/31/2023; P2004526, Exp. Date 7/31/2023; P2004527, Exp. Date 7/31/2023; P2004841, Exp. Date 8/31/2023; P2004842, Exp. Date 8/31/2023; P2004885, Exp. Date 8/31/2023; P2004899, Exp. Date 8/31/2023; P2004901, Exp. Date 8/31/2023; P2005406, Exp. Date 9/30/2023; P2005498, Exp. Date 9/30/2023; P2005671, Exp. Date 9/30/2023; P2005675, Exp. Date 9/30/2023; P2005672, Exp. Date 9/30/2023; P2005860, Exp. Date 10/31/2023; P2006077, Exp. Date 10/31/2023; P2006079, Exp. Date 10/31/2023; P2006125, Exp. Date 10/31/2023; P2006081, Exp. Date 10/31/2023; P2006111, Exp. Date 10/31/2023; P2006832, Exp. Date 11/30/2023; P2006831, Exp. Date 11/30/2023; P2006833, Exp. Date 11/30/2023; P2006834, Exp. Date 11/30/2023; P2006835, Exp. Date 11/30/2023; P2100266, Exp. Date 12/31/2023; P2100268, Exp. Date 12/31/2023; P2100269, Exp. Date 12/31/2023; P2100637, Exp. Date 1/31/2024; P2100636, Exp. Date 1/31/2024; P2100638, Exp. Date 1/31/2024; P2100795, Exp. Date 1/31/2024; P2100797, Exp. Date 1/31/2024; P2100803, Exp. Date 1/31/2024; P2101048, Exp. Date 1/31/2024; P2100794, Exp. Date 1/31/2024; P2100796, Exp. Date 1/31/2024; P2101403, Exp. Date 2/28/2024; P2101404, Exp. Date 2/28/2024; P2101819, Exp. Date 2/28/2024; P2101653, Exp. Date 2/29/2024; P2101654, Exp. Date 2/29/2024; P2101818, Exp. Date 2/29/2024; P2101820, Exp. Date 2/29/2024; P2102022, Exp. Date 3/31/2024; P2102023, Exp. Date 3/31/2024; P2102024, Exp. Date 3/31/2024; P2102025, Exp. Date 3/31/2024; P2102026, Exp. Date 3/31/2024; P2102096,

Exp. Date 3/31/2024; P2102097, Exp. Date 3/31/2024; P2102098, Exp. Date 3/31/2024; P2102145, Exp. Date 3/31/2024; P2102293, Exp. Date 3/31/2024; P2102294, Exp. Date 3/31/2024; P2102295, Exp. Date 3/31/2024; P2103218, Exp. Date 3/31/2024; P2102296, Exp. Date 3/31/2024; P2103063, Exp. Date 5/31/2024; P2103062, Exp. Date 5/31/2024; P2103064, Exp. Date 5/31/2024; P2103065, Exp. Date 5/31/2024; P2106836, Exp. Date 7/31/2024; P2106015, Exp. Date 8/31/2024; P2106017, Exp. Date 8/31/2024; P2106016, Exp. Date 8/31/2024; P2106020, Exp. Date 8/31/2024; P2106018, Exp. Date 8/31/2024; P2106019, Exp. Date 8/31/2024; P2106596, Exp. Date 9/30/2024; P2106597, Exp. Date 9/30/2024; P2106599, Exp. Date 9/30/2024; P2106598, Exp. Date 9/30/2024; P2106601, Exp. Date 9/30/2024; P2107420, Exp. Date 10/31/2024; P2107421, Exp. Date 10/31/2024; P2107423, Exp. Date 10/31/2024; P2107636, Exp. Date 11/30/2024; P2107635, Exp. Date 11/30/2024; P2107637, Exp. Date 11/30/2024; P2107638, Exp. Date 11/30/2024; P2107640, Exp. Date 11/30/2024; P2107641, Exp. Date 11/30/2024; P2107642, Exp. Date 11/30/2024; P2107756, Exp. Date 11/30/2024; P2107757, Exp. Date 11/30/2024; P2107840, Exp. Date 11/30/2024; P2107758, Exp. Date 11/30/2024; P2107841, Exp. Date 11/30/2024; P2107844, Exp. Date 11/30/2024; P2107843, Exp. Date 11/30/2024; P2107900, Exp. Date 11/30/2024; P2107902, Exp. Date 11/30/2024; P2107903, Exp. Date 11/30/2024; P2200313, Exp. Date 12/31/2024; P2200314, Exp. Date 12/31/2024; P2200823, Exp. Date 1/31/2025; P2200824, Exp. Date 1/31/2025; P2200825, Exp. Date 1/31/2025; P2201048, Exp. Date 1/31/2025; P2201049, Exp. Date 1/31/2025; P2201055, Exp. Date 1/31/2025; P2201051, Exp. Date 1/31/2025; P2201053, Exp. Date 1/31/2025; P2201494, Exp. Date 2/28/2025; P2201754, Exp. Date 2/28/2025; P2201755, Exp. Date 2/28/2025; P2202210, Exp. Date 2/28/2025; P2202235, Exp. Date 2/28/2025; P2201756, Exp. Date 2/28/2025; P2203018, Exp. Date 5/31/2025; P2203017, Exp. Date 5/31/2025; P2203015, Exp. Date 5/31/2025; P2203019, Exp. Date 5/31/2025; P2204008, Exp. Date 6/30/2025; P2204378, Exp. Date 6/30/2025; P2204010, Exp. Date 6/30/2025; P2204073, Exp. Date 6/30/2025;

Product Description:
Glimepiride Tablets USP, 1 mg, Rx Only, Packaged in: a) 100-count bottle NDC 16729-001-01 UPC 3 16729 00101 4; b) 500-count bottle NDC 16729-001-16 UPC 3 16729 00116 8; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
469,944 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0393-2023

Code Information:
Batches: a) R2000166, Exp. Date 4/30/2023, P2003528 Exp. Date 6/30/2023, P2005451 Exp. Date 8/31/2023, P2005438 Exp. Date 8/31/2023, P2005436 Exp. Date 8/31/2023, P2005437 Exp. Date 8/31/2023, P2005452 Exp. Date 8/31/2023, P2006055 Exp. Date 9/30/2023, P2101782 Exp. Date 2/28/2024, P2101783 Exp. Date 2/28/2024, P2101781 Exp. Date 2/29/2024, P2102171 Exp. Date 2/29/2024, P2101844 Exp. Date 3/31/2024, P2101846 Exp. Date 3/31/2024, P2101845 Exp. Date 3/31/2024; b) P2006510 Exp. Date 11/30/2023, P2100975 Exp. Date 1/31/2024, P2100625 Exp. Date 1/31/2024, P2101778 Exp. Date 2/29/2024, P2101779 Exp. Date 2/29/2024, P2103021 Exp. Date 4/30/2024, P2103020 Exp. Date 4/30/2024, R2100657 Exp. Date 5/31/2024, R2100656 Exp. Date 5/31/2024, R2100658 Exp. Date 5/31/2024, P2104735 Exp. Date 7/31/2024, P2104739 Exp. Date 7/31/2024, P2104737 Exp. Date 7/31/2024, P2104738 Exp. Date 7/31/2024, P2106260 Exp. Date 9/30/2024, P2107384 Exp. Date 9/30/2024, R2200045 Exp. Date 12/31/2024, R2200046 Exp. Date 12/31/2024, R2200054 Exp. Date 12/31/2024, R2200055 Exp. Date 12/31/2024, R2200057 Exp. Date 12/31/2024, R2200058 Exp. Date 12/31/2024, R2200053 Exp. Date 12/31/2024, R2200059 Exp. Date 12/31/2024, R2200056 Exp. Date 12/31/2024, P2201929 Exp. Date 2/28/2025, R2200663 Exp. Date 4/30/2025, P2203518 Exp. Date 5/31/2025, R2200897 Exp. Date 6/30/2025, R2200898 Exp. Date 6/30/2025, R2200899 Exp. Date 6/30/2025, P2205528 Exp. Date 8/31/2025

Product Description:
Glimepiride Tablets USP, 2 mg, Rx Only, Packaged in: a) 100 Tablets NDC 16729-002-01 UPC 3 16729 00201 1; b) 500 Tablets NDC 16729-002-16 UPC 3 16729 00216 5; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
992,622 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0394-2023

Code Information:
Batches: a) R2000184, Exp. Date 4/30/2023, R2000183 Exp. Date 4/30/2023, P2002969 Exp. Date 5/31/2023, P2002970 Exp. Date 5/31/2023, P2005346 Exp. Date 8/31/2023, P2005847 Exp. Date 10/31/2023, P2006133 Exp. Date 10/31/2023, P2100682 Exp. Date 1/31/2024, P2102065 Exp. Date 3/31/2024, P2102067 Exp. Date 3/31/2024, P2102068 Exp. Date 3/31/2024, P2102070 Exp. Date 3/31/2024, R2100659 Exp. Date 5/31/2024, R2100660 Exp. Date 5/31/2024, P2103898 Exp. Date 6/30/2024, P2106000 Exp. Date 7/31/2024, R2101442 Exp. Date 9/30/2024, P2201160 Exp. Date 1/31/2025, P2200695 Exp. Date 1/31/2025, P2200694 Exp. Date 1/31/2025; b) P2005530, Exp. Date 9/30/2023, P2005531 Exp. Date 9/30/2023, P2005532 Exp. Date 9/30/2023, P2005533 Exp. Date 9/30/2023, P2005846 Exp. Date 10/31/2023, P2006594 Exp. Date 11/30/2023, P2100602 Exp. Date 1/31/2024, P2100603 Exp. Date 1/31/2024, P2100604 Exp. Date 1/31/2024, P2100605 Exp. Date 1/31/2024,

P2101571 Exp. Date 2/29/2024, P2101572 Exp. Date 2/29/2024, P2102046 Exp. Date 3/31/2024, P2102047 Exp. Date 3/31/2024, P2102049 Exp. Date 3/31/2024, P2102050 Exp. Date 3/31/2024, P2102051 Exp. Date 3/31/2024, P2102052 Exp. Date 3/31/2024, P2103017 Exp. Date 4/30/2024, P2103018 Exp. Date 4/30/2024, P2103900 Exp. Date 6/30/2024, P2104436 Exp. Date 6/30/2024, P2105399 Exp. Date 7/31/2024, P2105400 Exp. Date 7/31/2024, P2106257 Exp. Date 9/30/2024, P2106258 Exp. Date 9/30/2024, P2106259 Exp. Date 9/30/2024, R2101443 Exp. Date 9/30/2024, R2101445 Exp. Date 9/30/2024, R2101444 Exp. Date 9/30/2024, R2200082 Exp. Date 12/31/2024, R2200080 Exp. Date 12/31/2024, R2200079 Exp. Date 12/31/2024, R2200081 Exp. Date 12/31/2024, P2200691 Exp. Date 1/31/2025, P2200692 Exp. Date 1/31/2025, P2200693 Exp. Date 1/31/2025, P2201499 Exp. Date 2/28/2025, P2201498 Exp. Date 2/28/2025, R2200579 Exp. Date 4/30/2025, P2203881 Exp. Date 5/31/2025, P2203441 Exp. Date 5/31/2025, P2203442 Exp. Date 5/31/2025, R2200949 Exp. Date 6/30/2025, R2201094 Exp. Date 6/30/2025, R2201003 Exp. Date 7/31/2025,

Product Description:
Glimepiride Tablets USP, 4 mg, Rx Only, Packaged in: a) 100-count bottle NDC 16729-003-01 UPC 3 16729 00301 8; b) 500-count NDC 16729-003-16 UPC 3 16729 00316 2; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
1,158,839 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0395-2023

Code Information:
Batches: a) P2001868, Exp. Date 3/31/2023, P2001869 Exp. Date 3/31/2023, P2002810 Exp. Date 5/31/2023, P2005473 Exp. Date 8/31/2023, P2005552 Exp. Date 9/30/2023, P2101986 Exp. Date 3/31/2024, P2101989 Exp. Date 3/31/2024, P2101988 Exp. Date 3/31/2024, P2101991 Exp. Date 3/31/2024, P2101992 Exp. Date 3/31/2024, R2100736 Exp. Date 6/30/2024, R2100737 Exp. Date 6/30/2024, P2105281 Exp. Date 7/31/2024, R2101441 Exp. Date 9/30/2024, R2101454 Exp. Date 10/31/2024, R2101455 Exp. Date 10/31/2024, R2101468 Exp. Date 10/31/2024, R2101469 Exp. Date 10/31/2024, R2200096 Exp. Date 12/31/2024; b)P2005550, Exp. Date 9/30/2023, P2005549 Exp. Date 9/30/2023, P2005551 Exp. Date 9/30/2023, P2005812 Exp. Date 10/31/2023, P2005813 Exp. Date 10/31/2023, P2005970 Exp. Date 10/31/2023, P2005971 Exp. Date 10/31/2023, P2005974 Exp. Date 10/31/2023, P2005814 Exp. Date 10/31/2023, P2005972 Exp. Date 10/31/2023, P2005973 Exp. Date 10/31/2023, P2005998 Exp. Date 10/31/2023, P2005999 Exp. Date 10/31/2023, P2006001 Exp. Date 10/31/2023, P2005997 Exp. Date 10/31/2023, P2006000 Exp. Date 10/31/2023, P2100701 Exp. Date 1/31/2024, P2100702 Exp. Date 1/31/2024, P2100703 Exp. Date 1/31/2024, P2100704 Exp. Date 1/31/2024, P2102512 Exp. Date 3/31/2024, P2101993 Exp. Date 3/31/2024, P2101994 Exp. Date 3/31/2024, P2102951 Exp. Date 4/30/2024, P2102952 Exp. Date 4/30/2024, P2102953 Exp. Date 4/30/2024, P2102954 Exp. Date 4/30/2024, R2100739 Exp. Date 6/30/2024, R2100738 Exp. Date 6/30/2024, R2100740 Exp. Date 6/30/2024, P2104668 Exp. Date 6/30/2024, P2104669 Exp. Date 6/30/2024, P2104670 Exp. Date 6/30/2024, P2105283 Exp. Date 7/31/2024, P2105291 Exp. Date 7/31/2024, P2105282 Exp. Date 7/31/2024, P2105794 Exp. Date 7/31/2024, P2105292 Exp. Date 7/31/2024, P2105297 Exp. Date 7/31/2024, P2105293 Exp. Date 7/31/2024, P2105295 Exp. Date 7/31/2024, P2105294 Exp. Date 7/31/2024, R2101408 Exp. Date 9/30/2024, R2101409 Exp. Date 9/30/2024, R2101410 Exp. Date 9/30/2024, R2101411 Exp. Date 9/30/2024, R2101412 Exp. Date 9/30/2024, R2101413 Exp. Date 9/30/2024, R2200089 Exp. Date 12/31/2024, R2200097 Exp. Date 12/31/2024, R2200100 Exp. Date 12/31/2024, R2200101 Exp. Date 12/31/2024, R2200088 Exp. Date 12/31/2024, P2200775 Exp. Date 1/31/2025, P2200776 Exp. Date 1/31/2025, P2201221 Exp. Date 1/31/2025, P2201347 Exp. Date 2/28/2025, P2201348 Exp. Date 2/28/2025, R2200481 Exp. Date 3/31/2025, R2200576 Exp. Date 4/30/2025, P2203378 Exp. Date 5/31/2025, P2203379 Exp. Date 5/31/2025, P2203377 Exp. Date 5/31/2025, R2200966 Exp. Date 6/30/2025, R2200964 Exp. Date 6/30/2025, R2200973 Exp. Date 6/30/2025, P2204893 Exp. Date 8/31/2025

Product Description:
Glycopyrrolate Injection, USP, 0.2 mg/mL, 1 mL Single Dose Vial x 25 vials, Rx Only, Manufactured for: Accord Healthcare, Inc. Durham, NC 27703, USA. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA 1 ml vial NDC 16729-471-63 UPC 3 16729 47163 3; 25 x 1 mL carton NDC 16729-471-08 UPC 3 16729 47108 4

Product Quantity:
23,814 vials

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0396-2023

Code Information:
Batches: R2200436, Exp. Date 1/31/2024, R2200159, Exp. Date 1/31/2024, R2200166, Exp. Date 1/31/2024, R2200618, Exp. Date 4/30/2024, R2201290, Exp. Date 8/31/2024, R2201324, Exp. Date 8/31/2024

Product Description:
Glycopyrrolate Injection, USP, 0.4 mg/2 mL (0.2 mg/mL) 2 mL Single Dose Vial X 25 vials carton, Rx Only, Manufactured for: Accord Healthcare, Inc.

Durham, NC 27703, USA. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA 2 ML vial NDC 16729-472-30 UPC 3 16729 47230 2; carton NDC 16729-472-08 UPC 3 16729 47208 1

Product Quantity:
5,273 vials

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0397-2023

Code Information:
Batches: R2200509, Exp. Date 4/30/2024, R2200507, Exp. Date 4/30/2024, R2200508, Exp. Date 4/30/2024

Product Description:
Glycopyrrolate Injection, USP 1 mg/5 mL (0.2 mg/mL) 5 mL Multiple Dose Vial, x 10 vials carton, Rx Only, Manufactured for: Accord Healthcare, Inc. Durham, NC 27703, USA. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA 5mL vial NDC 16729-473-31 UPC 3 16729 47331 6; carton NDC 16729-473-03 UPC 3 16729 47303 3

Product Quantity:
3,164 vials

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0398-2023

Code Information:
Batches: R2200259, Exp. Date 2/29/2024, R2200258, Exp. Date 2/29/2024, R2200617, Exp. Date 4/30/2024, R2201308, Exp. Date 8/31/2024

Product Description:
Glycopyrrolate Injection, USP 4 mg/20 mL (0.2 mg/mL) 20 mL Multiple Dose Vial, 10vial carton, Rx Only, Manufactured for: Accord Healthcare, Inc. Durham, NC 27703, USA. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA 20mL vial NDC 16729-474-05 UPC 3 16729 47405 4;carton NDC 16729-474-03 UPC 3 16729 47403 0

Product Quantity:
322 vials

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0399-2023

Code Information:
Batches: R2200431, Exp. Date 7/31/2023, R2200439, Exp. Date 9/30/2023

Product Description:
Montelukast Sodium Tablets, USP, 10 mg* Rx Only, Packaged as: a) 30-count bottle NDC 16729-119-10 UPC 3 16729 11910 8; b) 90-count bottle NDC 16729-119-15 UPC 3 16729 11915 3; c) 1,000-count bottle NDC 16729-119-17 UPC 3 16729 11917 7; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
665,469 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0400-2023

Code Information:
Batches: a) R2000831, Exp. Date 11/30/2023; R2000832, Exp. Date 11/30/2023; R2200661, Exp. Date 5/31/2025; b)R2000836, R2000837, R2000838, R2000840, R2000842, R2000835, R2000841, R2000833, Exp. Date 11/30/2023; R2100310, R2100311, R2100314, R2100312, R2100313, R2100315, R2100316, R2100317, R2100318, Exp. Date 2/29/2024; R2100859, Exp. Date 5/31/2024; R2100940, R2100993, Exp. Date 7/31/2024; c) R2000473, Exp. Date 8/31/2023; R2000517, Exp. Date 9/30/2023; R2100036, R2100005, R2100037, R2100002, R2100040, R2100044, R2100045, R2100039, R2100038, R2100104, R2100047, R2100048, R2100046, R2100049, R2100056, R2100057, R2100101, R2100058, R2100050, R2100103, R2100102, R2100116, R2100108, R2100105, R2100123, R2100117, R2100118, R2100121, R2100122,

R2100128, R2100119, R2100124, Exp. Date 12/31/2023; R2100124, R2100182, R2100184, R2100183, R2100188, R2100189, R2100186, R2100222, R2100197, R2100198, R2100203, R2100192, R2100196, R2100202, R2100199, R2100200, R2100223, R2100224, R2100225, R2100226, R2100228, R2100245, R2100227, R2100230, R2100229, Exp. Date 1/31/2024; R2100246, R2100253, R2100249, R2100251, R2100248, R2100263, R2100254, R2100264, R2100265, R2100266, R2100255, R2100256, R2100257,Exp. Date 2/29/2024; R2100445, R2100446, R2100449, R2100450, R2100451, Exp. Date 3/31/2024; R2100544, R2100545, R2100549, R2100550, R2100567, R2100568, R2100574, R2100576, R2100577, Exp. Date 4/30/2024; R2100594, R2100610, R2100600, R2100624, R2100626, R2100662, R2100661, R2100629, R2100776, R2100693, R2100681, R2100684, Exp. Date 5/31/2024; R2100725, R2100724, R2100726, R2100816, R2100804, R2100815, R2100834, R2100841, Exp. Date 6/30/2024; R2200188, R2200196, R2200195, Exp. Date 1/31/2025; R2200368, R2200366, R2200503, Exp. Date 3/31/2025; R2200659, R2200660, R2200751, R2200759, R2200761, R2200763, Exp. Date 5/31/2025; R2201016, R2201014, Exp. Date 7/31/2025;

Product Description:
Phenylephrine Hydrochloride Injection, USP 10 mg/mL Rx Only, 1 mL Single Dose Vial, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA; Vial NDC 16729-464-63, UPC 3 16729 46463 5; Carton NDC 16729-464-08, UPC 3 16729 46408 6

Product Quantity:
9,888 vials

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0401-2023

Code Information:
Batches: R2101555, R2101538, R2101564, Exp. Date 11/30/2023;

Product Description:
Phenylephrine Hydrochloride Injection, USP, 50 mg/5mL (10 mg/mL), Rx Only, 5 mL Vial, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA; Vial NDC 16729-465-31, UPC 3 16729 46531 1; Carton NDC 16729-465-03, UPC 3 16729 46503 8

Product Quantity:
5,090 vials

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0402-2023

Code Information:
Batches: R2101570, R2101574, R2101576, Exp. Date 11/30/2023

Product Description:
Phenylephrine Hydrochloride Injection, USP 100 mg/10 mL (10 mg/mL), Rx Only, 10 mL Vial, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA; NDC 16729-466-03, UPC 3 16729 46603 5

Product Quantity:
37,691 vials

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0403-2023

Code Information:
Batches: R2101591, R2101590, R2101599, Exp. Date 11/30/2023

Product Description:
Rosuvastatin Tablets, USP, 5 mg*, Rx Only, Packaged as: a) 90-count bottle, NDC 16729-284-15, UPC 3 16729 28415 8; b) 1,000-count bottle, NDC 16729-284-17, UPC 3 16729 28417 2; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA.

Product Quantity:
63,247 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0404-2023

Code Information:
Batches: a) P2101063, Exp. Date 1/31/2024; P2101707, Exp. Date 2/29/2024; P2203913 Exp. Date 6/30/2025; b) P2101064, Exp. Date 1/31/2024; P2101539, Exp. Date 1/31/2024; P2101709, Exp. Date 2/29/2024; P2102138, Exp. Date 2/29/2024; P2103186, Exp. Date 5/31/2024; P2104430, Exp. Date 6/30/2024; P2104703, Exp. Date 7/31/2024; P2104704, Exp. Date 7/31/2024; P2104705, Exp. Date 7/31/2024; P2104702, Exp. Date 7/31/2024; P2107176, Exp. Date 10/31/2024; P2107177, Exp. Date 10/31/2024; P2107178, Exp. Date 10/31/2024; P2107181, Exp. Date 10/31/2024; P2203915, Exp. Date 6/30/2025; P2203914, Exp. Date 6/30/2025; P2204998, Exp. Date 8/31/2025; P2204999, Exp. Date 8/31/202;

Product Description:
Rosuvastatin Tablets, USP, 10 mg*, Rx Only, Packaged as: a) 90-count bottle, NDC 16729-285-15, UPC 3 16729 28515 5; b) 1,000-count bottle NDC 16729-285-17, UPC 3 16729 28517 9; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
56,862 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0405-2023

Code Information:
Batches: a) P2006824, Exp. Date 11/30/2023; P2102223, Exp. Date 3/31/2024; b) P2004949, Exp. Date 8/31/2023; P2004948, Exp. Date 8/31/2023; P2004950, Exp. Date 8/31/2023; P2004953, Exp. Date 8/31/2023; P2004954, Exp. Date 8/31/2023; P2004956, Exp. Date 8/31/2023; P2004955, Exp. Date 8/31/2023; P2004957, Exp. Date 8/31/2023; P2004958, Exp. Date 8/31/2023; P2004959, Exp. Date 8/31/2023; P2005252, Exp. Date 9/30/2023; P2006607, Exp. Date 11/30/2023; P2101368, Exp. Date 2/29/2024; P2101777, Exp. Date 2/29/2024; P2102224, Exp. Date 3/31/2024; P2104397, Exp. Date 6/30/2024; P2104395, Exp. Date 6/30/2024; P2104398, Exp. Date 6/30/2024; P2105120, Exp. Date 7/31/2024; P2204835, Exp. Date 7/31/2025; P2204834, Exp. Date 7/31/2025; P2204837, Exp. Date 7/31/2025; P2205832, Exp. Date 9/30/2025; P2205833, Exp. Date 9/30/2025;

Product Description:
Rosuvastatin Tablets, USP 20 mg* Rx Only, Packaged as: a) 90-count bottle NDC 16729-286-15, UPC 3 16729 28615 2; b) 1,000-count bottles NDC 16729-286-17, UPC 3 16729 28617 6; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
43,302 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0406-2023

Code Information:
Batches: a) P2006560, Exp. Date 11/30/2023; P2101562, Exp. Date 2/28/2024; b) P2006561, Exp. Date 11/30/2023; P2006562, Exp. Date 11/30/2023; P2006587, Exp. Date 11/30/2023; P2100035, Exp. Date 11/30/2023; P2006600, Exp. Date 11/30/2023; P2006603, Exp. Date 11/30/2023; P2006604, Exp. Date 11/30/2023; P2006605, Exp. Date 11/30/2023; P2006606, Exp. Date 11/30/2023; P2100542, Exp. Date 12/31/2023; P2100543, Exp. Date 12/31/2023; P2100544, Exp. Date 12/31/2023; P2100545, Exp. Date 12/31/2023; P2101485, Exp. Date 2/28/2024; P2101484, Exp. Date 2/29/2024; P2205235, Exp. Date 8/31/2025; P2205236, Exp. Date 8/31/2025;

Product Description:
Rosuvastatin Tablets, USP 40 mg* Rx Only, Packaged as: a) 30-count bottle NDC 16729-287-10, UPC 3 16729 28710 4; b) 90-count bottle NDC 16729-287-15, UPC 3 16729 28715 9; c) 1,000-count bottle NDC 16729-287-17, UPC 3 16729 28717 3; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
102,360 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0407-2023

Code Information:
Batches: a) P2100343, Exp. Date 12/31/2023; P2102371, Exp. Date 3/31/2024; b) P2101966, Exp. Date 2/28/2024; P2104545, Exp. Date 6/30/2024; P2204500, Exp. Date 7/31/2025; P2205415, Exp. Date 8/31/2025; c) P2101591, Exp. Date 2/28/2023; P2200062, Exp. Date 12/31/2024; P2204336, Exp. Date 7/31/2025; P2204337, Exp. Date 7/31/2025; P2205416, Exp. Date 8/31/2025;

Product Description:
Simvastatin Tablets USP 5 mg Rx Only, Packaged as: a) 90-count bottle NDC 16729-156-15, UPC 3 16729 15615 8; b) 1,000-count bottle NDC 16729-156-17, UPC 3 16729 15617 2; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
256,648 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0408-2023

Code Information:
Batches: a) R2100818, Exp. Date 6/30/2023; R2100964, Exp. Date 6/30/2023; R2100824, Exp. Date 6/30/2023; R2100820, Exp. Date 6/30/2023; R2100822, Exp. Date 6/30/2023; R2101201, Exp. Date 9/30/2023; R2101198, Exp. Date 9/30/2023; R2101199, Exp. Date 9/30/2023; R2101200, Exp. Date 9/30/2023; R2101355, Exp. Date 10/31/2023; R2200035, Exp. Date 10/31/2023; R2200515, Exp. Date 4/30/2025; R2200514, Exp. Date 4/30/2025; R2200516, Exp. Date 4/30/2025; b) R2200310, Exp Date 9/30/2023; R2101354, Exp. Date 10/31/2023; R2200513, Exp. Date 4/30/2025; R2200768, Exp. Date 5/31/2025;

Product Description:
Simvastatin Tablets, USP, 10 mg, Rx Only, Packaged as: a) 90-count bottle NDC 16729-004-15, UPC 3 16729 00415 2; b) 1,000-count bottle NDC 16729-004-17, UPC 3 16729 00417 6; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
291,378 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0409-2023

Code Information:
Batches: a) P2106923, Exp. Date 9/30/2023; R2101544, Exp. Date 10/31/2023; R2200732, Exp. Date 5/31/2025; b) P2101634, Exp. Date 2/28/2023; P2102370, Exp. Date 3/31/2023; P2102321, Exp. Date 3/31/2023; P2102411, Exp. Date 3/31/2023; P2102454, Exp. Date 3/31/2023; P2103991, Exp. Date 5/31/2023; R2100954, Exp. Date 6/30/2023; R2100947, Exp. Date 6/30/2023; R2100951, Exp. Date 6/30/2023; P2106242, Exp. Date 8/31/2023; P2106928, Exp. Date 9/30/2023; P2107424, Exp. Date 9/30/2023; R2101542, Exp. Date 10/31/2023; R2101543, Exp. Date 10/31/2023; R2200026, Exp. Date 11/30/2023; R2200414, Exp. Date 2/29/2024; R2200416, Exp. Date 2/28/2025; R2200586, Exp. Date 4/30/2025; R2200679, Exp. Date 5/31/2025; R2200824, Exp. Date 5/31/2025;

Product Description:
Simvastatin Tablets USP 20 mg Rx Only, Packaged as: a) 90-count bottle NDC 16729-005-15, UPC 3 16729 00515 9; b) 1,000-count bottle NDC 16729-005-17, UPC 3 16729 00517 3; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
1,394,208 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0410-2023

Code Information:
Batches: a) P2102261, P2102284, P2102319, Exp. Date 3/31/2023, P2103536, Exp. Date 5/31/2023, P2104344, P2104342, P2104355, P2104356, P2104296, P2104380, Exp. Date 6/30/2023, R2200238, R2200239, Exp. Date 1/31/2024, R2200383, Exp. Date 2/28/2025; b) R2000554, R2000553, Exp. Date 9/30/2023; P2100562, P2100563,Exp. Date 12/31/2023; P2100692, P2100693, P2100722, P2100761, P2100762, P2101225,

P2101200, P2101148, P2101149, P2101276, P2101345, Exp. Date 1/31/2024; P2101622, P2101664, P2101638, P2101785, P2101904, Exp. Date 2/29/2024; P2101951, P2101984, P2102367, P2102369, P2102368, P2102311, P2102316, P2102406, P2102455, Exp. Date 3/31/2024; P2102553, P2102554, P2102635, P2103233, P2103253, Exp. Date 4/30/2024; P2103360, P2103322, P2103414, P2103444, P2103415, P2103447, P2103573, P2103594, P2103615, P2103679, P2103648, P2103691, P2103646, P2103629, P2103704, P2103731, P2103763, P2103788, P2103789, P2103766, P2103876, P2103959, P2103833, Exp. Date 5/31/2024; P2103992; P2104045, P2104002, P2104046, P2104381, P2104407, P2104389, P2104644, P2104409, P2104649, P2104673, P2104684, P2104743, P2104696, P2104695, P2104745, P2105154, R2100826, R2100819, R2100829, P2104697, P2104746, P2105194, R2100837, R2100830, R2100836, P2105196, P2105220, P2105195, P2105222, R2100851, R2100856, Exp. Date 6/30/2024; P2105879, P2105920, P2105937, P2105973, P2105940, P2105986, P2105997, P2106009, P2106001, P2106010, P2106159, P2106182, P2106168, P2106202, P2106203, P2106217, P2106233, P2106214, P2106245, Exp. Date 8/31/2024; P2106333, P2106327, P2106342, P2106374, P2106405, P2106416, P2106429, P2106423, P2106412, Exp. Date 9/30/2024; R2200377, R2200542, R2200543, Exp. Date 2/28/2025; P2202795, P2202420, P2202445, Exp. Date 3/31/2025; R2200598, R2200590, R2200596, R2200591, P2202817, P2203290, P2202818, P2202819, Exp. Date 4/30/2025; P2203050, P2203006, P2203051, Exp. Date 5/31/2025;

Product Description:
Simvastatin Tablets USP 40 mg Rx Only, Packaged as: a) 90-count tablets NDC 16729-006-15, UPC 3 16729 00615 6; b) 1,000-count tablets NDC 16729-006-17, UPC 3 16729 00617 0; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
1,190,484 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0411-2023

Code Information:
Batches: a) P2103713, P2103692, Exp. Date 5/31/2023, P2104950, P2104984, P2104969, P2104996, P2105274, P2105314, P2105316, Exp. Date 7/31/2023, R2101074, R2101077, R2101078, R2101079, R2101083, R2101084, R2101117, Exp. Date 8/31/2023, R2101330, R2101331, R2101335, R2101336, R2101334, R2101337, R2101339, Exp. Date 9/30/2023, R2101494, R2101495, R2101496, R2101497, Exp. Date 10/31/2023, R2200527, R2200531, Exp. Date 3/31/2024, R2200606, R2200625, Exp. Date 4/30/2024; b) P2101911, P2101913, R2100344, R2100351, R2100354, R2100346, R2100357, R2100358, R2100359, R2100361, R2100362, R2100385, R2100386, R2100388, R2100394, R2100397, R2100345, Exp. Date 2/28/2023; P2101930, P2101983, R2100435, R2100457, R2100433, R2100462, R2100466, R2100465, R2100469, R2100468, Exp. Date 3/31/2023; P2103223, P2103229, P2103234, Exp. Date 4/30/2023; P2103254, P2103258, P2103261, P2103323, P2103362, P2103364, P2103310, P2103671, P2103678, P2103545, P2103568, P2103599, P2103616, P2103627, P2103649, P2103813, P2103832, P2103834, P2103867, P2103868, P2103901, P2103912, Exp. Date 5/31/2023; P2105024, P2105027, P2105028, P2105049, P2105047, P2105052, P2105340, P2105341, P2105420, P2105432, P2105445, P2105455, P2105456, P2105467, P2105461, Exp. Date 7/31/2024; R2101118, R2101119, R2101127, R2101128, R2101134, R2101145, R2101133, R2101146, R2101149, R2101164, R2101169, R2101165, R2101187, R2101188, R2101192, R2101193, R2101168, R2101194, Exp. Date 8/31/2024; R2101516, R2101517, R2101515, R2101523, R2101525, R2101524, R2101530, R2101531, R2101532, R2101534, R2101533, R2101541, R2101547, R2101569, R2101567, R2101568, R2101571, R2101580, R2101582, R2101592, R2101583, R2101581, R2101593, P2107446, Exp. Date 10/31/2024; P2107791, P2107792, Exp. Date 11/30/2024; R2200271, R2200272, R2200275, Exp. Date 1/31/2025; R2200374, R2200379, R2200378, R2200391, Exp. Date 2/28/2025; R2200457, R2200458, R2200540, R2200470, R2200541, R2200459, R2200451, R2200471, Exp. Date 3/31/2025; R2200610, R2200611, R2200616, R2200615,R2200624, R2200628, R2200736, Exp. Date 4/30/2025, R2200688, R2200681, R2200687, Exp. Date 5/31/2025;

Product Description:
Simvastatin Tablets USP 80 mg Rx Only, Packaged as: a) 90-count bottle NDC 16729-007-15, UPC 3 16729 00715 3; b) 1,000-count bottle NDC 16729-007-17, UPC 3 16729 00717 7; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
205,631 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0412-2023

Code Information:
Batches: a) R2100387, R2100393, Exp. Date 2/28/2023, P2102556, P2102558, P2102636, Exp. Date 4/30/2023, P2103981, P2103877, P2103958, Exp. Date 5/31/2023, R2101393, R2101395, R2101394, Exp. Date 10/31/2023, P2202681, P2202653, Exp. Date 4/30/2025; b)R2000555, R2000587, R2000599, R2000604, Exp. Date 9/30/2023; P2100023, P2006857, Exp. Date 11/30/2023, P2101094, P2101096, P2101110, P2101111, P2101113, P2101145, P2101198, P2101223, P2101199, Exp. Date 1/31/2024, P2101877, P2101885, P2101886, P2101929, R2100402, R2100406, R2100403, Exp. Date 2/28/2024, P2101786, P2101787, P2101789, P2101790, Exp. Date 2/29/2024, R2100440, R2100439, Exp. Date 3/31/2024

Product Description:
Succinylcholine Chloride Injection, USP, 200 mg/10 mL (20 mg/mL), 10 mL Multiple-dose vial in 10x10 carton, Rx Only, Manufactured for: Accord Healthcare, Inc. USA. Manufactured by: Intas Pharmaceuticals Limited, India, Vial NDC 16729-493-03, UPC 3 16729 49303 1; Carton NDC 16729-493-45, UPC 3 16729 49345 1.

Product Quantity:
48,089 cartons

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0413-2023

Code Information:
Batches: R2101372, R2101397, R2101404, Exp. Date 4/30/2023; R2200264, R2200270, Exp. Date 8/31/2023; R2200382, Exp. Date 9/30/2023; R2200849, Exp. Date 12/31/2023; R2201017, R2201138, Exp. Date 1/31/2024; R2201249, Exp. Date 2/29/2024

Product Description:
Tadalafil Tablets, USP, 2.5 mg Rx Only, Packaged as: a) 30-count bottle NDC 16729-369-10, UPC 3 16729 36910 7; b) 500-count bottle NDC 16729-369-16, UPC 3 16729 36916 9; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
36,773 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0414-2023

Code Information:
Batches: a) P2002522, Exp. Date 4/30/2023; P2005817, P2005816, Exp. Date 10/31/2023; P2203687, Exp. Date 6/30/2025; b) P2002521, Exp. Date 4/30/2023; P2005818, Exp. Date 10/31/2023; P2100075, Exp. Date 12/31/2023; P2100996, P2100997, P2100998, P2100999, Exp. Date 1/31/2024;

Product Description:
Tadalafil Tablets, USP, 5 mg Rx Only, Packaged as: a) 30-count bottle NDC 16729-370-10, UPC 3 16729 37010 3; b) 500-count bottle NDC 16729-370-16, UPC 3 16729 37016 5; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
1,113,264 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0415-2023

Code Information:
Batches: a) P2002450, Exp. Date 4/30/2023, P2003222, Exp. Date 5/31/2023; P2003223, Exp. Date 5/31/2023; P2003224, Exp. Date 5/31/2023; P2004636, Exp. Date 8/31/2023; P2005035, Exp. Date 8/31/2023; P2005038, Exp. Date 8/31/2023; P2005040, Exp. Date 8/31/2023; P2005039, Exp. Date 8/31/2023; P2005041, Exp. Date 8/31/2023; P2005606, Exp. Date 9/30/2023; P2100340, Exp. Date 9/30/2023; P2100009, Exp. Date 12/31/2023; P2100010, Exp. Date 12/31/2023; P2100044, Exp. Date 12/31/2023; P2100045, Exp. Date 12/31/2023; P2100046, Exp. Date 12/31/2023; P2101129, Exp. Date 1/31/2024; P2101880, Exp. Date 1/31/2024; P2101130, Exp. Date 1/31/2024; P2101131, Exp. Date 1/31/2024; P2106689, Exp. Date 9/30/2024; P2106691, Exp. Date 9/30/2024; P2203585, Exp. Date 6/30/2025; b) P2002451 Exp. Date 4/30/2023; P2005365, Exp. Date 8/31/2023; P2005036, Exp. Date 8/31/2023; P2005037, Exp. Date 8/31/2023; P2005607, Exp. Date 9/30/2023; P2005608, Exp. Date 9/30/2023; P2100048, Exp. Date 12/31/2023; P2100052, Exp. Date 12/31/2023; P2100053, Exp. Date 12/31/2023; P2100055, Exp. Date 12/31/2023; P2100054, Exp. Date 12/31/2023; P2100387, Exp. Date 12/31/2023; P2100526, Exp. Date 12/31/2023; P2100525, Exp. Date 12/31/2023; P2100528, Exp. Date 12/31/2023; P2100530, Exp. Date 12/31/2023; P2100532, Exp. Date 12/31/2023; P2100531, Exp. Date 12/31/2023; P2100533, Exp. Date 12/31/2023; P2101127, Exp. Date 1/31/2024; P2101128, Exp. Date 1/31/2024; P2106094, Exp. Date 8/31/2024; P2106091, Exp. Date 8/31/2024; P2106093, Exp. Date 8/31/2024; P2200039, Exp. Date 9/30/2024; P2107771, Exp. Date 11/30/2024; P2107774, Exp. Date 11/30/2024; P2107772, Exp. Date 11/30/2024; P2200505, Exp. Date 12/31/2024; P2200506, Exp. Date 12/31/2024; P2200503, Exp. Date 12/31/2024; P2200510, Exp. Date 12/31/2024; P2200508, Exp. Date12/31/2024; P2203056, Exp. Date 5/31/2025; P2203058, Exp. Date 5/31/2025; P2203060, Exp. Date 5/31/2025; P2203057, Exp. Date 5/31/2025; P2203059, Exp. Date 5/31/2025; P2203584, Exp. Date 6/30/2025; P2205372, Exp. Date 8/31/2025; P2205376, Exp. Date 8/31/2025;

Product Description:
Tadalafil Tablets, USP 10 mg Rx Only, Packaged as: a) 30-count bottle NDC 16729-371-10, UPC 3 16729 37110 0; b) 500-count bottle NDC 16729-371-16, UPC 3 16729 37116 2; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
176,323 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0416-2023

Code Information:
Batches: a) P2002525, Exp. Date 4/30/2023; P2004442, Exp. Date 7/31/2023; P2005014, Exp. Date 8/31/2023; P2005015, Exp. Date 8/31/2023; P2005016, Exp. Date 8/31/2023; P2005825, Exp. Date 10/31/2023; P2005824, Exp. Date 10/31/2023; P2005826, Exp. Date 10/31/2023; P2100368, Exp. Date 12/31/2023; P2100444, Exp. Date 12/31/2023; P2101262, Exp. Date 2/29/2024; P2101263, Exp. Date 2/29/2024; P2200813, Exp. Date 1/31/2025; P2200814, Exp. Date 1/31/2025; b) P2002526, Exp. Date 4/30/2023; P2003781, Exp. Date 6/30/2023; P2003782, Exp. Date 6/30/2023; P2003783, Exp. Date 6/30/2023; P2004440, Exp. Date 7/31/2023; P2004441, Exp. Date 7/31/2023; P2005820, Exp. Date 10/31/2023; P2005821, Exp. Date 10/31/2023; P2005823, Exp. Date 10/31/2023; P2100077, Exp. Date 12/31/2023; P2100076, Exp. Date 12/31/2023; P2100078, Exp. Date 12/31/2023; P2100079, Exp. Date 12/31/2023; P2100080, Exp. Date 12/31/2023; P2100366, Exp. Date 12/31/2023; P2100442, Exp. Date 12/31/2023; P2100443, Exp. Date 12/31/2023; P2101265, Exp. Date 2/29/2024; P2101264, Exp. Date 2/29/2024; P2101718, Exp. Date 2/29/2024; P2108091, Exp. Date 11/30/2024; P2108092, Exp. Date 11/30/2024; P2108093, Exp. Date 11/30/2024; P2203589, Exp. Date 6/30/2025; P2203588, Exp. Date 6/30/2025; P2205379, Exp. Date 8/31/2025;

Product Description:
Tadalafil Tablets, USP, 20 mg, Rx Only, Packaged as: a) 30-count bottle NDC 16729-372-10, UPC 3 16729 37210 7; b) 500-count bottle NDC 16729-372-16, UPC 3 16729 37216 9; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA

Product Quantity:
613,553 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0417-2023

Code Information:
Batches: a) P2002461, Exp. Date 4/30/2023; P2002457, Exp. Date 4/30/2023; P2002460, Exp. Date 4/30/2023; P2002464, Exp. Date 4/30/2023; P2002463, Exp. Date 4/30/2023; P2002462, Exp. Date 4/30/2023; P2002465, Exp. Date 4/30/2023; P2003153, Exp. Date 5/31/2023; P2003155, Exp. Date 5/31/2023; P2003156, Exp. Date 5/31/2023; P2003154, Exp. Date 5/31/2023; P2003152, Exp. Date 5/31/2023; P2003157, Exp. Date 5/31/2023; P2003158, Exp. Date 5/31/2023; P2003159, Exp. Date 5/31/2023; P2003162, Exp. Date 5/31/2023; P2003160, Exp. Date 5/31/2023; P2003778, Exp. Date 6/30/2023; P2003779, Exp. Date 6/30/2023; P2004315, Exp. Date 6/30/2023; P2004818, Exp. Date 8/31/2023; P2004819, Exp. Date 8/31/2023; P2005158, Exp. Date 8/31/2023; P2005156, Exp. Date 8/31/2023; P2005157, Exp. Date 8/31/2023; P2005247, Exp. Date 9/30/2023; P2006641, Exp. Date 11/30/2023; P2101002, Exp. Date 1/31/2024; P2101004, Exp. Date 1/31/2024; P2101003, Exp. Date 1/31/2024; P2101006, Exp. Date 1/31/2024; P2101005, Exp. Date 1/31/2024; P2101008, Exp. Date 1/31/2024; P2101023, Exp. Date 1/31/2024; P2101022, Exp. Date 1/31/2024; P2101274, Exp. Date 2/29/2024; P2202085, Exp. Date 3/31/2025; b) P2002467, Exp. Date 4/30/2023; P2002466, Exp. Date 4/30/2023; P2002468, Exp. Date 4/30/2023; P2003780, Exp. Date 6/30/2023; P2005154, Exp. Date 8/31/2023; P2005244, Exp. Date 9/30/2023; P2005246, Exp. Date 9/30/2023; P2005809, Exp. Date 10/31/2023; P2005810, Exp. Date 10/31/2023; P2006642, Exp. Date 11/30/2023; P2006643, Exp. Date 11/30/2023; P2006644, Exp. Date 11/30/2023; P2006645, Exp. Date 11/30/2023; P2006646, Exp. Date 11/30/2023; P2006647, Exp. Date 11/30/2023; P2100463, Exp. Date 12/31/2023; P2100462, Exp. Date 12/31/2023; P2100464, Exp. Date 12/31/2023; P2100465, Exp. Date 12/31/2023; P2100498, Exp. Date 12/31/2023; P2100497, Exp. Date 12/31/2023; P2100499, Exp. Date 12/31/2023; P2100573 ,Exp. Date 1/31/2024; P2100572, Exp. Date 1/31/2024; P2100574, Exp. Date 1/31/2024; P2101007, Exp. Date 1/31/2024; P2202084, Exp. Date 3/31/2025;

Product Description:
Vigabatrin for Oral Solution, USP, 500 mg, Rx Only, 50-packets/carton, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA. Packet NDC 16729-521-63, UPC 3 16729 52163 5; Carton NDC 16729-521-11, UPC 3 16729 52111 6.

Product Quantity:
821 cartons

Reason for Recall:

CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0418-2023

Code Information:
Batches: R2100308, Exp. Date 2/28/2023

Product Description:
Pirfenidone Tablets 267 mg 90-count bottle x3/Carton, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA. Bottle NDC 16729-467-15, UPC 3 16729 46715 5; Carton NDC 16729-467-85, UPC 3 16729 46785 8.

Product Quantity:
2614 cartons

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0419-2023

Code Information:
Batches: P2202518, P2202512, Exp. Date 4/30/2024, P2204588, P2204589, Exp. Date 7/31/2024

Product Description:
Pirfenidone Tablets 801 mg, Rx Only, 90-count bottle, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA. NDC 16729-468-15, UPC 3 16729 46815 2.

Product Quantity:
2641 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0420-2023

Code Information:
Batches: P2202519, P2202513 Exp. Date 4/30/2024

Product Description:
Pravastatin Sodium Tablets USP, 10 mg, Rx Only, Packaged as: a) 90-count bottle NDC 16729-008-15, UPC 3 16729 00815 0; b) 500-count bottle NDC 16729-008-16, UPC 3 16729 00816 7; Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA

Product Quantity:
9600 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0421-2023

Code Information:
Batches: a) R2201093, Exp. Date 4/30/2024; b) R2201222, R2201231, Exp. Date 4/30/2024;

Product Description:
Pravastatin Sodium Tablets USP 20 mg, Rx Only, 90-count bottle, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA. NDC 16729-009-15, UPC 3 16729 00915 7.

Product Quantity:
32,688 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0422-2023

Code Information:
Batches: a)R2200589, R2200689, R2200690, R2201232, Exp. Date 4/30/2024

Product Description:
Pravastatin Sodium Tablets USP, 40 mg, Rx Only, 1,000-count bottle Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA. NDC 16729-010-17, UPC 3 16729 01017 7

Product Quantity:
120 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0423-2023

Code Information:
Batches: R2201294, Exp. Date 8/31/2025

Product Description:
Pravastatin Sodium Tablets USP, 80 mg, Rx Only, 90- count bottle, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA, NDC 16729-011-15, UPC 3 16729 01115 0

Product Quantity:
1970 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0424-2023

Code Information:
Batches: R2201233, Exp. Date 4/30/2024

Product Description:
rOPINIRole Tablets USP 0.25 mg*, 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA. NDC 16729-232-01, UPC 3 16729 23201 2;

Product Quantity:
139,332 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0425-2023

Code Information:
Batches: P2102086, Exp. Date 3/31/2023; P2105094, P2105095, P2105097, P2105096, P2105093, Exp. Date 7/31/2023; P2106490, P2106491, P2106493, P2106492, P2106494, Exp. Date 9/30/2023; P2201069, P2201068, P2201067, Exp. Date 1/31/2024; P2203516, Exp. Date 5/31/2024

Product Description:
rOPINIRole Tablets USP 0.5 mg*, 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA. NDC 16729-233-01, UPC 3 16729 23301 9

Product Quantity:
181,848 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0426-2023

Code Information:
Batches: P2102133, P2102135, P2102136, Exp. Date 3/31/2023, P2104998, P2104997, P2104991, P2104992, P2104990, P2104993, P2105000, P2104999, P2105002, P2105001, Exp. Date 7/31/2023, P2106812, Exp. Date, 9/30/2023, P2200433, P2200434, P2200435, Exp. Date, 12/31/2023, P2202730, P2202729, Exp. Date 4/30/2024, P2203517, Exp. Date 5/31/2024

Product Description:
rOPINIRole Tablets USP 1 mg*, 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA, NDC 16729-234-01, UPC 3 16729 23401 6

Product Quantity:
104,945 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0427-2023

Code Information:
Batches: P2103544 Exp. Date 5/31/2023, P2106132, P2106131, P2106128, P2106129, P2106130, P2106133, Exp. Date 8/31/2023, P2107662, P2107663, P2107664, Exp. Date 11/30/2023, P2203543, Exp. Date 5/31/2024

Product Description:
rOPINIRole Tablets USP 2 mg*, 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA. NDC 16729-235-01, UPC 3 16729 23501 3

Product Quantity:
25,344 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0428-2023

Code Information:
Batches: P2106370, P2106369, Exp. Date 9/30/2023, P2201254, Exp. Date 2/29/2024

Product Description:
rOPINIRole Tablets USP 3 mg*, 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA, NDC 16729-236-01, UPC 3 16729 23601 0

Product Quantity:
14,928 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0429-2023

Code Information:
Batches: P2105099, P2105098, Exp. Date 7/31/2023, P2106507, P2106508, P2106510, P2106509, Exp. Date 9/30/2023, P2202750, Exp. Date 4/30/2024

Product Description:
rOPINIRole Tablets USP 4 mg* 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA, NDC 16729-237-01, UPC 3 16729 23701 7

Product Quantity:
8,184 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0430-2023

Code Information:
Batches: P2106136, Exp. Date 8/31/2023, P2106813, P2106814, Exp. Date 9/30/2023, P2202764, Exp. Date 4/30/2024

Product Description:
rOPINIRole Tablets USP 5 mg* 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA, NDC 16729-238-01, UPC 3 16729 23801 4

Product Quantity:
5,112 bottles

Reason for Recall:
CGMP Deviations: recalling drug products following an FDA inspection.

Recall Number:
D-0431-2023

Code Information:
Batches: P2104150, P2104151, Exp. Date 6/30/2023, P2202065, Exp. Date 3/31/2024

Class II Drugs Event

Event ID:
91749

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/22/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/27/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nephron Sterile Compounding Center LLC
4500 12th Street Ext
West Columbia SC United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Diltiazem HCl in 0.7% Sodium Chloride Injection, 125 mg/125 mL (1 mg/mL), 125 mL Single-Dose Container bottle, packaged in 15 x 1 IV Bottles per carton, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC 69374-997-15.

Product Quantity:
4,743 bottles

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0355-2023

Code Information:
Lots: DS2053, Exp. 2/27/2023

Product Description:
Norepinephrine Bitartrate in 0.9% Sodium Chloride Injection, USP, 8 mg/250 mL (32 mcg/mL*), 250 mL Single-Dose Container, packaged in 15 x 1 IV Bottles per carton, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC 69374-316-25.

Product Quantity:
443,483 bottles

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0356-2023

Code Information:
Lots: NB2015A, Exp. 02/27/2023; NB2016A, Exp. 02/19/2023; NB2021A, Exp. 03/05/2023; NB2023A, Exp. 03/12/2023; NB2026A, Exp. 03/29/2023; NB2029A, Exp. 04/21/2023; NB2031A, Exp. 04/21/2023; NB2033A, Exp. 05/10/2023; NB2034A, Exp. 05/19/2023; NB2037A, Exp. 05/25/2023;

NB2039A, Exp. 06/05/2023; NB2041A, Exp. 06/14/2023; NB2044A, Exp. 06/18/2023; NB2050A, Exp. 07/19/2023; NB2054A, Exp. 08/04/2023; NB2057A, Exp. 08/12/2023; NB2059A, Exp. 08/20/2023; NB2061A, Exp. 09/14/2023; NB2067A, Exp. 09/22/2023

Product Description:
Norepinephrine Bitartrate in 0.9% Sodium Chloride Injection, USP, 4 mg/250 mL (16 mcg/mL*), 250 mL Single-Dose Container bottle, packaged in 15 IV Bottles per carton, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC 69374-319-25.

Product Quantity:
305,895 bottles

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0357-2023

Code Information:
Lots: NB2017A, Exp. 03/04/2023; NB2019A, Exp. 02/21/2023; NB2024A, Exp. 03/27/2023; NB2025A, Exp. 03/24/2023; NB2027A, Exp. 04/07/2023; NB2035A, Exp. 05/22/20123; NB2038A, Exp. 06/02/2023; NB2045A, Exp. 06/25/2023; NB2053A, Exp. 07/29/2023; NB2058B, Exp. 08/16/2023; NB2064A, Exp. 09/07/2023; NB2069A, Exp. 09/25/2023; NB2071A, Exp. 10/01/2023

Product Description:
Norepinephrine Bitartrate in 0.9% Sodium Chloride Injection, USP, 16 mg/250 mL (64 mcg/mL*), 250 mL Single-Dose Container bottle, packaged in 15 IV Bottles per carton, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC 69374-315-25.

Product Quantity:
270,291 bottles

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0358-2023

Code Information:
Lots: NB2018A, Exp. 02/24/2023; NB2022A, Exp. 03/08/2023; NB2028A, Exp. 04/04/2023; NB2032A, Exp. 04/24/2023; NB2036A, Exp. 05/24/2023; NB2043A, Exp. 06/17/2023; NB2046A, Exp. 06/26/2023; NB2049A, Exp. 07/21/2023; NB2052A, Exp. 07/27/2023; NB2062A, Exp. 09/13/2023; NB2068A, Exp. 09/23/2023

Product Description:
Phenylephrine HCl Injection, USP, 1 mg/10 mL (100 mcg/mL), 10 mL Single-Dose Vial, packaged in 30 x 10 mL Sterile Single-Dose Vials per carton, 12 x 30 Vials Carton per case, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC 69374-302-10.

Product Quantity:
546,450 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0359-2023

Code Information:
Lots: PE2025, Exp. 05/28/2023; PE2026, Exp. 06/02/2023; PE2027, Exp. 06/04/2023; PE2030, Exp. 06/29/2023; PE2031, Exp. 06/27/2023; PE2032, Exp. 07/09/2023; PE2032A, Exp. 07/09/2023; PE2033, Exp. 08/03/2023; PE2034, Exp. 08/31/2023; PE2035, Exp. 09/11/2023

Product Description:
Phenylephrine HCl Injection, USP, 0.4 mg/10 mL (40 mcg/mL), 10 mL Single-Dose Vial, packaged in 30 x 10 mL Single-Dose Vials per carton, 12 x 30 Vials Carton per case, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC 69374-305-10.

Product Quantity:
31,500 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0360-2023

Code Information:
Lots: PE2028, Exp. 06/15/2023

Product Description:
Phenylephrine HCl Injection, USP, 0.8 mg/10 mL (80 mcg/mL), 10 mL Single-Dose Vial, packaged in 30 x 10 mL Single-Dose Vials per carton, 12 x 30 Vials Carton per case, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC 69374-301-10.

Product Quantity:
24,870 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0361-2023

Code Information:
Lots: PE2029, Exp. 06/17/2023

Product Description:
Phenylephrine HCl in 0.9% Sodium Chloride Injection, USP, 50 mg/250 mL (200 mcg/mL), 250 mL Single-Dose Container bottle, packaged in 15 x 1 IV Bottles per carton, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC 69374-321-25.

Product Quantity:
10,980 bottles

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0362-2023

Code Information:
Lots: PS2008A, Exp. 03/07/2023

Class II Drugs Event

Event ID:
91751

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/23/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/02/2023

Initial Firm Notification of Consignee or Public:

Recalling Firm:
The Harvard Drug Group
341 Mason Rd
La Vergne TN United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Carbidopa and Levodopa Tablets, USP 25 mg/100 mg, 10x10 Unit Dose carton, Rx Only, Manufactured in Czech Republic by: Teva Czech Industries, s.r.o. Opava-Komarov, Czech Republic, Manufactured for: Teva Pharmaceuticals USA, Inc. Parsippany, NJ 07054, Packaged and Distributed by: Major Pharmaceuticals Indianapolis, IN 46268 USA. NDC 0904-7257-61, UPC 3 09047 25761 4

Product Quantity:
17,586 cartons

Reason for Recall:
Packaging defect: observed packaging defect, blister packaging inadequately sealed.

Recall Number:
D-0432-2023

Code Information:
Lot: M04145 Exp. 01/2024

Class II Drugs Event

Event ID:
91767

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/23/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/01/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nephron Sc Inc
4500 12th Street Ext
West Columbia SC United States

Distribution Pattern:
United States

Associated Products

Product Description:
Sterile Water for Injection, USP, 30x5 mL Single-Dose Vials, Rx Only, Nephron 4500 12th Street Extension West Columbia, SC 29172, NDC 0487-6105-01

Product Quantity:
325,080 vials

Reason for Recall:
CGMP Deviations: Potential product carryover.

Recall Number:
D-0364-2023

Code Information:
Lot #: 224011, 224021, 224022, 224023 Exp 12/31/2023

Class III Drugs Event

Event ID:
91616

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/01/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/24/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
DuPont Nutrition USA, Inc
1301 Ogletown Rd
Newark DE United States

Distribution Pattern:
Product was distributed nationwide in the United States and Puerto Rico, and to Australia, China, Canada, Columbia, Mexico, Brazil, Malaysia, Chile, Dominic Republic, Singapore, Thailand, Ireland, Germany, South Korea, Argentina, Pakistan, Oman, India

Associated Products

Product Description:
Avicel PH- 101 NF, Microcrystalline Cellulose, NF, Ph. Eur., Jp. Net Content/Gross Weight 50.0 KG / 54.5 KG bulk container, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown Road, Newark, DE 19711, USA. Headquarters: DuPont Nutrition Biosciences ApS, Langebrogade 1, Copenhagen, Denmark

Product Quantity:
131,060 kg. polyethylene lined fiber drums, boxes & sacks

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.

Recall Number:
D-0349-2023

Code Information:
Batch # 2173763874, 2173771315, P120834254, P120834263, P120834267, P120834275, P120834441, P120834442, P120834472, P120834507, P120834517, P120834518, P120834519, P120834520, These excipients are noted not to have an expiration date.

Product Description:
Avicel PH- 102 NF, Microcrystalline Cellulose, NF, Ph. Eur., Jp, Net Content/Gross Weight 20.0 KG / 21.1 KG bulk container, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown Road, Newark, DE 19711, USA. Headquarters: DuPont Nutrition Biosciences ApS, Langebrogade 1, Copenhagen, Denmark

Product Quantity:
368,980 kg polyethylene lined fiber drums, boxes & sacks

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.

Recall Number:
D-0350-2023

Code Information:
Batch # 2173747038, 2173773188, 2173777535, P220834401, P220834402, P220834404, P220834406, P220834422, P220834425, P220834429, P220834430, P220834482, P220834505, P220834508, P220834543, These excipients are noted not to have an expiration date.

Product Description:
Avicel PH-200 NF, Microcrystalline Cellulose, NF, Ph. Eur., Jp, Net Content/Gross Weight 20.0 KG / 21.1 KG bulk container, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown Road, Newark, DE 19711, USA. Headquarters: DuPont Nutrition Biosciences ApS, Langebrogade 1, Copenhagen, Denmark

Product Quantity:
7,740 kg polyethylene lined fiber drums, boxes & sacks

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.

Recall Number:
D-0351-2023

Code Information:
Batch # PN20834322, PN20834335 These excipients are noted not to have an expiration date.

Product Description:
BD-102 NF, Microcrystalline Cellulose, NF, Ph. Eur., Jp., Net Content/Gross Weight 20.0 KG / 21.1 KG bulk container, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown Road, Newark, DE 19711, USA. Headquarters: DuPont Nutrition Biosciences ApS, Langebrogade 1, Copenhagen, Denmark

Product Quantity:
106,560 kg. polyethylene lined fiber drums, boxes & sacks

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.

Recall Number:
D-0352-2023

Code Information:
Batch # 2173784100, B220834549 These excipients are noted not to have an expiration date.

Class III Drugs Event

Event ID:
91717

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/17/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/27/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sciegen Pharmaceuticals Inc
89 Arkay Dr
Hauppauge NY United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Gabapentin Tablets, USP 600 mg, 500 tablets per bottle, RX Only, Manufactured by ScieGen Pharmaceuticals Inc., Hauppauge, NY 11788, NDC: 50228-177-05.

Product Quantity:
4,392 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: Pharmacist reported presence of some Gabapentin tablets 800 mg comingled in Gabapentin 600 mg 500 count bottles.

Recall Number:
D-0354-2023

Code Information:
Lot # G177092, Exp. 11/24

Class III Drugs Event

Event ID:
91774

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/24/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/28/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCA Pharmaceuticals
755 Rainbow Rd Ste B
Windsor CT United States

Distribution Pattern:
Nationwide in the US.

Associated Products

Product Description:
Fentanyl 1,500 mcg/30 mL syringe, Injection for Intravenous Use, Concentration = 50 mcg/mL, Preservative Free, Rx Only, Single Dose Container, SCA Pharmaceuticals, Windsor CT 06095, NDC# 70004-0200-16.

Product Quantity:
2125 syringes

Reason for Recall:
Subpotent Drug

Recall Number:
D-0363-2023

Code Information:
Lot # 1222043351, exp. date 03/29/2023 1222043387, exp. date 04/05/2023 1222043352, exp. date 04/05/2023 1222043463, exp. date 04/06/2023 1223043922, exp. date 05/04/2023

Not Yet Classified Drugs Event

Event ID:
91711

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/13/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Volt Candy Wholesale Club
324 S Diamond Bar Blvd #212
Diamond Bar CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
PrimeZEN Black 6000 capsule, 2000mg, Male Sexual Performance Enhancement, 1-count blister card, Distributed by: Prime Premier Group, Los Angeles, CA 90006, UPC 7 28175 52189 1.

Product Quantity:
432 capsules

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found the product to be tainted with undeclared sildenafil and tadalafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.

Recall Number:

Code Information:
Lot number: NPINPB 1003, Expiration date: 08/16/2025