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# Drug Information Update

March 2023

**TABLE OF CONTENTS**

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NEWLY AVAILABLE GENERICS .....2  
NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS .....3  
RECALLS .....6  
CURRENT DRUG SHORTAGES .....95

## NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Hylan G-F 20 48 mg/6 mL syringe	Synvisc-One	Sanofi	For the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics (e.g., acetaminophen)
Fluticasone propionate/salmeterol 45 mcg-21 mcg, 115 mcg-21 mcg, 230 mcg-21 mcg inhaler	Advair HFA	GSK	For treatment of asthma in adult and adolescent patients aged 12 years and older
Teriflunomide 7 mg, 14 mg oral tablet	Aubagio	Sanofi	For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
Bismuth/metronidazole/tetracycline 140 mg-125 mg-125 mg oral capsule	Pylera	Allergan	To be used in combination with omeprazole for the treatment of patients with <i>H. pylori</i> infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate <i>H. pylori</i>
Diltiazem HCl 120 mg Tablet ER 24H	Cardizem LA	Bausch Health	<ul style="list-style-type: none"> <li>• Treatment of hypertension, to lower blood pressure</li> <li>• Improving exercise tolerance in patients with chronic stable angina</li> </ul>

## NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Lamzedo 10 mg intravenous solution	velmanase alfa-tycv	Indicated for the treatment of the non-central nervous system manifestations of alpha-mannosidosis, a rare genetic condition characterized by the lack of the alpha-mannosidase enzyme in the body; cost is approximately \$112,000 per month (based on 70kg patient)	New Entity
Xenoview 1,000 mL inhalation gas	xenon xe-129 hyperpolarized	Diagnostic agent	New Diagnostic
Syfovre 15 mg/0.1 mL intravitreal solution	pegcetacoplan	Complement inhibitor indicated for the treatment of Geographic Atrophy (GA) secondary to age-related macular degeneration (AMD); pegcetacoplan is already approved as a subcutaneous infusion formulation for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) under the brand name Empaveli; annual costs will range from \$13000 to \$26000 depending on injection frequency	New Formulation
Filspari 200 mg, 400 mg oral tablets	sparsentan	Endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) $\geq 1.5$ g/g; this indication is granted under accelerated approval based on reduction in proteinuria; first and only non-immunosuppressive therapy approved for the treatment of this condition; cost is approximately \$9,900 per month based on maintenance dosing	New Entity

Drug Name	Generic Name	Description	Comments
Orenitram Titration 0.125 mg (126)-0.25 mg (42), 0.125 mg (126)-0.25 mg(210), 0.125 mg(126)-0.25 mg(42)-1 mg oral tablet dose pack	treprostinil diolamine	New dosage form and strength of already existing prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension	New Dosage Form and Strength
Erleada 240 mg oral tablet	apalutamide	New strength of antineoplastic indicated for prostate cancer treatment; also available in 60mg tablet	New Strength
Konvomep 2 mg-84 mg/mL oral suspension	omeprazole/sodium bicarbonate	New dosage form and strength; indicated for adults with active benign gastric ulcer and reduction of GI bleeding in critically ill; this product would compete with Zegerid which is available as generic	New Dosage Form and Strength
Clenpiq 10 mg-3.5 gram-12 gram/175 mL oral solution	sod picosulfate/magnesium oxide/citric acid	New strength, indicated for bowel cleansing	New Strength
Emerphed 50 mg/10 mL (5 mg/mL) intravenous syringe	ephedrine sulfate	New strength of IV ephedrine	New Strength
Oxybutynin chloride 2.5 mg oral tablet	oxybutynin chloride	New strength of already approved generic, indicated for overactive bladder	New Strength
Ervebo (PF) 1 mL intramuscular suspension	ebola (zaire) vaccine, live	Ebola vaccine, part of national stockpile	New Entity
Rezvoglar KwikPen 100 unit/mL (3 mL) subcutaneous	insulin glargine-aglr	Biosimilar to Lantus	New BLA Biosimilar to Insulin Glargine (Lantus)
Altuviiiio 250 unit, 500 unit, 1000 unit, 2000 unit, 3000 unit, 4000 unit intravenous solution	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl	Indicated for routine prophylaxis and on-demand treatment to control bleeding episodes, as well as perioperative management (surgery) for adults and children with hemophilia A; Altuviiiio is a novel von Willebrand Factor (VWF) independent recombinant factor VIII therapy that is designed to extend	New BLA

Drug Name	Generic Name	Description	Comments
		protection from bleeds with once-weekly prophylactic dosing for adults and children with hemophilia A; it has a 3 to 4 fold longer half-life relative to standard and extended half-life factor VIII products	
AtorvaliQ 20 mg/5 mL (4 mg/mL) oral suspension	atorvastatin calcium	New dosage form and strength of atorvastatin	New Dosage Form and Strength
Lumakras 320 mg oral tablet	sotorasib	New strength of KRAS protein inhibitor indicated for NSCLC; also available in 120mg tablets	New Strength
Daybue 200 mg/mL oral solution	trofinetide	Indicated for Rett syndrome in adults and pediatric patients two years of age and older; pricing will vary based on patient weight but ranges from \$31,650 to \$75,600 per month	New Entity
Skyclarys 50 mg oral capsule	omaveloxolone	NucleaNoner factor erythroid 2- related factor 2 activator for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older; first approved treatment for Friedreichs ataxia; cost is approximately \$31,000 per month	New Entity

## RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 13 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0105-5	Class I	Drugs	Lot #: 220409, Exp. 10/2023; 220956, Exp. 03/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 100 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0130-5	Class I	Drugs	Lot #: 220413, Exp. 10/2023; 220964, Exp. 3/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 125 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0140-5	Class I	Drugs	Lot #: 220855, Exp. 2/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 175 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0155-5	Class I	Drugs	Lot #: 220416, Exp. 10/2023; 221053, Exp. 4/2024.	Subpotent Drug	IBSA PHARMA INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 25 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0110-5	Class I	Drugs	Lot #: 220856, Exp. 2/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 37.5 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0112-5	Class I	Drugs	Lot #: 220552, Exp. 11/2023; 221055, Exp. 04/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 44 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0113-5	Class I	Drugs	Lot #: 220553, Exp. 11/2023; 221056, Exp. 04/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 50 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0115-5	Class I	Drugs	Lot #: 220407, Exp. 10/2023; 220960, Exp. 03/2024.	Subpotent Drug	IBSA PHARMA INC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 62.5 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0117-5	Class I	Drugs	Lot #: 220556, Exp. 11/2023; 221058, Exp. 04/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 75 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0120-5	Class I	Drugs	Lot #: 220853, Exp. 02/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 88 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0125-5	Class I	Drugs	Lot #: 220411, Exp. 10/2023; 220854, Exp. 02/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 112 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0135-5	Class I	Drugs	Lot #: 220414, Exp. 10/2023; 220852, Exp. 02/2024; 220970, Exp. 03/2024.	Subpotent Drug	IBSA PHARMA INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 137 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0145-5	Class I	Drugs	Lot #: 220415, Exp. 10/2023; 221052, Exp. 04/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 150 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0150-5	Class I	Drugs	Lot #: 220959, Exp. 3/2024.	Subpotent Drug	IBSA PHARMA INC
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 200 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0160-5	Class I	Drugs	Lot #: 220418, Exp. 10/2023; 220560, Exp. 11/2023.	Subpotent Drug	IBSA PHARMA INC
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.	Class I	Drugs	Lot number: NPINPB 1003, Expiration date: 08/16/2025	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.	Volt Candy Wholesale Club

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Purely Soothing 15% MSM Drops, packaged in a)15 ml, .5 fl oz bottle, UPC 7 31034 91382 9; and b) 30 ml, 1.014 fl oz bottle, UPC 7 31034 91379 9; Manufactured by: Pharmedica USA, Phoenix, AZ.	Class I	Drugs	Lot #s: a) 1808051, Exp.: 01/01/2027; b) 2203PS01, Exp.: 01/01/2027	Non-Sterility	Pharmedica USA, LLC
Snowy Range Blue Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-Sterile Solution, 4fl. oz. [118mL], Distributed by Reliable Products, LLC, Cheyenne, WY 82003, NDC 75288-100-04.	Class I	Drugs	All Lots	Chemical Contamination: FDA analysis found the product to contain methanol, acetaldehyde, and acetal above the limits.	Nanomaterials Discovery Corporation
0.9% Sodium Chloride Injection, USP, 1000 mL Excel Plus Container, Rx Only, B. Braun Medical Inc. Bethlehem, PA 18018, NDC 0264-5802-00	Class II	Drugs	Lots: 0061786962 Exp. 11/30/2023; 0061797767 Exp. 04/30/2024; 0061797768 Exp. 05/31/2024; 0061787769 Exp. 05/31/2024; 0061797770 Exp. 05/31/2024; 0061797771 Exp. 05/31/2024; 0061797772 Exp. 05/31/2024; 0061797773 Exp. 05/31/2024; 0061797774 Exp. 05/31/2024; 0061797775 Exp. 05/31/2024; 0061797776 Exp. 05/31/2024; 0061812946 Exp. 05/31/2024; 0061812947 Exp. 05/31/2024; 0061812948	Lack of sterility assurance: Recall of certain batches of 0.9% Sodium Chloride for Injection USP in EXCEL <sup>+</sup> Plus IV Container product due to the possibility of an incomplete seal that may cause leakage. The impacted lots may exhibit microscopic channel leaks near the port assembly of the product.	B. Braun Medical Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. 05/31/2024; 0061812949 Exp. 05/31/2024; 0061812950 Exp. 05/31/2024; 0061816017 Exp. 06/30/2024; 0061816018 Exp. 06/30/2024; 0061816019 Exp. 06/30/2024; 0061816020 Exp. 06/30/2024; 0061816021 Exp. 06/30/2024; 0061816358 Exp. 06/30/2024; 0061816359 Exp. 06/30/2024; 0061816361 Exp. 07/31/2024; 0061816362 Exp. 07/31/2024; 0061816363 Exp. 07/31/2024; 0061816364 Exp. 07/31/2024; 0061818516 Exp. 07/31/2024; 0061818517 Exp. 07/31/2024; 0061818518 Exp. 07/31/2024; 0061821562 Exp. 08/31/2024; 0061821563 Exp. 08/31/2024; 0061821564 Exp. 08/31/2024; 0061823709		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. 08/31/2024; 0061823710 Exp. 08/31/2024; 0061823711 Exp. 08/31/2024; 0061823714 Exp. 08/31/2024; 0061823715 Exp. 08/31/2024; 0061823716 Exp. 08/31/2024; 0061824770 Exp. 08/31/2024; 0061824771 Exp. 08/31/2024; 0061824772 Exp. 08/31/2024; 0061824773 Exp. 08/31/2024; 0061824774 Exp. 08/31/2024; 0061824775 Exp. 08/31/2024; 0061824776 Exp. 08/31/2024; 0061824777 Exp. 08/31/2024; 0061826486 Exp. 08/31/2024; 0061826487 Exp. 08/31/2024; 0061826488 Exp. 08/31/2024		
0.9% Sodium Chloride Injection, USP, 500 mL Excel Plus Container, Rx Only, B. Braun Medical Inc. Bethlehem, PA 18018, NDC 0264-5802-10	Class II	Drugs	Lots: 0061794230 Exp. 01/31/2024; 0061794232 Exp. 01/31/2024; 0061797779 Exp. 02/29/2024; 0061797780	Lack of sterility assurance: Recall of certain batches of 0.9% Sodium Chloride for Injection USP in EXCEL <sup>®</sup> Plus IV Container product due to the possibility of an	B. Braun Medical Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. 02/29/2024; 0061797781 Exp. 02/29/2024; 0061797783 Exp. 02/29/2024; 0061797784 Exp. 03/31/2024; 0061797785 Exp. 03/31/2024; 0061797786 Exp. 03/31/2024; 0061797787 Exp. 03/31/2024; 0061797788 Exp. 03/31/2024; 0061809680 Exp. 04/30/2024	incomplete seal that may cause leakage. The impacted lots may exhibit microscopic channel leaks near the port assembly of the product.	
Tacrolimus Capsules, USP, 0.5 mg, 100-count bottle, Rx Only, Mfd. by Dr. Reddy's Laboratories Limited, Bachupally - 500 090, INDIA; NDC 55111-525-01.	Class II	Drugs	Lot # C2106445; Exp. 03/2024	Presence of Foreign Tablets/Capsules: Presence of one Tacrolimus 1 mg capsule co-mingled in a bottle containing and labeled as Tacrolimus 0.5 mg capsules.	Dr. Reddy's Laboratories, Inc.
Warfarin Sodium Tablets, USP 1 mg, 100-count bottle, Rx Only, Distributed by: Rising Health, LLC, Saddle Brook, NJ 07663, NDC# 57237-119-01	Class II	Drugs	Batch #: NB101596, Exp. 04/30/2023	Failed Impurities/Degradation Specifications	RISING PHARMACEUTICALS
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.	Class II	Drugs	Lot # HE02221, Exp. 05/2023	Sub-Potent Drug: Out of specification for assay at the 24-month interval.	Alvogen, Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>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</p>	Class II	Drugs	<p>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;</p>	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
<p>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</p>	Class II	Drugs	<p>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,</p>	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			P2204437, Exp. Date 7/31/2025;		
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	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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.	Class II	Drugs	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,	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			R2201038, Exp. Date 6/30/2024;		
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: a)R2100283, R2100288, R2100289, Exp. Date 2/28/2023;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>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</p>			<p>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;</p>		
<p>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,</p>	Class II	Drugs	<p>Batches: P2105532, Exp.            Date 6/30/2024;            P2200348, Exp. Date            12/31/2024;</p>	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ahmedabad-382 213, INDIA, NDC 16729-201-01					
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	Class II	Drugs	Batches: a) P2200530, Exp. Date 12/31/2024; b) P2105583, Exp. Date 6/30/2024;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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;	Class II	Drugs	Batches: P2105483, Exp. Date 7/31/2024;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: P2105472, Exp. Date 4/30/2024;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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,	Class II	Drugs	Batches: P2105551, Exp. Date 7/31/2024;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ahmedabad-382 213, INDIA, NDC 16729-289-12 UPC 3 16729 28912 2					
<p>Clpidogrel 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</p>	Class II	Drugs	<p>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,</p>	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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	Class II	Drugs	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,	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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.	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			P2205373, P2205412, Exp. Date 8/31/2025;		
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: P2101582, P2101661, P2101482, P2101686, Exp. Date 2/28/2023; P2102581, P2102598, Exp. Date 4/30/2023; P2103623, P2103653, P2103670, Exp.	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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.	Class II	Drugs	Batches: a) R2200401, Exp. Date 5/31/2024; R2200675, Exp. Date 5/31/2024; R2200676 Exp. Date 11/30/2024; R2201070, Exp. Date	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA			7/31/2025; b) R2200680, Exp. Date 9/30/2024;		
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: a) P2005979, Exp. Date 10/31/2023; P2100252, Exp. Date 12/31/2023; P2101710, Exp. Date 2/29/2024; b)	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA			P2100253, Exp. Date 12/31/2023; P2103035, Exp. Date 4/30/2024; P2103036, Exp. Date 4/30/2024;		
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
Finasteride Tablets USP, 5 mg, Rx Only, packaged as: a) 30-count bottles NDC 16729-090-10 UPC 3 16729 09010 0; b) 90-	Class II	Drugs	Batches: a) P2001383, Exp. Date 2/28/2023; P2004886, Exp. Date	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>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</p>			<p>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,</p>		



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		
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;	Class II	Drugs	Batches: a) R2000184, Exp. Date 4/30/2023, R2000183 Exp. Date 4/30/2023, P2002969 Exp.	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA</p>			<p>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.</p>		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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.		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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.		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Date 5/31/2025, R2200949 Exp. Date 6/30/2025, R2201094 Exp. Date 6/30/2025, R2201003 Exp. Date 7/31/2025,		
<p>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</p>	Class II	Drugs	<p>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</p>	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		
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	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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.	Class II	Drugs	Batches: R2200509, Exp. Date 4/30/2024, R2200507, Exp. Date	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
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			4/30/2024, R2200508, Exp. Date 4/30/2024		
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	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: R2200431, Exp. Date 7/31/2023, R2200439, Exp. Date 9/30/2023	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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.,	Class II	Drugs	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,	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, INDIA			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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,	Class II	Drugs	Batches: R2101555, R2101538, R2101564, Exp. Date 11/30/2023;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ahmedabad-382 213, INDIA; Vial NDC 16729-464-63, UPC 3 16729 46463 5; Carton NDC 16729-464-08, UPC 3 16729 46408 6					
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	Class II	Drugs	Batches: R2101570, R2101574, R2101576, Exp. Date 11/30/2023	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: R2101591, R2101590, R2101599, Exp. Date 11/30/2023	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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.	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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 8/31/2025;		
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	Class II	Drugs	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,	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>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</p>	<p>Class II</p>	<p>Drugs</p>	<p>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;</p>	<p>CGMP Deviations: recalling drug products following an FDA inspection.</p>	<p>Accord Healthcare, Inc.</p>

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>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</p>	Class II	Drugs	<p>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;</p>	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
<p>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</p>	Class II	Drugs	<p>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,</p>	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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	Class II	Drugs	Batches: a) P2103713, P2103692, Exp. Date 5/31/2023, P2104950, P2104984, P2104969, P2104996, P2105274, P2105314, P2105316, Exp. Date 7/31/2023,	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Limited, Pharmez, Ahmedabad-382 213 INDIA			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			R2200610, R2200611, R2200616, R2200615, R2200624, R2200628, R2200736, Exp. Date 4/30/2025, R2200688, R2200681, R2200687, Exp. Date 5/31/2025;		
<p>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</p>	Class II	Drugs	<p>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</p>	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		
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.	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>Limited, Pharmez, Ahmedabad-382 213 INDIA</p>			<p>10/31/2023; P2100075, Exp. Date 12/31/2023; P2100996, P2100997, P2100998, P2100999, Exp. Date 1/31/2024;</p>		
<p>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</p>	<p>Class II</p>	<p>Drugs</p>	<p>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,</p>	<p>CGMP Deviations: recalling drug products following an FDA inspection.</p>	<p>Accord Healthcare, Inc.</p>

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. Date 12/31/2024; 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;		
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	Class II	Drugs	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;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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	Class II	Drugs	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,	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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;		
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.	Class II	Drugs	Batches: R2100308, Exp. Date 2/28/2023	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
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.	Class II	Drugs	Batches: P2202518, P2202512, Exp. Date 4/30/2024, P2204588, P2204589, Exp. Date 7/31/2024	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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.	Class II	Drugs	Batches: P2202519, P2202513 Exp. Date 4/30/2024	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: a) R2201093, Exp. Date 4/30/2024; b) R2201222, R2201231, Exp. Date 4/30/2024;	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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,	Class II	Drugs	Batches: a) R2200589, R2200689, R2200690, R2201232, Exp. Date 4/30/2024	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
INDIA. NDC 16729-009-15, UPC 3 16729 00915 7.					
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	Class II	Drugs	Batches: R2201294, Exp. Date 8/31/2025	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: R2201233, Exp. Date 4/30/2024	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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;	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
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	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	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	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
rOPINIRole Tablets USP 2 mg*, 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703	Class II	Drugs	Batches: P2106370, P2106369, Exp. Date	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 INDIA. NDC 16729-235-01, UPC 3 16729 23501 3			9/30/2023, P2201254, Exp. Date 2/29/2024		
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	Class II	Drugs	Batches: P2105099, P2105098, Exp. Date 7/31/2023, P2106507, P2106508, P2106510, P2106509, Exp. Date 9/30/2023, P2202750, Exp. Date 4/30/2024	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: P2106136, Exp. Date 8/31/2023, P2106813, P2106814, Exp. Date 9/30/2023, P2202764, Exp. Date 4/30/2024	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Batches: P2104150, P2104151, Exp. Date 6/30/2023, P2202065, Exp. Date 3/31/2024	CGMP Deviations: recalling drug products following an FDA inspection.	Accord Healthcare, Inc.
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	Class II	Drugs	Lots: DS2053, Exp. 2/27/2023	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
12th St. Extension, West Columbia, SC 29172, NDC 69374-997-15.					
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.	Class II	Drugs	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;	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			NB2067A, Exp. 09/22/2023		
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.	Class II	Drugs	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	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
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.	Class II	Drugs	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,	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			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		
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.	Class II	Drugs	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	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
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.	Class II	Drugs	Lots: PE2028, Exp. 06/15/2023	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
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	Class II	Drugs	Lots: PE2029, Exp. 06/17/2023	Lack of Assurance of Sterility	Nephron Sterile

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
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.					Compounding Center LLC
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.	Class II	Drugs	Lots: PS2008A, Exp. 03/07/2023	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
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	Class II	Drugs	Lot: M04145 Exp. 01/2024	Packaging defect: observed packaging defect, blister packaging inadequately sealed.	The Harvard Drug Group
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	Class II	Drugs	Lot #: 224011, 224021, 224022, 224023 Exp 12/31/2023	CGMP Deviations: Potential product carryover.	Nephron Sc Inc
Verapamil Hydrochloride Extended-Release Tablets, USP, 120 mg, Rx Only, 100 Tablets per Carton (10 x 10), Distributed by: American Health Packaging, Columbus, Ohio	Class II	Drugs	Lot 1009065, Exp 12/31/2023	Failed Dissolution Specification: Out of specification dissolution results at time point zero. The OOS was above specified values.	Amerisource Health Services LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
43217. NDC Carton: 60687-493-01; NDC Unit Dose: 60687-493-11.					
Purely Soothing MSM Nasal Spray, 15%, packaged in 30ml, 1.014 fl. oz bottles, Manufactured by: Pharmedica USA, Phoenix, AZ, UPC 7 31034 91380 5	Class II	Drugs	Lot #: 1808051, Exp.: 01/01/2027	CGMP Deviations	Pharmedica USA, LLC
NaturalCare bioAllers, Allergy Nasal Spray, Homeopathic, All Region Formula, 0.8 fl oz (24mL), Mfd. Nutraceutical Corp., NaturalCare Park City, UT, 84098 USA, UPC 3 71400 70801 9	Class II	Drugs	Lot: 221263, Exp: 10/24; 222047, 222048 Exp: 02/25; 222099, 222100, Exp: 03/25	CGMP Deviations: Raw material recalled by repackager, due to discoloration.	Nutraceutical Corporation
NatraBio, Cold& Sinus Nasal Spray, Homeopathic Medicine, 0.8 FL Oz. (24ml), Mfd. for Healthway Corp. Comments or Questions NatraBio Shelburne Falls, MA 01370 USA, UPC 3 71400 55711 2	Class II	Drugs	Lot: 222016, Exp: 01/25;	CGMP Deviations: Raw material recalled by repackager, due to discoloration.	Nutraceutical Corporation
NaturalCare bioAllers, Mold, Yeast, and Dust, Homeopathic, Liquid Drops, 20% Alcohol, 1 FL OZ (30mL), Mfd. for Nutraceutical Corp. NaturalCare Park City, UT, 84098 USA	Class II	Drugs	Lot 222076, Exp: 03/27;	CGMP Deviations: Raw material recalled by repackager, due to discoloration.	Nutraceutical Corporation
NaturalCare, children's, Allergy Care, Homeopathic, 4 Months and Up, Liquid Drops, 0.1% Alcohol, 1 FL OZ (30mL), Mfd. Nutraceutical Corp., Salt Lake City, UT, 84101 USA, UPC 3 71402 30101 0	Class II	Drugs	Lot 222148, Exp: 05/25;	CGMP Deviations: Raw material recalled by repackager, due to discoloration.	Nutraceutical Corporation
Alcolado Relampago (menthol 1%, camphor 1.5%), packaged in a) 7 fluid oz. (207 ml) and b) 16 fluid oz. (472 ml) bottles, Distributed	Class II	Drugs	Lot #: a) and b) 2E018A, 2E021A, 2E286A, Exp. date Jan-25	CGMP DEVIATIONS	Ecometics, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
by: The Larkspur Group Inc. South Norwalk, CT 06854					
Vencedor medicated balm (capsaicin 0.028%) 1.5 oz. (43g) tubes, Distributed by: The Larkspur Group Inc. Norwalk, CT 06854	Class II	Drugs	Lot #: 2E021A, Exp. Date Jan-25	CGMP DEVIATIONS	Ecometics, Inc.
Ungentine Original Ointment for Burns (Camphor 3.0%, Phenol 2.5%, Tannic Acid 2.2%, Oxide 6.6%) packaged in 1 oz. (28g) metal tubes, Distributed by: Oakhurst Company Levittown, NY 11756	Class II	Drugs	Lot # 2E116A, Exp. Date APR-24	CGMP DEVIATIONS	Ecometics, Inc.
Soltice Quick-RUB (Menthol 5.1%, Camphor 5.1%) packaged in a) 1.33 oz (37g) plastic jars and b) 3 Oz (85g) plastic jars	Class II	Drugs	Lot #: a) 0E344A /AA, exp. date N/A; b) 2E243A, Exp. Aug-25	CGMP DEVIATIONS	Ecometics, Inc.
Nose Better Gel (0.75% Camphor, 0.50% Menthol, 0.50% Allantoin), packaged in 0.46 oz. (13g) metal tubes, Distributed by: Oakhurst Company Levittown, NY 11756	Class II	Drugs	Lot #: 1E253A, Exp. Date AUG-2024	CGMP DEVIATIONS	Ecometics, Inc.
Activator Concentrate (sodium fluoride 0.96% in Activator) 1 fl. Oz, liquid oral rinse plastic bottles, Manufactured for: All USA Direct LLC, Broadview, IL 60155	Class II	Drugs	Lot #: 2E055A, Exp. Date Feb-2025	CGMP DEVIATIONS	Ecometics, Inc.
Ungentine Original Maximum Strength Pain Relieving/Antiseptic Ointment (Camphor 3.0%, Phenol 2.5%, Tannic Acid 2.2%, Oxide 6.6%), packaged in 1 oz. (28.3g) metal tubes, Distributed by: Oakhurst Company Levittown, NY 11756	Class II	Drugs	Lot #: 1E346A, Exp. Date Nov-23; 2E304A, Exp. Date Oct-24	CGMP DEVIATIONS	Ecometics, Inc.
Metformin hydrochloride Extended-Release Tablets, 1000 mg, 60-count bottle, RX only, manufactured by: Actavis Laboratories FL,	Class II	Drugs	Lot #: 1410946A; Exp. 06/2023	CGMP Deviations: Detection of N-Nitrosodimethylamine (NDMA)	Teva Pharmaceutical USA Inc



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Inc., Fort Lauderdale, FL 33314 USA, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054 USA, NDC 00591- 2720-60				levels more than the Acceptable Daily Intake Limit.	
Phenylephrine HCl 0.5 mg per 5 mL (100 mcg/mL), 5 mL Syringe, Rx only, Leiters 13796 Compark Blvd Englewood CO 80112, NDC 71449-001-11	Class II	Drugs	Lot #: 2230960, Exp date 3/12/2023; 2231080, Exp date 4/9/2023.	CGMP DEVIATIONS	Denver Solutions, LLC DBA Leiters Health
Phenylephrine HCl 1mg per 10mL (100 mcg/mL) 10 mL syringes, Rx only, Leiters 13796 Compark Blvd Englewood CO 80112, NDC 71449-001-15	Class II	Drugs	Lot #: 2230895, Exp. Date 3/5/2023; 2230911, Exp. Date 3/11/2023; 2230913, Exp. Date 3/18/2023; 2230994, Exp. Date 3/27/2023; 2231006, Exp. Date 4/1/2023; 2231109, Exp. Date 4/19/2023; 2231126, Exp. Date 5/6/2023; 2231134, Exp. Date 5/10/2023; 2231140, Exp. Date 5/14/2023; 2231142, Exp. Date 5/20/2023; 2231156, Exp. Date 5/29/2023; 2231273, Exp. Date 6/3/2023; 2231285, Exp. Date 6/10/2023; 2231299, Exp. Date 6/17/2023; 2231331, Exp. Date 6/26/2023; 2330014, Exp. Date	CGMP DEVIATIONS	Denver Solutions, LLC DBA Leiters Health

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			7/9/2023; 2330025, Exp. Date 7/15/2023		
Phenylephrine HCl 40 mg (160 mcg/mL) added to 0.9% Sodium Chloride 250 mL IV Bag, Leiter Compounding Health 13796 Compark Blvd Englewood CO 80112, NDC 71449-150-82	Class II	Drugs	Lot #: 2231017, Exp. Date 3/12/2023	CGMP DEVIATIONS	Denver Solutions, LLC DBA Leiters Health
Phenylephrine HCl 20 mg (80 mcg/mL) added to 0.9% Sodium Chloride 250 mL IV Bag, Rx only, Leiters Compounding Health 13796 Compark Blvd Englewood CO 80112, NDC 71449-148-94	Class II	Drugs	Lot #: 2231026, Exp. Date 2/23/2023; 2231051, Exp. Date 3/11/2023; 2231156, Exp. Date 5/29/2023; 2231163, Exp. Date 3/26/2023; 223130, Exp. Date 4 5/7/2023; 2231308, Exp. Date 5/11/2023	CGMP DEVIATIONS	Denver Solutions, LLC DBA Leiters Health
Heparin Sodium, 25,000USP units per 250 mL, (100 USP units per mL) in 5% Dextrose Injection, 250 mL Excel Container, B.Braun Medical Inc, Bethlehem, PA. 18018-3524 USA. NDC 0264-9587-20.	Class II	Drugs	Lot J2C017; Expiration: 9/30/2023.	Superpotent Drug: low Anti-Factor IIa potency.	B. Braun Medical Inc
Heparin Sodium Injection, USP, 20,000 USP units per mL, 25 x 1 mL Multi-Dose Vials, Rx Only, For Intravenous or Subcutaneous Use, Mfd. for: Sagent Pharmaceuticals, Schaumburg, IL 60195; Made in India, NDC carton: 25021-404-01	Class II	Drugs	Lot#: WP201, Exp 2/2024	Labeling: Not elsewhere classified	Sagent Pharmaceutic als Inc
Brimonidine Tartrate Ophthalmic Solution 0.15%, Rx Only, packaged as: a) 5 mL dropper bottle, NDC 60505-0564-1, UPC 3	Class II	Drugs	Lots: a) TJ9848 Exp. 02/2024, TJ9849 Exp. 02/2024, TK0258 Exp.	Lack of sterility assurance: Cracks have developed in some of the units caps of Brimonidine tartrate	Apotex Corp.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
60505 05641 5; b) 10 mL dropper bottle NDC 60505-0564-2, UPC 3 60505 05642 2; c) 15 mL dropper bottle, NDC 60505-0564-3, UPC 3 60505 05643 9; Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, FL 33326			04/2024, TK5341 Exp. 04/2024; b) TK0261 Exp. 04/2024; c) TK0262 Exp. 04/2024	ophthalmic solution bottles. There is a possibility the broken cap may impact sterility.	
Clear Eyes, Once Daily, Eye Allergy Itch Relief, olopatadine hydrochloride ophthalmic solution, USP, 0.2%, Antihistamine, 2.5 mL (0.085 fl oz) bottle, Sterile, Distributed by Medtech Products Inc. Tarrytown, NY 10591, A Prestige Consumer Healthcare company, Made in Israel, UPC 678112000708; NDC 67172-504-01.	Class II	Drugs	Lot #114349, Exp. 05/2023; 117396, Exp. 09/2023; 120128, Exp. 11/2023; 114371, Exp. 06/2023; 123781, Exp. 02/2024.	Failed Impurities Specification: Out-of-specification (OOS) stability test result was obtained for unspecified impurity.	Teva Pharmaceutic als USA Inc
JARDIANCE (Empagliflozin), 25 mg Tablets, packaged in a) 30-count (NDC0597-0153-30) and b) 90-count (NDC 0597-0153-90) bottles, Rx only, Marketed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 USA and Eli Lilly and Company Indianapolis, IN 46285 USA	Class II	Drugs	Lot #: a) and b) E61835, exp. date JUN 2025	Labeling: Label Mix-up	Boehringer Ingelheim Pharmaceutic als, Inc.
Daytrana (methylphenidate transdermal system) CII, 10mg, 30-count carton, Rx only, Manufactured for Noven Therapeutics, LLC., Miami by Noven Pharmaceuticals, Inc., NDC 68968-5552-3.	Class II	Drugs	Lot#: 91955, Exp. 7/2023; 93039, Exp. 10/2023	Defective Delivery System: Out of specification for shear.	Noven Pharmaceutic als Inc
Daytrana (methylphenidate transdermal system) CII, 15 mg, 30-count carton, Rx only, Manufactured for Noven Therapeutics, LLC.,	Class II	Drugs	Lot#: 91956, Exp. 6/2023; 92475, Exp. 7/2023	Defective Delivery System: Out of specification for shear.	Noven Pharmaceutic als Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Miami by Noven Pharmaceuticals, Inc., NDC 68968-5553-3					
Daytrana (methylphenidate transdermal system) CII, 20mg, 30-count carton, Rx only, Manufactured for Noven Therapeutics, LLC., Miami by Noven Pharmaceuticals, Inc., NDC 68968-5554-3.	Class II	Drugs	Lot#: 91957, 92197, Exp. 7/2023; 92476, Exp. 9/2023; 92477, Exp. 10/2023	Defective Delivery System: Out of specification for shear.	Noven Pharmaceuticals Inc
Daytrana (methylphenidate transdermal system) CII, 30 mg, 30-count carton, Rx only, Manufactured for Noven Therapeutics, LLC., Miami by Noven Pharmaceuticals, Inc., NDC 68968-5555-3	Class II	Drugs	Lot#: 91474, 91959, Exp. 3/2023; 91958, Exp. 6/2023; 92478, Exp. 7/2023; 92479 & 92198, Exp. 8/2023; 92199, 93040, Exp. 9/2023; 93041, Exp. 10/2023.	Defective Delivery System: Out of specification for shear.	Noven Pharmaceuticals Inc
Dermoplast FIRST AID ANTIBACTERIAL SPRAY (Benzethonium chloride 0.2% First aid antiseptic, Benzocaine 20%) Topical analgesic, NET WT. 2.75 oz (78 g), Distributed by Advantice Health, LLC Cedar Knolls, NJ 07927, NDC# 16864-670-01	Class III	Drugs	Lot # 22336A	Subpotent Drug: Low assay observed in one of the two active ingredients during stability testing.	Advantice Health, LLC
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	Class III	Drugs	Batch #: 2173763874, 2173771315, P120834254, P120834263, P120834267, P120834275, P120834441, P120834442, P120834472, P120834507, P120834517, P120834518, P120834519, P120834520, These excipients are noted not	Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.	DuPont Nutrition USA, Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			to have an expiration date.		
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	Class III	Drugs	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.	Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.	DuPont Nutrition USA, Inc
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	Class III	Drugs	Batch #: PN20834322, PN20834335 These excipients are noted not to have an expiration date.	Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.	DuPont Nutrition USA, Inc
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	Class III	Drugs	Batch #: 2173784100, B220834549 These excipients are noted not to have an expiration date.	Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.	DuPont Nutrition USA, Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Gabapentin Tablets, USP 600 mg, 500 tablets per bottle, RX Only, Manufactured by ScieGen Pharmaceuticals Inc., Hauppauge, NY 11788, NDC: 50228-177-05.	Class III	Drugs	Lot #: G177092, Exp. 11/24	Presence of Foreign Tablets/Capsules: Pharmacist reported presence of some Gabapentin tablets 800 mg comingled in Gabapentin 600 mg 500 count bottles.	Sciegen Pharmaceuticals Inc
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.	Class III	Drugs	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	Subpotent Drug	SCA Pharmaceuticals
DIBUCAINE 1% HEMORRHOIDAL OINTMENT, 1 oz. (28 gm), Manufactured for: Akron Pharma Inc. Fairfield NJ 07004, NDC 71399-2829-1	Class III	Drugs	Lot #: 2206016, Exp. date 05/2024	Labeling: Incorrect or Missing Lot and/or Exp Date	Akron Pharma, Inc.
Buprenorphine Transdermal System, CIII 10 mcg/hour, 4 Transdermal Systems One package of 4 disposal units, Rx Only, manufactured by: Aveva Drug Delivery Systems Inc. Miramar, FL. 33025, Manufactured for: Apotex Corp Weston, FL. 33326, NDC 60505-7077-05	Class III	Drugs	Lot#: 51835 Exp: 06/2023	Failed Impurities/Degradation Specifications: Out of specification for related substance 10-hydroxy buprenorphine N-Oxide results generated at the 18-month stability timepoint.	AVEVA Drug Delivery Systems, Inc.
Buprenorphine Transdermal System, CIII 20 mcg/hour, 4 Transdermal Systems One package of 4 disposal units, Rx Only, manufactured by: Aveva Drug Delivery Systems Inc. Miramar, FL. 33025,	Class III	Drugs	Lot#: 51836 Exp: 07/2023	Failed Impurities/Degradation Specifications: Out of specification for related substance 10-hydroxy buprenorphine N-Oxide results	AVEVA Drug Delivery Systems, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured for: Apotex Corp Weston, FL 33326, NDC 60505-7079-05				generated at the 18-month stability timepoint.	
Colchicine Tablets, USP 0.6 mg, Rx Only, a) 30 tablets per bottle, NDC 16714-0039-01, b) 100 tablets per bottle, NDC 16714-0039-02, Manufactured for: NorthStar Rx LLC., Memphis, TN 38141, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, c) 100 tablets per bottle, NDC 70710-1351-01, Manufactured by: Cadila Healthcare Ltd., Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534.	Class III	Drugs	Lot #s: a) E203821, Exp. 05/2024; b) E203822, Exp. 05/2024, E206186, Exp. 10/2024; c) E203820, Exp. 05/2024.	Failed Impurities/Degradation Specifications: An out-of-specification (OOS) result was observed during release testing of one lot for a related substance, i.e., Beta-lumicolchicine.	Zydus Pharmaceuticals (USA) Inc
Evamist (estradiol transdermal spray), 1.53 mg of estradiol per spray, 0.27 fl oz (8.1 mL) per metered-dose pump, Rx Only, Manufactured by DPT Laboratories, Ltd San Antonio, TX 78215, Manufactured for: Perrigo, Allegan, Minneapolis, MN 55427, NDC: 0574-2067-27	Class III	Drugs	Lot# SCDR, Exp 02/2024	Failed Content Uniformity Specifications: The Spray Content Uniformity (SCU) requirement for Standard Deviation did not meet the requirement at the 18-month stability time point.	Padagis US LLC
Dofetilide Capsules, 500 mcg (0.5 mg), 60-count bottle, Rx only, Manufactured by: Sun Pharmaceutical Industries Limited, Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), India, NDC 47335-0063-86	Class III	Drugs	Lot # DND1541A, Exp 08/2024	Failed Content Uniformity Specifications	SUN PHARMACEUTICAL INDUSTRIES INC

\*Please refer to FDA website for further information at: <http://www.fda.gov/Safety/Recalls>

## CURRENT DRUG SHORTAGES

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Below is the list of drugs listed by the FDA as currently in shortage. Please refer to the FDA website for more information at: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

### Generic Name or Active Ingredient

Albuterol Sulfate Inhalational Solution  
Alprostadil (Muse) Suppository  
Amifostine Injection  
Amino Acids  
Amoxapine Tablets  
Amoxicillin Oral Powder for Suspension  
Amphetamine; Dextroamphetamine Tablets  
Atropine Sulfate Injection  
Azacitidine for Injection  
Azithromycin (Azasite) Ophthalmic Solution 1%  
Bacteriostatic 0.9% Sodium Chloride Injection  
Bacteriostatic Water for Injection  
Belatacept (Nulojix) Lyophilized Powder for Injection  
Belladonna and Opium Suppositories  
Bumetanide Injection  
Bupivacaine Hydrochloride and Epinephrine Injection  
Bupivacaine Hydrochloride Injection  
Calcium Gluconate Injection  
Capecitabine Tablets  
Cefixime Oral Capsules  
Cefotaxime Sodium Injection  
Cefotetan Disodium Injection  
Chloroprocaine Hydrochloride Injection  
Chlorothiazide Oral Suspension  
Cisplatin Injection  
Clindamycin Phosphate Injection  
Clonazepam Tablets  
Collagenase Ointment  
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container  
Conjugated Estrogens/Bazedoxifene (DUAVEE) Tablet, Film Coated  
Cyclopentolate Ophthalmic Solution  
Cytarabine Injection  
Dacarbazine Injection  
Desmopressin Acetate Nasal Spray  
Dexamethasone Sodium Phosphate Injection  
Dexmedetomidine Injection  
Dextrose 10% Injection  
Dextrose 25% Injection  
Dextrose 5% Injection



Dextrose 50% Injection  
Diazepam Rectal Gel  
Diflunisal Tablets  
Difluprednate Ophthalmic Emulsion  
Digoxin Injection  
Diltiazem Hydrochloride Injection  
Dimercaprol (Bal in Oil) Injection  
Disopyramide Phosphate (Norpace) Capsules  
Dobutamine Hydrochloride Injection  
Dopamine Hydrochloride Injection  
Dulaglutide (Trulicity) Injection  
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution  
Edetate Calcium Disodium Injection  
Enalaprilat Injection  
Epinephrine Injection, 0.1 mg/mL  
Erythromycin Ophthalmic Ointment  
Etomidate Injection  
Fentanyl Citrate (Sublimaze) Injection  
Fludarabine Phosphate Injection  
Flurazepam Hydrochloride Capsules  
Furosemide Injection  
Gentamicin Sulfate Injection  
Guanfacine Hydrochloride Tablets  
Heparin Sodium and Sodium Chloride 0.9% Injection  
Hydrocortisone Sodium Succinate Injection  
Hydromorphone Hydrochloride Injection  
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert  
Ibutilide Fumarate Injection  
Indigotindisulfonate Sodium Injection  
Isoniazid Injection  
IV Fat Emulsion  
Ketamine Injection  
Ketorolac Tromethamine Injection  
Leucovorin Calcium Lyophilized Powder for Injection  
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags  
Lidocaine Hydrochloride (Xylocaine) Injection  
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine  
Lorazepam Injection  
Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection  
Mannitol Injection  
Mepivacaine Hydrochloride Injection  
Methamphetamine Hydrochloride Tablets  
Methotrexate Injection  
Methyldopa Tablets  
Methylprednisolone Acetate Injection  
Metronidazole Injection

Midazolam Injection  
Morphine Sulfate Injection  
Multi-Vitamin Infusion (Adult and Pediatric)  
Neomycin Sulfate Tablets  
Nizatidine Capsules  
Oxybutynin Chloride Syrup  
Oxytocin Injection  
Palifermin (Kepivance) Lyophilized Powder for Injection  
Pantoprazole Sodium for Injection  
Parathyroid Hormone (Natpara) Injection  
Pentostatin Injection  
Physostigmine Salicylate Injection  
Potassium Acetate Injection  
Potassium Chloride Concentrate Injection  
Quinapril and Hydrochlorothiazide Tablets  
Quinapril Hydrochloride Tablets  
Remifentanil Injection  
Rifampin Capsules  
Rifampin Injection  
Rifapentine Tablets  
Rocuronium Bromide Injection  
Ropivacaine Hydrochloride Injection  
Semaglutide (Ozempic) Injection  
Semaglutide (Wegovy) Injection  
Sincalide (Kinevac) Lyophilized Powder for Injection  
Sodium Acetate Injection  
Sodium Bicarbonate Injection  
Sodium Chloride 0.9% Injection Bags  
Sodium Chloride 14.6% Injection  
Sodium Chloride 23.4% Injection  
Sodium Chloride Injection USP, 0.9% Vials and Syringes  
Sodium Phosphates Injection  
Somatropin Injection  
Sterile Water for Injection  
Streptozocin (Zanosar) Sterile Powder  
Sucralfate Tablets  
Sufentanil Citrate Injection  
Sulfasalazine Tablets  
Technetium TC-99M Mebrofenin Injection  
Teprotumumab-trbw  
Tirzepatide Injection  
Triamcinolone Acetonide Injectable Suspension  
Triamcinolone Hexacetonide Injectable suspension  
Trimethobenzamide Hydrochloride Capsules  
Valproate Sodium Injection  
Vecuronium Bromide for Injection