

Capital Rx Drug Recall Report

NOVEMBER 2025



Welcome to the **Capital Rx Drug Recall Report**. This report is designed to keep you up to date on the latest FDA Class 1 and Class 2 recalled drugs and market withdrawals that impact our members. It is one of the many ways we, at Capital Rx, demonstrate our commitment to providing clients and partners the tools and resources they desire.

WHO WE ARE

Capital Rx is a full-service pharmacy benefit manager (PBM) and pharmacy benefit administrator (PBA), advancing our nation's electronic healthcare infrastructure to improve drug price visibility and patient outcomes. As a Certified B Corp™, Capital Rx is executing its mission through the deployment of JUDI®, the company's cloud-native enterprise health platform, and a Single-Ledger Model™, which increases visibility and reduces variability in drug prices. JUDI connects every aspect of the pharmacy ecosystem in one efficient, scalable platform, servicing over 2.4 million members for Medicare, Medicaid, and commercial plans. Together with our clients, we are reimagining the administration of pharmacy benefits and rebuilding trust in healthcare. **The drug recall report is subject to change: information in this report is current as of **11/19/2025****

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RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
10/15/2025	Class 2	Chlorpromazine Hcl 100 Mg Tabs	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories	00904-7132-61	N01920, EXP 12/31/2025; N02023, EXP 02/28/2026; N02202, EXP 06/30/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Desmethyl Chlorpromazine were found to be higher than the FDA recommended limit
10/15/2025	Class 2	Chlorpromazine Hcl 50 Mg Tabs	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories	00904-7131-61	N02009 & N02026, EXP 02/28/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Desmethyl Chlorpromazine were found to be higher than the FDA recommended limit

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
10/15/2025	Class 2	Doxycycline Hyclate 100 Mg Tabs	Acella Pharmaceuticals, LLC	42192-0501-05	P24ZLK1, EXP 5/31/2027	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
10/15/2025	Class 2	Levothyroxine Sodium 88 Mcg Tabs	ACCORD HEALTHCARE, INC.	16729-0450-15	D2300045, EXP 12/31/2025	The product being subpotent (not strong enough)
10/15/2025	Class 2	Norgestim-Eth Estrad Triphasic 0.18/0.215/0.25 Mg-25 Mcg Tabs	AvKARE	42291-0565-84, 42291-0565-28	LF41138A EXP 06/30/2027	Failed content uniformity specifications
2025-10-22	Class 2	Atorvastatin Calcium 10 Mg Tabs	Ascend Laboratories, LLC	67877-0511-90, 67877-0511-05, 67877-0511-10	25141249, EXP 2/2027; 24144938, EXP 11/2026; 24144868, EXP 11/2026; 24144867, EXP 11/2026; 24144458, EXP 9/2026; 24143994, EXP 9/2026; 24142987, EXP 7/2026; 24143316, EXP 7/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
2025-10-22	Class 2	Atorvastatin Calcium 20 Mg Tabs	Ascend Laboratories, LLC	67877-0512-90, 67877-0512-05, 67877-0512-10	25140150, EXP 12/2026; 25140173, EXP 12/2026; 25140172, EXP 12/2026; 24144720, EXP 11/2026; 24144798, EXP 11/2026; 24144692, EXP 10/2026; 24143755, EXP 8/2026; 24143913, EXP 8/2026; 24143754, EXP 8/2026; 24143047, EXP 6/2026; 24142936, EXP 7/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly

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2025-10-22	Class 2	Atorvastatin Calcium 40 Mg Tabs	Ascend Laboratories, LLC	67877-0513-90, 67877-0513-05, 67877-0513-10	25140933, EXP 2/2027; 25140477, EXP 12/2026; 24144254, EXP 10/2026; 24144163, EXP 9/2026; 24143995, EXP 9/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
2025-10-22	Class 2	Atorvastatin Calcium 80 Mg Tabs	Ascend Laboratories, LLC	67877-0514-90, 67877-0514-05	25140249, EXP 12/2026; 25140247, EXP 12/2026; 24144999, EXP 11/2026; 24144942, EXP 11/2026; 24144845, EXP 11/2026; 24144713, EXP 11/2026; 24144652, EXP 10/2026; 24143898, EXP 8/2026; 24143412, EXP 8/2026; 24143582, EXP 8/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
2025-10-22	Class 1	Carbidopa-Levodopa-Entacapone 25-100-200 Mg Tabs	Rising Pharma Holding, Inc.	16571-0691-01	CS25070, EXP 03/31/2027	A product mix up. There was a complaint received that a sealed medication bottle contained Carbidopa, Levodopa, and Entacapone film-coated tablets (37.5 mg/150 mg/200 mg) instead of labelled lower strength Carbidopa, Levodopa, and Entacapone film-coated tablets (25 mg/100 mg/200 mg).
2025-10-22	Class 2	Fasenra 30 Mg/ML Soly	ASTRAZENECA PHARMACEUTICALS	00310-1730-30	YJ0152, EXP 01/31/2028	A lack of assurance of sterility
2025-10-22	Class 2	Tavaborole 5 % Soln	VIONA PHARMACEUTICALS INC	72578-0102-04	T400819, T400820, EXP 4/30/26; T401969, EXP 9/30/26	Discoloration

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2025-10-22	Class 2	Viorele 0.15-0.02/0.01 Mg (21/5) Tabs	Glenmark Pharmaceuticals Inc., USA	68462-0318-29	BATCH 20230733, EXP 10/2025	Failing to meet impurity and degradation standards
2025-10-29	Class 2	Bupropion Hcl Er (Xl) 300 Mg Tb24	Graviti Pharmaceuticals Private Limited	16571-0863-03	BATCH BPB124341A, EXP 10/2026	Failing to meet specifications
2025-10-29	Class 2	Gabapentin 100 Mg Caps	The Harvard Drug Group LLC	A) 00904-6665-61, 55154-3363-00 B) 00904-6665-61	A) M04989A [BAG], M04989 [BLISTER PACK], EXP 02/2026; M05056A [BAG], M05056 [BLISTER PACK], EXP 04/2026; M05150A [BAG], M05150 [BLISTER PACK], EXP 07/2026; M05312A [BAG], M05312 [BLISTER PACK], AND M05342A [BAG], M05342 [BLISTER PACK], EXP 01/2027 B) M04950, EXP 01/2026; M04989, M04990, EXP 02/2026; M05056, EXP 04/2026; M05150, EXP DATE: 07/2026; M05290, EXP 11/2026; M05312, M05342, EXP 01/2027; M05369, M05386, EXP 02/2027	Failing to meet impurity and degradation standards
2025-10-29	Class 2	Niacin Er (Antihyperlipide mic) 1000 Mg Tbcr	Lannett Company Inc.	62175-0322-46	21264027A, EXP 10/30/2025; 22266446A, EXP 12/31/2025; 22266901A, EXP 02/28/2026; 22267553A, 22267554A, EXP 03/31/2026; 22267555A, EXP 02/28/2026; 22267992A, EXP 04/30/2026; 22267993A, 22267994A, EXP 05/31/2026	Failing to meet impurity and degradation standards
2025-10-29	Class 2	Olopatadine Hcl 0.1 % Soln	USV Private Limited	70512-0520-05	35000409, EXP 01/2026	Failing to meet impurity and degradation standards

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2025-11-05	Class 2	Desipramine Hcl 10 Mg Tabs	Heritage Pharmaceuticals Inc	23155-0578-01	18036908, EXP 09/30/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-Nitroso Desipramine being higher than the acceptable limit
2025-11-05	Class 2	Desipramine Hcl 100 Mg Tabs	Heritage Pharmaceuticals Inc	23155-0582-01	18035574, EXP 10/31/2025 18036758, EXP 08/31/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-Nitroso Desipramine being higher than the acceptable limit
2025-11-05	Class 2	Desipramine Hcl 25 Mg Tabs	Heritage Pharmaceuticals Inc	23155-0579-01	18035876, EXP 12/31/2025 18036909, EXP 09/30/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-Nitroso Desipramine being higher than the acceptable limit
2025-11-05	Class 2	Desipramine Hcl 50 Mg Tabs	Heritage Pharmaceuticals Inc	23155-0580-01	18036713, EXP 08/31/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-Nitroso Desipramine being higher than the acceptable limit
2025-11-05	Class 2	Desipramine Hcl 75 Mg Tabs	Heritage Pharmaceuticals Inc	23155-0581-01	18036662, EXP 07/31/2026 18037649, EXP 03/31/2027	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-Nitroso Desipramine being higher than the acceptable limit
2025-11-05	Class 2	Duloxetine Hcl 60 Mg Cpep	Breckenridge Pharmaceutical, Inc.	51991-0748-90, 51991-0748-10	90-COUNT- 240721C; EXP. 02/28/2027 1000-COUNT- #230286C; EXP.02/28/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-nitroso-duloxetine being higher than the acceptable limit
2025-11-05	Class 2	Hadlima 40 Mg/0.8ml Sosy	Samsung Bioepis Co., Ltd.	78206-0183-01	F2505017, EXP 24-JAN-2027	A lack of assurance of sterility
2025-11-05	Class 2	Lisdexamfetamin e Dimesylate 10 Mg Caps	SUN PHARMACEUTICAL INDUSTRIES INC	57664-0046-88	AD42468, EXP 2/28/2026; AD48705, EXP 4/30/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly

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2025-11-05	Class 2	Lisdexamfetamine Dimesylate 20 Mg Caps	SUN PHARMACEUTICAL INDUSTRIES INC	57664-0047-88	AD42469, EXP 2/28/2026; AD48707, EXP 4/30/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
2025-11-05	Class 2	Lisdexamfetamine Dimesylate 30 Mg Caps	SUN PHARMACEUTICAL INDUSTRIES INC	57664-0048-88	AD42470, EXP 2/28/2026; AD48708, EXP 4/30/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
2025-11-05	Class 2	Lisdexamfetamine Dimesylate 40 Mg Caps	SUN PHARMACEUTICAL INDUSTRIES INC	57664-0049-88	AD48709, EXP 4/30/2026; AD50894, EXP 5/31/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
2025-11-05	Class 2	Lisdexamfetamine Dimesylate 50 Mg Caps	SUN PHARMACEUTICAL INDUSTRIES INC	57664-0050-88	AD48710, EXP 4/30/2026; AD50895, EXP 5/31/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
2025-11-05	Class 2	Lisdexamfetamine Dimesylate 60 Mg Caps	SUN PHARMACEUTICAL INDUSTRIES INC	57664-0051-88	AD48711, EXP 4/30/2026; AD50896, EXP 5/31/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
2025-11-05	Class 2	Lisdexamfetamine Dimesylate 70 Mg Caps	SUN PHARMACEUTICAL INDUSTRIES INC	57664-0052-88	AD48712, EXP 4/30/2026; AD50898, EXP 5/31/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
2025-11-05	Class 2	Prazosin Hcl 1 Mg Caps	Teva Pharmaceuticals USA, Inc	00093-4067-01, 00093-4067-10	A) NDC 0093-4067-01: 3010544A AND 3010545A, EXP 10/2025; 3010567A, EXP 12/2025; 3010590A, EXP 02/2026; 3010601A, 3010602A, 3010603A, EXP 03/2026; 3010652A, 3010670A, 3010671A, EXP 07/2026; 3010678A, 3010700A, 3010701A, EXP 08/2026 B) NDC 0093-4067-10: 3010440A, EXP 12/2025; 3010672A, EXP 07/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-nitroso Prazosin being higher than the Carcinogenic Potency Categorization Approach (CPCA) acceptable limit

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2025-11-05	Class 2	Prazosin Hcl 2 Mg Caps	Teva Pharmaceuticals USA, Inc	00093-4068-01, 00093-4068-10	A) NDC 0093-4068-01: 3010398A, 3010399A, 3010400A, 3010401A, 3010353A, EXP 12/2025; 3010439A, 3010388A, EXP 01/2026; 3010526A, 3010527A, EXP 03/2026; 3010591A, 07/2026; 3010343A, EXP 10/2025; 3010352A, EXP 11/2025; 3010468A, 3010469A, 3010461A, EXP 02/2026; 3010629A, EXP 09/2026; 3010653A, EXP 01/2027; 3010654A, 3010679A, 3010702A, EXP 02/2027; 3010547A, EXP 04/2026 B) NDC 0093-4068-10: 3010402A EXP 02/2028; 3010593A, EXP 07/2026, 3010610A, EXP 09/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-nitroso Prazosin being higher than the Carcinogenic Potency Categorization Approach (CPCA) acceptable limit
2025-11-05	Class 2	Prazosin Hcl 5 Mg Caps	Teva Pharmaceuticals USA, Inc	00093-4069-01, 00093-4069-52, 00093-4069-05	A) NDC 0093-4069-01: 3010403A, 3010385A, 3010404A, EXP 02/2026; 3010405A, 3010510A, 3010528A, 3010354A, EXP 03/2026; 3010592A, 3010605A, 3010611A, 3010612A, EXP 08/2026; 3010655A, 3010703A, EXP 02/2027 B) NDC 0093-4069-52: 3010430A, EXP 11/2025, 3010613A, EXP 08/2026 C) NDC 0093-4069-05: 3010406A, EXP 02/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-nitroso Prazosin being higher than the Carcinogenic Potency Categorization Approach (CPCA) acceptable limit

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2025-11-12	Class 2	Clomipramine Hcl 25 Mg Caps	Zydus Pharmaceuticals (USA) Inc	16714-0849-01, 16714-0849-02, 16714-0849-03	A) E408871, EXP 10/2026; E405282, EXP 06/2026; E400386, EXP 12/2025 B) E408872, EXP 10/2026; E405280, EXP 06/2026 C) E408873, EXP 10/2026; E405281, EXP 06/2026; E400387, EXP 12/2025	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-Nitroso Desmethyl-Clomipramine being higher than the acceptable limit
2025-11-12	Class 2	Clomipramine Hcl 50 Mg Caps	Zydus Pharmaceuticals (USA) Inc	16714-0850-01, 16714-0850-02, 16714-0850-03	A) E410157, EXP 12/2026; E407176, EXP 08/2026; E405845, EXP 06/2026; E400943, EXP 01/2026 B) E410156, EXP 12/2026; E400942, EXP 01/2026 C) E410158, EXP 12/2026; E407128, EXP 08/2026; E405846, EXP 06/2026; E400944, EXP 01/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-Nitroso Desmethyl-Clomipramine being higher than the acceptable limit
2025-11-12	Class 2	Clomipramine Hcl 75 Mg Caps	Zydus Pharmaceuticals (USA) Inc	16714-0851-01, 16714-0851-02, 16714-0851-03	A) E403069, EXP 04/2026; E406504, EXP 07/2026; E309177, EXP 11/2025; E400262, EXP 12/2025; E404200, EXP 05/2026 B) E403070, EXP 04/2026; E406505, EXP 07/2026; E407631, EXP 08/2026; E400263, EXP 12/2025; E404202, EXP 05/2026 C) E403071, EXP 04/2026; E407632, EXP 08/2026; E405848, E405284, EXP 07/2026; E400264, EXP 12/2025; E404201, EXP 05/2026	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-Nitroso Desmethyl-Clomipramine being higher than the acceptable limit

How do I find out more information about the recall? View the FDA website URL for more information.

RECALL TYPE	DRUG RECALLED	FDA NOTIFICATION URL
Class 2	Chlorpromazine Hcl 100 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215994
Class 2	Chlorpromazine Hcl 50 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215993
Class 2	Doxycycline Hyclate 100 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216391
Class 2	Levothyroxine Sodium 88 Mcg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216116
Class 2	Norgestim-Eth Estrad Triphasic 0.18/0.215/0.25 Mg-25 Mcg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215899
Class 2	Atorvastatin Calcium 10 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216202
Class 2	Atorvastatin Calcium 20 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216518
Class 2	Atorvastatin Calcium 40 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216517
Class 2	Atorvastatin Calcium 80 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216520
Class 1	Carbidopa-Levodopa-Entacapone 25-100-200 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216544
Class 2	Fasenra 30 Mg/ML Sosy	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216525
Class 2	Tavaborole 5 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216513

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Class 2	Viorele 0.15-0.02/0.01 Mg (21/5) Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215905
Class 2	Bupropion Hcl Er (Xl) 300 Mg Tb24	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216148
Class 2	Gabapentin 100 Mg Caps	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216556 ; B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216555
Class 2	Niacin Er (Antihyperlipidemic) 1000 Mg TbcR	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216557
Class 2	Olopatadine Hcl 0.1 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216543
Class 2	Desipramine Hcl 10 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216553
Class 2	Desipramine Hcl 100 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216865
Class 2	Desipramine Hcl 25 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216862
Class 2	Desipramine Hcl 50 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216863
Class 2	Desipramine Hcl 75 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216864
Class 2	Duloxetine Hcl 60 Mg Cpep	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216594
Class 2	Hadlima 40 Mg/0.8ml Sosy	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216379

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Class 2	Lisdexamfetamine Dimesylate 10 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216857
Class 2	Lisdexamfetamine Dimesylate 20 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216983
Class 2	Lisdexamfetamine Dimesylate 30 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216984
Class 2	Lisdexamfetamine Dimesylate 40 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216985
Class 2	Lisdexamfetamine Dimesylate 50 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216986
Class 2	Lisdexamfetamine Dimesylate 60 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216987
Class 2	Lisdexamfetamine Dimesylate 70 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216988
Class 2	Prazosin Hcl 1 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216510
Class 2	Prazosin Hcl 2 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216512
Class 2	Prazosin Hcl 5 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216514
Class 2	Clomipramine Hcl 25 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216770
Class 2	Clomipramine Hcl 50 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216772
Class 2	Clomipramine Hcl 75 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216774