

Capital Rx Drug Recall Report

OCTOBER 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 10/08/2025****

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RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
09/17/2025	Class 2	Amphetamine-Dextroamphetamine 10 Mg Tabs	Lannett Company Inc.	00527-0762-37	25283185A. EXP 02/28/2027	The presence of a foreign Tablet/Capsule. Two bottles labeled as Amphetamine-Dextroamphetamine 10mg Tablets, 100ct, contained one tablet of Amphetamine-Dextroamphetamine 5mg Tablets.
09/17/2025	Class 2	Chlorpromazine Hcl 10 Mg Tabs	Zydus Pharmaceuticals (USA) Inc	A) 16714-0047-01 B) 70710-1129-01	A) Z403011, EXP 30-04-26; Z407335, EXP 30-11-26; B) Z403012, EXP 30-04-26; Z406657, EXP 30-11-26	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Desmethy Chlorpromazine were found to be higher than the FDA recommended limit

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09/17/2025	Class 2	Chlorpromazine Hcl 100 Mg Tabs	Zydus Pharmaceuticals (USA) Inc	A) 16714-0050-01 B) 70710-1132-01	A) Z305456, EXP 31-10-25; Z401156, EXP 28-02-26; Z407306, EXP 30-11-26; B) Z305079, Z305080, EXP 30-09-25; Z305454, Z305455, Z305457, Z400492, Z400493, Z400494, EXP 31-12-25; Z401158, Z401725, Z401726, EXP 28-02-26; Z404118, Z404119, Z404120, EXP 30-06-26; Z405648, EXP 30-09-26	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Desmethyl Chlorpromazine were found to be higher than the FDA recommended limit
09/17/2025	Class 2	Chlorpromazine Hcl 200 Mg Tabs	Zydus Pharmaceuticals (USA) Inc	16714-0051-01	Z305085, EXP 30-09-25; Z401166, Z401167, EXP 28-02-26	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Desmethyl Chlorpromazine were found to be higher than the FDA recommended limit
09/17/2025	Class 2	Chlorpromazine Hcl 25 Mg Tabs	Zydus Pharmaceuticals (USA) Inc	A) 70710-1130-01 B) 16714-0048-01	A) Z305060, Z305061, EXP 31-08-25; Z306323, EXP 30-11-25; Z401153, EXP 28-02-26; Z403015, Z403016, EXP 30-04-26; Z405591, EXP 30-09-26; B) Z305062, EXP 31-08-25; Z306324, EXP 30-11-25; Z401151, Z401152, EXP 28-02-26	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Desmethyl Chlorpromazine were found to be higher than the FDA recommended limit
09/17/2025	Class 2	Chlorpromazine Hcl 50 Mg Tabs	Zydus Pharmaceuticals (USA) Inc	A) 70710-1131-01 B) 16714-0049-01	A) Z306327, EXP 30-11-25; Z306748, EXP 30-11-25; Z401154, EXP 28-02-26; Z403738, EXP 31-05-26; Z405645, EXP 30-09-26; B) Z306326, EXP 30-11-25; Z401155, EXP 28-02-26	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Desmethyl Chlorpromazine were found to be higher than the FDA recommended limit
09/17/2025	Class 2	Ciprofloxacin-Dexamethasone 0.3-0.1 % Susp	Sandoz Inc	00781-6186-67	VNF35A, EXP 08/31/2026	Being exposed to temperatures outside of manufacturer's recommended storage temperature.

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09/17/2025	Class 2	Duloxetine Hcl 30 Mg Cpep	Breckenridge Pharmaceutical, Inc.	82009-0030-10	240927C, EXP 04/30/2027	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-nitroso-duloxetine being higher than the acceptable limit
09/17/2025	Class 2	Sulfamethoxazole -Trimethoprim 800-160 Mg Tabs	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories	A) 55154-7895-00, 00904-2725-61 B) 00904-2725-61	A) BAG: N02309A AND N02309B, EXP 03/31/2027; INNER BLISTER: N02309, EXP 03/31/2027; B) N02309, EXP 03/31/2027	The presence of a foreign substance. A specific lot of auxiliary polyester coil, used in product packaging was found to contain a micro-organism. Although no contamination was found on any tablets, the recall was issued as a precaution
09/24/2025	Class 1	Cyclobenzaprine Hcl 10 Mg Tabs	Unichem Pharmaceuticals USA Inc.	29300-0415-19	GMML24026A, EXP 09/30/2027	A label mix Up. Bottles of Meloxicam USP, 7.5mg, 90-count tablets (yellow in color), were labeled as Cyclobenzaprine Hydrochloride Tablets USP, 10 mg 90-count tablets (blue in color).
09/24/2025	Class 2	Aripiprazole 10 Mg Tabs	Ascend Laboratories, LLC	67877-0432-03	24144162, EXP 09/2027	The product being super potent (too strong)
09/24/2025	Class 2	Entecavir 0.5 Mg Tabs	Zydus Pharmaceuticals (USA) Inc	68382-0920-06	E309376 EXP 11/30/2025	Failing to meet impurity and degradation standards

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10/01/2025	Class 2	Azelaic Acid 15 % Gel	Glenmark Pharmaceuticals Inc., USA	68462-0626-52	BATCH # 19252524, EXP MAY 2027	Deviations from the Current Good Manufacturing Practices (CGMP). There were market complaints received for the texture being gritty/grainy
10/08/2025	Class 2	Brimonidine Tartrate-Timolol 0.2-0.5 % Soln	Apotex Corp.	60505-0589-01, 60505-0589-02	A) VE0614 EXP 12/2025 (5 ML) B) VE0616 EXP 12/2025 (10 ML)	A lack of assurance of sterility
10/08/2025	Class 2	Entecavir 0.5 Mg Tabs	Zydus Pharmaceuticals (USA) Inc	68382-0920-06	E409308, EXP 12/31/2026	Failing to meet impurity and degradation standards
10/08/2025	Class 2	Ketorolac Tromethamine 0.5 % Soln	Apotex Corp.	60505-1003-01	VA0444, VA4608 EXP 01/2026; TZ7016, EXP 12/2025	A lack of assurance of sterility

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	Amphetamine-Dextroamphetamine 10 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215642
Class 2	Chlorpromazine Hcl 10 Mg Tabs	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215948 ; B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215874
Class 2	Chlorpromazine Hcl 100 Mg Tabs	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215954 ; B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215953
Class 2	Chlorpromazine Hcl 200 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215956
Class 2	Chlorpromazine Hcl 25 Mg Tabs	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215949 ; B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215950
Class 2	Chlorpromazine Hcl 50 Mg Tabs	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215951 ; B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215952
Class 2	Ciprofloxacin-Dexamethasone 0.3-0.1 % Susp	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215584
Class 2	Duloxetine Hcl 30 Mg Cpep	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215564
Class 2	Sulfamethoxazole-Trimethoprim 800-160 Mg Tabs	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215845 ; B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215843
Class 1	Cyclobenzaprine Hcl 10 Mg Tabs	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/unichem-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-cyclobenzaprine-hydrochloride
Class 2	Aripiprazole 10 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215826
Class 2	Entecavir 0.5 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215921

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Class 2	Azelaic Acid 15 % Gel	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216121
Class 2	Brimonidine Tartrate-Timolol 0.2-0.5 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215926
Class 2	Entecavir 0.5 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216334
Class 2	Ketorolac Tromethamine 0.5 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215927