

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Sun Pharmaceutical Industries, Inc would like to inform you of a product recall involving Lisdexamfetamine Dimesylate Capsules, CII, 100 count bottle 10mg, 20mg, 30mg, 40 mg, 50 mg, 60mg, 70 mg.

This recall has been initiated in response to Out of Specification (OOS) results observed in dissolution test for Lisdexamfetamine Dimesylate Capsules, 60 mg, Batch AD50896, during analysis at the 12 month long term stability station (25°C, 60%RH). Based on the Health Hazard Evaluation, *"Dissolution is important for drugs to be absorbed and have a physiological effect on the human body, they must be in solution. The impacted capsules would not be able to deliver optimal level of medicine and may impact therapeutic efficacy of the product. However, as physician will titrate the dose and considering the nature of the indications (ADHD and BED) i.e., neuropsychiatric disorders for which Lisdexamfetamine Dimesylate 60 mg capsules is prescribed, impact on patient safety can be ruled out".*

The other thirteen (13) listed batches, manufactured with the same formulation as the OOS batch, are impacted and, therefore, subject to recall.

All lots complied with all of the established product specifications at the time the products were released for distribution.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product between May 1, 2024 and November 13, 2024.

Product Name	Package Description	NDC#	Lot#	Expiration Date
Lisdexamfetamine Dimesylate Capsules, 10 mg	100 count bottle	57664-046-88	AD42468	2/28/2026
Lisdexamfetamine Dimesylate Capsules, 10 mg	100 count bottle	57664-046-88	AD48705	4/30/2026

Lisdexamfetamine Dimesylate Capsules, 20 mg	100 count bottle	57664- 047-88	AD42469	2/28/2026
Lisdexamfetamine Dimesylate Capsules, 20 mg	100 count bottle	57664- 047-88	AD48707	4/30/2026
Lisdexamfetamine etamine Dimesylate Capsules, 30 mg	100 count bottle	57664- 048-88	AD42470	2/28/2026
Lisdexamfetamine Dimesylate Capsules, 30 mg	100 count bottle	57664- 048-88	AD48708	4/30/2026
Lisdexamfetamine Dimesylate Capsules, 40 mg	100 count bottle	57664- 049-88	AD48709	4/30/2026
Lisdexamfetamine Dimesylate Capsules, 40 mg	100 count bottle	57664- 049-88	AD50894	5/31/2026
Lisdexamfetamine Dimesylate Capsules, 50 mg	100 count bottle	57664- 050-88	AD48710	4/30/2026
Lisdexamfetamine Dimesylate Capsules, 50 mg	100 count bottle	57664- 050-88	AD50895	5/31/2026
Lisdexamfetamine Dimesylate Capsules, 60 mg	100 count bottle	57664- 051-88	AD4871 l	4/30/2026
Lisdexamfetamine Dimesylate Capsules, 60 mg	100 count bottle	57664- 051-88	AD50896	5/31/2026

Lisdexamfetamine Dimesylate Capsules, 70 mg	100 count bottle	57664- 052-88	AD48712	4/30/2026
Lisdexamfetamine Dimesylate Capsules, 70 mg	100 count bottle	57664- 052-88	AD50898	5/31/2026