

Drug Recall

DATE OF RECALL: September 11, 2023

DRUG NAME: Sandimmune® Oral Solution 100 mg/mL

RECALLING FIRM: Novartis.

REASON FOR RECALL: This recall was issued due to crystal formation observed in some bottles, which could potentially result in incorrect dosing.

FDA LINK: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novartis-issues-voluntary-nationwide-recall-one-lot-sandimmun-oral-solution-cyclosporine-oral>

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Lot Number	Expiration Date
Sandimmune® Oral Solution 100 mg/mL	00078-0110-22	FX001691	12/2025