

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.

Dr. Reddy's Laboratories Ltd. has initiated a recall for Sapropterin Dihydrochloride Powder for Oral Solution 100mg. This recall is initiated as a precaution due to product complaints regarding powder discoloration in addition to sub-potency. Consumers reported that the powder appeared yellow and brown instead of off-white to pale yellow.

For the defective product sachets, discoloration is clearly visible to the naked eye and hence is unlikely to be consumed. However, Reduced efficacy of the product would result in elevated phenylalaninemia (Phe) levels in patients. Chronically elevated Phe levels in infants and children is likely to cause permanent neurocognitive deficits, including permanent and irreversible intellectual disability, developmental delay, and seizures. Furthermore, elevated Phe levels during pregnancy, especially in early gestation, are associated with microcephaly and congenital heart disease.

The product Distribution Dates: February 18, 2022 – January 29, 2024

Product Name	Lot Number	Expiration date	NDC Number
	T2202812	07/2025	43598-097-30
Javygtor™ (Sapropterin Dihydrochloride) Powder for Oral Solution 100mg	T2204053	10/2025	43598-097-30
	T2300975	02/2026	43598-097-30
	T2300976	02/2026	43598-097-30
Sapropterin Dihydrochloride Powder for Oral Solution 100mg	T2200352	12/2024	43598-477-30
	T2304356	08/2026	43598-097-30