

vialose™ trehalose dihydrate

stabilize your biologic for optimum health

description

Vialose™ trehalose dihydrate is produced as a high purity excipient intended for injectable use, and is tested to meet low levels of bioburden and endotoxin. The natural sugar composed of two glucose molecules formed by a 1,1 glycosidic bond is found in plant, microbial and animal species and serves as a source of energy and a protection against freezing and lack of water.

Vialose™ trehalose dihydrate is Ashland's brand of trehalose, a common ingredient found in biological medicines used to stabilize proteins by inhibiting degradation of the protein and its structure, while minimizing aggregation. It is produced and manufactured to comply with USP-NF <1078> and The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients

key features and benefits

- lyo/cryoprotectant and stabilizer for proteins, cells and particle
- reduces protein aggregation & cycle times
- produces excellent lyo-cake appearance
- easily dispersed in water
- compatible with most active ingredients

bioburden & endotoxin limits

Vialose™ trehalose dihydrate is tested to meet the following limits:

specification	limits	test method
TAMC	<100 CFU/g	USP<61>, <62>
TYMC	<100 CFU/g	USP<61>, <62>
Salmonella	Absent/10g	USP<61>, <62>
E. Coli	Absent/g	USP<61>, <62>
Endotoxin	0.6 EU/g	USP<85>, kinetic chromogenic method



application

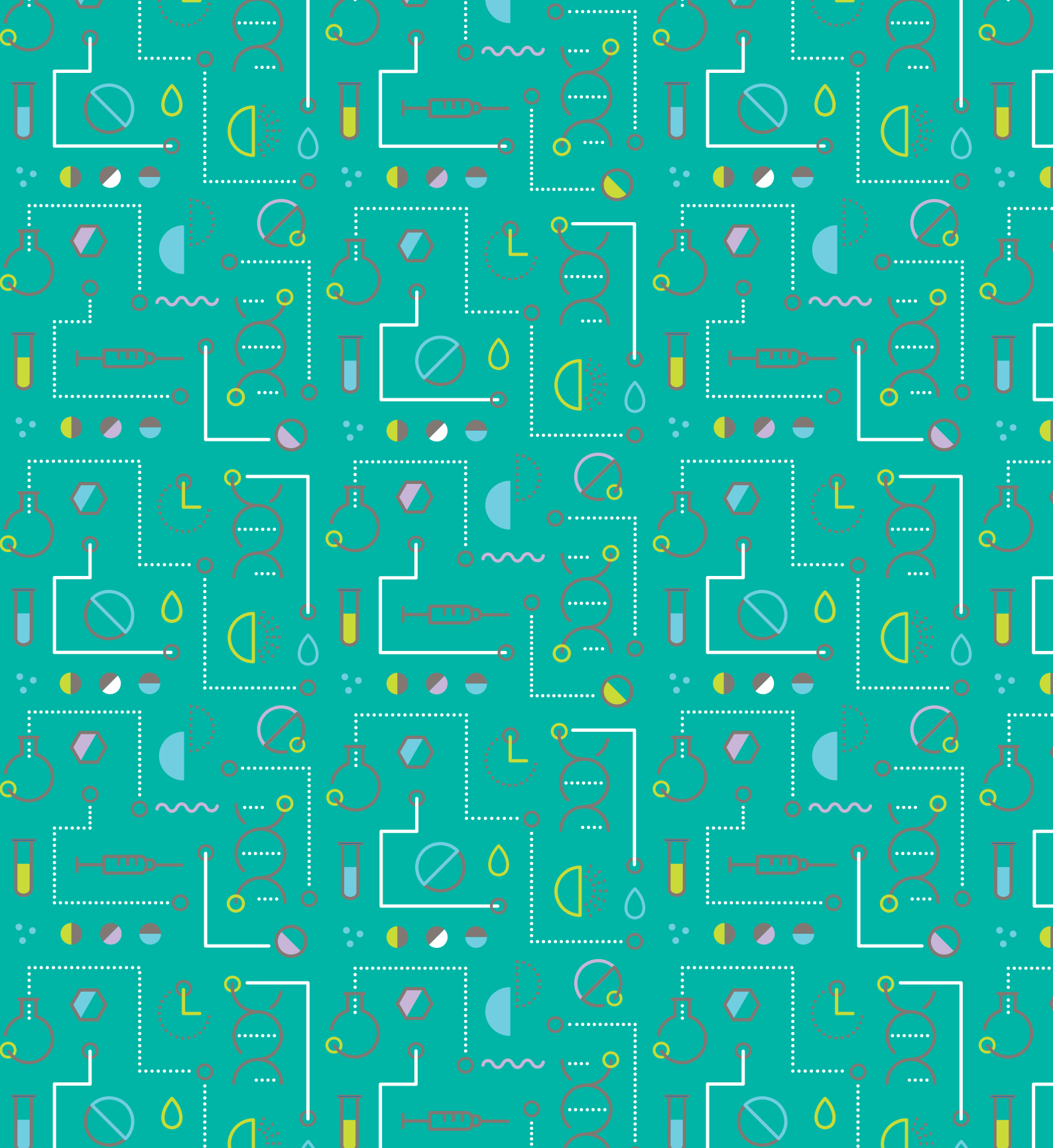
- small and large molecules
- frozen solutions
- lyophilized powders

monograph status

Product conforms to the NF, EP, JP and ChP monograph for trehalose dihydrate.

packaging

Each package of Vialose™ trehalose dihydrate contains 10 kg or 20kg of powder in a double polyethylene bag of 4mm thickness, twisted closed and secured with a zip tie. The PE bag is inserted into an 8-gallon HDPE Euro Open Head Drum with a rubber gasket inserted into galvanized steel locking ring cover. A safety seal is installed to ensure package integrity. The drum complies with FDA regulations for food and drugs.



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