



SureSpheres™ 14/18
Product Information
609717 - 320# Drums

Product Description: 14/18 Colorcon® Inc. SureSpheres™, drug layering substrates, are uniform, mostly spherical, white seeds composed of Sucrose and Starch. 14/18 Colorcon Inc. SureSpheres are primarily used by the pharmaceutical industry in the production of sustained or timed-released dosage forms. 14/18 Colorcon SureSpheres meet all specifications for Sugar Spheres as outlined in the current version of USP/NF, JPE, and PhEur.

Ingredients: Sucrose, Starch

Microbiological: Meets Requirements

Chemical and Physical Specifications:	Range
Appearance:	Product is uniform, mostly spherical, white seeds
Specific Rotation:	+41° - +61°
Identification:	Responds to ID test B under Starch, USP
Sucrose Content:	62.5% – 91.5%
Loss on Drying:	≤ 4.0%
Residue on Ignition:	≤ 0.2%
Heavy Metals:	≤ 5ppm
Organic Volatile Impurities (OVI):	Meets Requirements
Particle Size:	Thru a 12 US mesh sieve: 100% Minimum
	Thru a 14 US mesh sieve: 90% Minimum
	Thru a 18 US mesh sieve: 10% Maximum

Storage: Store in well closed containers, protect from moisture, freezing and excessive heat.

Stability: Under proper conditions, thirty-six months in unopened containers.

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