



# INNOKOAT-SSP

## (Sugar Spheres USP/NF)

### Information Sheet:

- INNOKOAT-SSP (Sugar Spheres USP/NF)** are uniform drug layering pellets, contains 62.5 - 91.5% of sucrose, calculated on the dried basis and remaining consists of maize starch, for sustained or extended release dosage form with uniform sphericity, tight particle size control with high batch to batch uniformity.
- Compliance with Ph.Eur, USP/NF.

### SPECIFICATION:

Sr No.	Test	SPECIFICATION
1	Appearance	White to off white free flowing spherical pellets.
2	Identification	A water slurry of the insoluble portion of the sample is coloured reddish violet to deep blue by iodine TS.
3	pH (10% w/v)	Between: 5.0 to 9.0
4	Specific rotation (on dried basis)	NLT + 41° & NMT + 61°
	Microbial Limits	
5	Total Aerobic microbialcount	NMT 100 cfu/g
	Salmonella species	Absent in 1g
	Escherichia coli	Absent in 1g
	Staphylococcus Aureus	Absent in 1g
	Pseudomonas aeruginosa	Absent in 1g
6	Loss on drying (at 105°C for 4 hours)	Not more than 4.0 %
7	Residue on Ignition	NMT 0.25%
8	Particle size	*Based on the size of the pellets
9	Heavy metals	NMT 5µg/g
10	Organic volatile impurities (method IV)	Meets the requirement
11	Assay Sugar content (on dried basis)	NLT 62.5 % & NMT 91.5 %

Expiry: 24 months from the date of manufacturing.

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## (Sugar Spheres USP/NF)

### Advantage:

- Uniform sphere size
- Higher yield of final product
- Smooth pellets and excellent flow for efficient manufacturing.
- Local GMP Good Manufacturing Practice Certifications
- Conformity to innovators Product Profile
- Cost effective.
- In-house Product Specifications, test method & document support
- Efficient delivery time
- Packing in HDPE container

### Product Application:

- Batch to batch reproducibility.
- Manufacturing dedicated to pharmaceuticals grade product.
- Low friability and high mechanical strength.
- Sphericity maintained throughout manufacturing.
- Meets GMP requirements based on the USP/NF General chapter <1078> and GMP processes for bulk pharmaceuticals excipients.
- Complies with all specification for sugar spheres as outlined in USP/NF and Ph.Eur
- Non – TSE/BSE implicated.

### INNOKOAT- SSP (Sugar Spheres) Particle Sizes

Mesh Size (ASTM)	Size (µm)
12-14	1400 – 1700
14-18	1000 – 1400
16-18	1000 – 1180
16-20	850 – 1180
18-20	850 – 1000
20-25	710 – 850
20-30	600 – 850
25-30	600 – 710
30-35	500 – 600
30-40	425 - 600

\*Customized sizes will be available on request

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