



# PHARMATRANS SANAQ AG

PHARMACEUTICALS

## SPECIFICATIONS

### DICOM SANAQ<sup>®</sup>

solutions for direct compression formulations  
(USP/NF / JP / Ph. EUR)

Type	LS 004	ML 011	SP 204	SP 205	SP 206	SR 300
Composition	Lactose - Starch	MCC - Lactose	MCC - MgO <sub>2</sub> -Starch - Pregelatizend starch - Sodium starch glycolate	MCC - Colloidal Silicon dioxide - Povidone K30 - Crosspovidone	MCC - Colloidal silicon dioxide - Polyvinyl pyrrolidone - Sodium starch glycolate	Hydroxypropyl Methylcellulose EC - MCC - HPC - Starch - Colloidal Silicon dioxide - Talcum - Mg Stearate"
Functionality	Diluent - Disintegrant	Diluent - Binder	Diluent and dry binder	Diluent	Diluent	Matrix type of tablets
Description	Off white free flowing granules	Off white free flowing granules	Off white free flowing granules	Off white free flowing granules	Off white free flowing granules	Off white free flowing granules
Particle Size	NMT 5.0% w/w Retained on 20# NLT 65.0% w/w Retained on 100# NMT 35.0% w/w Retained on 100#	NMT 5.0% w/w Retained on 20# NLT 65.0% w/w Retained on 100# NMT 35.0% w/w Retained on 100#	NMT 5.0% w/w Retained on 20# NLT 65.0% w/w Retained on 100# NMT 35.0% w/w Retained on 100#	NMT 5.0% w/w Retained on 20 # NLT 65% w/w Retained on 100 # NMT 35% w/w Passed through 100 #	NMT 5.0% w/w Retained on 20 # NLT 65% w/w Retained on 100 # NMT 35% w/w Passed through 100 #	NMT 5.0% w/w Retained on 20 # NLT 65% w/w Retained on 100 # NMT 35% w/w Passed through 100 #
Loss on drying	NMT 3.0%	NMT 3.0%	NMT 3.0 %	NMT 3.0 %	NMT 3.0 %	NMT 5.0 %
Bulk Density	0.5 – 1.0 g/mL	0.5 - 1.0 g/mL	0.5 – 1.0 g/mL	0.75 g/mL	0.75 g/mL	0.35-0.60 g/mL
Repose Angle		NMT 35°	NMT 35°			
pH (2% aq susp)	4.0 – 8.0	4.0 - 8.0	10.0 – 12.0	4.0 – 8.0	4.0 – 8.0	4.0 – 8.0
TAMC	< 1000 CFU/g	< 1000 CFU/g	< 1000 CFU/g	< 1000 CFU/g	< 1000 CFU/g	< 1000 CFU/g
TYMC	< 100 CFU/g	< 100 CFU/g	< 100 CFU/g	< 100 CFU/g	< 100 CFU/g	< 100 CFU/g
E. coli, Pseudomonas aeruginosa	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample
St. Aureus, Salmonella species	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample

#### Application fields

<b>LS 004</b>	Diluent - Disintegrant
<b>ML 011</b>	Diluent - Binder

<b>SP 204</b>	Designed for moisture sensitive APIs and where alkaline conditions are needed for stability purpose
<b>SP 205</b>	Designed for moisture sensitive and low bulk density and fluffy API's formulations.
<b>SP 206</b>	Designed for moisture sensitive and low bulk density and fluffy API's formulations
<b>SR 300</b>	Designed for modified release, matrix type of tablets

Contact

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