PHARMATRANS SANAQ AG

PHARMACEUTICALS

SPECIFICATIONS

DiCom SANAQ®

solutions for direct compression formulations

(USP/NF / JP / Ph. EUR)

Type	LS 004	ML 011	SP 204
Composition	Lactose - Starch	MCC - Lactose	MCC - MgO2 -Starch - Pregelatizend starch - Sodium starch glycolate
Functionality	Diluent - Disintegrant	Diluent - Binder	Diluent and dry binder
Description	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#
Loss on drying	NMT 3.0%	NMT 3.0%	NMT 3.0 %
Bulk Density	0.5 – 1.0 g/mL	0.5 - 1.0 g/mL	0.5 – 1.0 g/mL
Repose Angle		NMT 35°	NMT 35°
pH (2% aq susp)	4.0 – 8.0	4.0 - 8.0	10.0 – 12.0
TAMC	< 1000 CFU/g	< 1000 CFU/g	< 1000 CFU/g
TYMC	< 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
St. Aureus, Salmonella species	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample

Application fields

LS 004	Diluent - Disintegrant
ML 011	Diluent - Binder
SP 204	Designed for moisture sensitive APIs and where alkaline conditions are needed for stability purpose

Contact

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