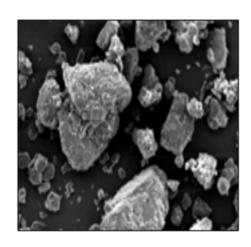
SANAQ® SL 004

Starch & Lactose

SANAQ SL 004 (Lactose Monohydrate USP/ Maize Starch USP)		
Chemical Name	Lactose Monohydrate - 85% Maize Starch - 15%	
Chemical Description	Lactose monohydrate with Maize starch	
CAS Number	64044-51-5 / 9005258	
DMF – FDA (USA)	032957 Type IV	
GMP standard	ISO 9001-2015, WHO GMP, EXCIPACT (in progress)	
Inactive Ingredient Database (maximum potency per unit dose)	1990 mg of Starlose (calculated based on IID limits of individual excipient)	
	Lactose Monohydrate - 1691.8 mg, GRANULES, FOR SOLUTION	
	Maize Starch – 430 mg, CAPSULE	



Tests	Specification	Results
Bulk density (g/mL)	INH	0.663
Tapped density (g/mL)	INH	0.840
Hausner's ratio	INH	1.27
Compressibility index (%)	INH	21.05
LOD (105 OC – 3h)	NMT 3.0 %	2.30
Angle of repose(°)	INH	36.22
PSD (Malvern mastersizer)	INH	D(10) =34.1 D(50)=243 D(90)=583

SANAQ SL 004 have average particle size of 300 – 550 microns. It is a combination of Lactose Monohydrate and Starch (maize). Lactose is water loving and soluble in water, at high compression force it hampers disintegration. Starch has multifunction characters and act as binder as well as disintegrant. Starlose has optimized composition of these two ingredients.

It's a unique product used as a filler for tablets and capsules; with,

- Uniform drug distribution
- Content uniformity
- Better compressibility as it contains suitable proportion of fines
- Reduced weight variation
- And higher production rates.
- Choice of higher average weight
- Robust tablet with reduced friability

High bulk density makes this product suitable to formulate high tablet weight / capsule fill weight in smaller die / capsule size respectively.

Contact

Pharmatrans Sanaq AG Gewerbestrasse 18 - CH-4123 Allschwil Tel.: +41 61 225 90 00

Fax: +41 61 225 90 01 Email: info@pharmatrans-sanaq.com Web: www.pharmatrans-sanaq.com