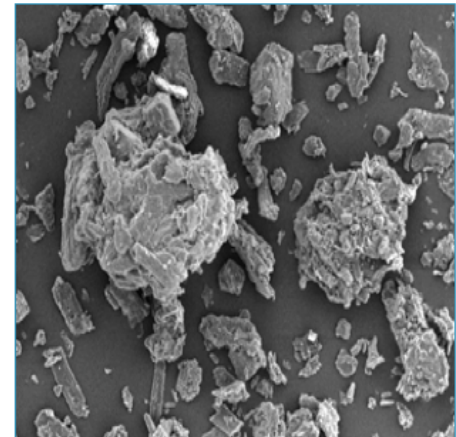




DICOM SANAQ® ML 011

Lactose Monohydrate & Microcrystalline Cellulose

DICOM SANAQ ML 011 (Lactose Monohydrate USP/ Microcrystalline Cellulose USP)	
Chemical Name	Lactose Monohydrate - 40% Microcrystalline cellulose - 60%
Chemical Description	Lactose monohydrate with Microcrystalline cellulose
CAS Number	64044-51-5 / 9004346
DMF - FDA (USA)	033804 Type IV
GMP standard	ISD 9001-2015, WHO GMP, EXCiPACT (in progress)



Test	Specifications	Results
pH (2% suspension in water)	4.0 - 8.0	6.19
Bulk density	0.5 - .9 g/mL	0.55
Tap density	For Information	0.67
Hausner's Ratio	INH	1.22
Compressibility Index (%)	INH	17.91
Residue on ignition	NMT 2%	0.52
Loss on drying	NMT 3.0%	1.54
Angle of repose	INH	34.12
PSD (Malvern mastersizer)	<32	D(10)=34.3
	<160	D(50)=252
	<250	D(90)=579

Co-processed LACTOSE MONOHYDRATE and MICROCRYSTALLINE CELLULOSE, results in a optimised solution to make a balance to achieve superior compression properties and desired quality attributes

- Lactose increase DT (erosion type), while MCC act as disintegrant by swelling (bursting type). Prevents sticking and heap formation tendency in dissolution testing
- MCC is sensitive to lubricant, while Lactose is not
- Inconsistent Die filling at high speed Compression, because of low BD of MCC, while Lactose have relatively high BD.
- MCC – Plastic fracture
Lactose – Brittle fracture
- MCC gives Stronger tablets compared to lactose at same compression parameters
- MCC loses its compressibility on exposure to water, while Lactose do not
- Combination Mitigates sensitivity of Compression pressure on tablet hardness, DT, Friability & Dissolution
- Balance of cohesion and adhesion

Supplier

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