SIGACHI® Experience Excellence..	SIGACHI INDUSTRIES PVT. LTD., Dahej SEZ-1, DAHEJ.
	FINISHED PRODUCT SPECIFICATIONS
Product Name :	MICROCRYSTALLINE CELLULOSE USP-NF/Ph. Eur.
Document No. :	SP/CS/IC/M01.00

Sr. No.	TESTS		SPECIFICATIONS	REFERENCE
A.	**PHARMACOPOIEAL TESTS**:			
1.	Description		White or almost white, Fine or granular powder. It consists of free flowing, non fibrous particles.	USP
2.	Solubility		Practically insoluble in sodium hydroxide solution (1 in 20); insoluble in water; in dilute acids and in most-organic solvents.	
3.	Identification	A.	The substance takes on a violet blue color with iodinated zinc chloride solution.	
		B.	The degree of polymerization is NMT 350.	
4.	Solubility		Dissolves in ammonical solution of copper tetramine.	Ph.Eur.
5.	Conductivity		Max. 75 µS/cm	USP
6.	Ether soluble substance		Max. 0.05%	
7.	Heavy Metals		Max. 10 ppm	
8.	Sulphated Ash / ROI		Max. 0.10%	
9.	pH		Between 5.0 and 7.5	USP
10.	Water soluble substance		Max. 0.25%	
11.	Loss on drying		*Between 3.0 and 5.0%	
			Max. 1.5% for XLM grade	In-house
			Max. 3.0% for LM grade	
12.	MICROBIAL CONTAMINATION:			
a.	Total aerobic microbial count		< 1000 CFU/g	USP
b.	Total yeasts and moulds count		< 100 CFU/g	
c.	Escherihchia coli		Absent /g	
d.	Salmonella species		Absent /10g	
e.	Staphylococcus aureus		Absent /g	
f.	Pseudomonas aeruginosa		Absent /g	
B.	**INHOUSE TESTS**:			
1.	Bulk density		Refer Page 2	In-house
2.	Sieve analysis		Refer Page 2	

Remarks: The raw materials, manufacturing process, and product do not contain any of the solvents listed in Residual Solvents (Ph.Eur <5.4>, USP<467>).

*Stringent to pharmacopeia limit.

CROSS REFERENCE TABLE FOR DIFFERENT GRADES OF MICROCRYSTALLINE CELLULOSE

INHOUSE TESTS: Analyze the sample for one of the following grade as per the requirement.

	A. Sieve Analysis Specifications							**B.**
Grade	**RETENTION**						**Passed**	**Bulk Density (Untapped) g/cc**
	(+) 40	**(+) 60**	**(+) 200**	**(+) 100**	**(+) 300**	**(+) 400**	**(-) 200**	
50M	---	<1.0%	---	---	---	---	>70.0%	0.28–0.34
HD50M	---	< 1.0%	---	---	---	---	>70.0%	0.35-0.46
90M	---	< 8.0%	>45.0%	---	---	---	---	0.28–0.34
HD90M	---	< 8.0%	>45.0%	---	---	---	---	0.35-0.46
LP200	---	>10.0%	---	>50.0%	---	---	---	0.30–0.36
25M	---	< 0.1%	---	---	---	< 1.0%	---	0.25-0.30
12	<1.0%	---	---	< 50.0%	>70.0%	---	---	0.30-0.36
XLM 50	---	< 1.0%	---	---	---	---	>70.0%	0.28-0.34
XLM 90	---	< 8.0%	>45.0%	---	---	---	---	0.28–0.34
XLM 200	---	>10.0%	---	>50.0%	---	---	---	0.30–0.36
14	<1.0%	---	--	< 50.0%	>70.0%	---	---	0.30-0.36
LM 50	---	< 1.0%	---	---	---	---	>70.0%	0.28-0.34
LM 90	---	< 8.0%	>45.0%	---	---	---	---	0.28–0.34
90M SCG	---	< 8.0%	>45.0%	---	---	---	---	0.27–0.30

For Sigachi Industries Pvt. Ltd., Dahej SEZ Unit.

Dr.A.K.Singh

Dy. Geneal Manager – Quality