



# Trafa Pharmaceutical Inc.

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## SPECIFICATION SHEET

Product Name	Microcrystalline Cellulose
TESTS	SPECIFICATION
<b>PHYSICAL CONTROL</b>	
Appearance	White to off white powder
Assay	Not less than 97.0% and not more than 102% of cellulose
Identification A & B	Meet the requirements
Degree of polymerization	210-270
Water soluble substances	<0.25%
Ether-soluble substances	<0.050%
Conductivity	<75 $\mu$ s/cm
Loss on Drying	$\leq$ 7.0%
Particle size Distribution (By Laser)	D10 <50 $\mu$ m D50 90~140 $\mu$ m D90 >170 $\mu$ m
pH	5.5-7.0
Residue on Ignition (Sulfated Ash)	$\leq$ 0.05%
Bulk density	0.28-0.35 g/ml
<b>CHEMICAL CONTROL</b>	
Heavy Metals	$\leq$ 10ppm
Lead (Pb)	$\leq$ 2ppm
Arsenic (As)	$\leq$ 2ppm
Cadmium (Cd)	$\leq$ 1ppm
Mercury (Hg)	$\leq$ 0.1ppm
Residual solvents	Meet the requirement
<b>MICROBIOLOGICAL CONTROL</b>	
Total plate Count	$\leq$ 100cfu/g
Yeast & Mold	$\leq$ 10cfu/g
Salmonella	Negative /10g
Staphylococcus aureus	Negative/1g
Pseudomonas aeruginosa	Negative/1g
E.Coli	Negative/1g
<b>STORAGE</b>	
Store in a well-sealed container away from direct sunlight and moisture.	
CONCLUSION: Complies with NF/USP/EP/BP/JP	

Note: The above information is based on the certificate of analysis received from the manufacturer of this product and not intended as a substitute for strict quality control analysis by the purchaser of this product.

Reviewed by: \_\_\_\_\_

Abdullah Malik (QA)