



**Todo Droga**  
Química Mayorista

**QUALITY CONTROL  
CERTIFICATE OF ANALYSIS**

Product: MICROCRYSTALLINE CELLULOSE  
Grade: ACCEL 200

Patch No.: DI02190112  
Mfg. Date: February 2019  
Re-evaluation Date: January 2024  
Batch Qty: 5000 Kgs.

MOA: USP/NF,JP,Ph.Eur.,BP

Description: White or almost white, Practically insoluble in water, dilute acid and most of organic solvents. Slightly soluble in dilute NaOH solution

Pharmacopoeial test items	Batch Results	Specification
Identification A(Zinc Chloride test)	Passes	Have to correspond as USP/NF,JP,Ph.Eur.,BP
Identification B (Degree of Polymerization)	Complies	NMT 350 as USP/NF,JP,Ph.Eur.,BP
Solubility (coppertetramine solution)	Complies	Have to correspond as Ph. Eur.,BP
pH	6.56	5.0-7.0 as USP/NF,JP,Ph.Eur.,BP
Conductivity	46 $\mu\text{S.cm}^{-1}$	NMT 75 $\mu\text{S.cm}^{-1}$ as USP/NF,JP,Ph.Eur.,BP
Water - Soluble Substance	0.1340 %	NMT 0.25% as USP/NF,JP,Ph.Eur.,BP
Ether - Soluble Substance	0.0279 %	NMT 0.05% as USP/NF,JP,Ph.Eur.,BP
Loss on Drying	3.622 %	NMT 7.0% as USP/NF,JP,Ph.Eur.,BP
Heavy Metals	Complies	NMT 10 PPM as USP/NF,JP,Ph.Eur.,BP-
Residue on Ignition / Sulphated Ash	0.0286 %	NMT 0.1% as USP/NF,JP,Ph.Eur.,BP

Standards	Batch Results	In house Specification
Bulk Density	0.3452 g/ml	0.31 to 0.39 g/ml
Assay (Dried)	99.63 %	97.0% to 102.0%
Sieve Analysis (% Retention)		
60 Mesh	14.88 %	$\geq 10.0\%$
100 Mesh	60.26 %	$\geq 50.0\%$
Particle Size Distribution		
D <sub>10</sub>	53 $\mu$	$\leq 70 \mu$
D <sub>50</sub>	179 $\mu$	150 - 200 $\mu$
D <sub>90</sub>	308 $\mu$	$\geq 260 \mu$

**MICROBIAL LIMITS**

Total Viable Aerobic Count	Complies	N.M.T. 1000cfu/g as USP/NF,JP,Ph.Eur.,BP
Total yeast & Mould Count	Complies	N.M.T 100cfu/g as USP/NF,JP,Ph.Eur.,BP
<i>Staphylococcus aureus</i>	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
<i>Escherichia Coli.</i>	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
<i>Pseudomonas aeruginosa</i>	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
<i>Salmonella species</i>	Complies	Absent as USP/NF,JP,Ph.Eur.,BP

The raw materials, manufacturing process, and product do not contain any of solvents listed in Organic Volatile Impurities (USP<467>) & residual solvents (Ph - Eur<5.4>).

**Storage recommendation:** Preserve in tight containers.



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