



accent

QUALITY CONTROL CERTIFICATE OF ANALYSIS

Date: 21.11.2022

Product MICROCRYSTALLINE CELLULOSE Batch No.: D107220717
Grade ACCEL 112 Mfg. Date: July'2022
Party Name PT. ALKALI GRUNHEIM INDONESIA Re-evaluation Date: June'2027
MOA USP/NF, JP, Ph. Eur., BP Batch Qty: 5000 Kgs.

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	6.33	5.0-7.5 as USP/NF,JP,Ph.Eur.,BP
Conductivity	41 $\mu\text{S.cm}^{-1}$	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	0.0278 %	NMT 0.05% as USP/NF,JP,Ph.Eur.,BP
Loss on Drying	0.929 %	NMT 1.5 % 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	0.0294%	NMT 0.1% as USP/NF,JP,Ph.Eur.,BP

Standards	Batch Results	In house Specification
Bulk Density	0.2960 g/ml	0.26 to 0.50 g/ml
Assay (Dried)	99.63%	97.0% to 102.0%
Sieve Analysis (% Retention)		
60 Mesh	1.26 %	$\leq 8.0\%$
200 Mesh	61.54%	$\geq 45.0\%$
Particle Size Distribution		
D ₁₀	25 μ	$\leq 45 \mu$
D ₅₀	93 μ	70 – 100 μ
D ₉₀	201 μ	$\geq 140 \mu$

MICROBIAL LIMITS

Total Viable Aerobic Count	40	N.M.T. 1000cfu/g as USP/NF,JP,Ph.Eur.,BP
Total yeast & Mould Count	<10	N.M.T 100cfu/g as USP/NF,JP,Ph.Eur.,BP
Staphylococcus aureus	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
Escherichia Coli.	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
Pseudomonas aeruginosa	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
Salmonella species	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.

Prepared By

Checked By



Approved By

Qad 1 (Pharm) Survey No. 633/P, Paldi Kankaj, Prana Road, Ta. Daskra,
Dist. Ahmedabad - 382425, Gujarat, India. Phone: +91 2148 288001/288002
Fax: +91 2148 288003
E-mail: info@accentmicrocell.com
www.accentmicrocell.com
Phone: +91 79 40042367 32456689
32527633/40094906
info@accentmicrocell.com
www.accentmicrocell.com
MERSIFARMA TM
KPSUKA RUMI
4/4 Shyambhaji Arcade,
Shyambhaji Cross Road, Anandnagar Road,
Subhite Ahmedabad - 380015
G. G. Patel, India