



QUALITY CONTROL CERTIFICATE OF ANALYSIS

Date: 23.11.2023

Product MICROCRYSTALLINE CELLULOSE Batch No.: D111231033
Grade ACCEL 102 Mfg. Date: November'2023
Party Name PT. ALKALI GRUNHEIM INDONESIA Re-evaluation Date: October'2028
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	6.51	5.0-7.5 as USP/NF,JP,Ph.Eur.,BP
Conductivity	59.1 $\mu\text{S.cm}^{-1}$	NMT 75 $\mu\text{S.cm}^{-1}$ as USP/NF,JP,Ph.Eur.,BP
Water - Soluble Substance	0.1478 %	NMT 0.25% as USP/NF,JP,Ph.Eur.,BP
Ether - Soluble Substance	0.0255 %	NMT 0.05% as USP/NF,JP,Ph.Eur.,BP
Loss on Drying	3.702 %	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	0.0297 %	NMT 0.1% as USP/NF,JP,Ph.Eur.,BP

Standards	Batch Results	In house Specification
Bulk Density	0.3068 g/ml	0.26 to 0.50 g/ml
Assay (Dried)	99.54 %	97.0% to 102.0%
Sieve Analysis (% Retention)		
60 Mesh	1.32 %	$\leq 8.0\%$
200 Mesh	61.20 %	$\geq 45.0\%$
Particle Size Distribution		
D ₁₀	22 μ	$\leq 45 \mu$
D ₅₀	93 μ	70 - 100 μ
D ₉₀	201 μ	$\geq 140 \mu$

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
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



Approved By

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Butuh penyesuaian
terlampir

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU

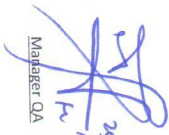
No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Microcrystalline Cellulose	Accent	USP/JP/EP/BP	USP 47/FI VI	Pemerian : Batas partikel hitam 5 9/600 cm2 Solubility (Coppertetramine solution) Heavy Metals Identifikasi D (Nanoram)	Identifikasi IR (USP 47)		RD-02-SBP/060.03	Penyesuaian CoA dari Manufacturer Update SPBB

Diperiksa Oleh


25/10/2024
Koordinator QC


03/09/2024
Koordinator TS


25/10/2024
Koordinator QA

Diserujui Oleh,

25/10/2024
Manager QA