



accent
bonding precision

**QUALITY CONTROL
CERTIFICATE OF ANALYSIS**

Date: 16.03.2022

Product MAGNESIUM STEARATE (200 Mesh)
Grade MACCEL
Party Name PT. TIGAKA DISTRINDO PERKASA
MOA USP/NF,JP,Ph.Eur.,BP

Batch No. : D303230015
Mfg. Date : March'2023
Re-evaluation Date: February'2028
Batch Qty: 2000Kgs.

Description	White, very fine, light powder, greasy to the touch, .Practically insoluble in water & in anhydrous ethanol.
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Pharmacopoeial test items	BatchResults	Specification
Identification A(Freezing point)	Passes	Have to correspond as USP/NF,,Ph.Eur.,BP
Identification B(Acid Value)	203	195 to 210 as USP/NF,,Ph.Eur.,BP
Identification C,D	Complies	Have to correspond as USP,BP,Ph.Eur
Acidity or Alkalinity	Complies	Have to correspond as USP,BP,Ph.Eur
Chloride	0.050 %	NMT0.1% as USP/NF,,Ph.Eur.,BP
Sulphates	0.13 %	NMT 0.5% as USP/NF,,Ph.Eur.,BP
Cadmium	2 PPM	NMT 3 PPM as USP/NF,,Ph.Eur.,BP
Lead	5 PPM	NMT 10 PPM as USP/NF,,Ph.Eur.,BP
Nickel	3PPM	NMT 5 PPM as USP/NF,,Ph.Eur.,BP
LOD	2.83 %	NMT 6% as USP/NF,,Ph.Eur.,BP
Assay of Magnesium	4.57 %	4.0% to 5.0% as USP/NF,,Ph.Eur.,BP
Fatty Acid composition	45.20 % & 97.24 %	NLT 40% of Stearic Acid & NLT 90% of sum of stearic acids & palmitic acid as USP/NF,,Ph.Eur.,BP
Bulk Density	0.2272 gm/ml	0.22 to 0.35 gm/ml
Sieve Analysis		
200 mesh(%Passes through)	99.65 %	NLT 99.00%

MICROBIAL LIMITS

Total Viable Aerobic Count	30 cfu/g	N.M.T. 1000cfu/g as USP/NF,Ph.Eur.,BP
Total yeast & Mould Count	10 cfu/gm	N.M.T 100cfu/g as USP/NF,Ph.Eur.,BP
Escherichia Coli.	Complies	Absent as USP/NF
Salmonella species	Complies	Absent as USP/NF

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

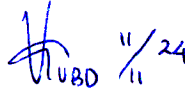


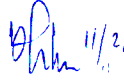

Approved By

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU

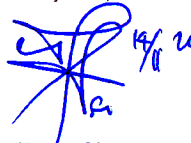
No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Magnesium Stearate	Accent	USP/IP/BP/EP	USP 47/FI VI	Identifikasi A, B dan C	Cemaran Organik (USP 47) - Chloride : 0,1 % - Sulfate 1.0 % - Cadmium NMT 3 ppm - Nickel : NMT 5 ppm	Identifikasi disesuaikan dengan USP 47 : Very fine, light, white powder, slippery to touch.	RD.02-SBP/052.01	Update SPBB
							Acidity or Alkalinity : NMT 0.05 mL of 0.1 N hydrochloric acid or 0.1 N sodium hydroxide is required to change the color of the indicator. (USP 47)		
					RELATIVE CONTENT OF STEARIC ACID AND PALMITIC ACID : NLT 40% for the stearate peak. The sum of the stearate and palmitate peaks is NLT 90% of the total peak areas of all the fatty acids (USP 47)		Identifikasi disesuaikan dengan Usp 47 : - Uji Megnesium - HPLC		
					Cemaran Mikrobiologi - ALT 1000 CFU/g - AKK 100 CFU/g - Salmonela Species - Escherichia coli		Assay : 4.0%–5.0% on the dried basis (USP 47)		
					Particle Size		LOD : NMT 6.0% (USP 47)		
					Bulk density				
					Identifikasi A, B, C dan D		Solubility di sesuaikan dengan USP 47 : Insoluble in water, in alcohol, and in ether	Penyesuaian CoA dari Manufacturer	
							Identifikasi disesuaikan dengan Usp 47 : - Uji Megnesium - HPLC		
					Cemaran Organik (USP 47) - Sulfate 1.0 %				
					Acidity or Alkalinity : NMT 0.05 mL of 0.1 N hydrochloric acid or 0.1 N sodium hydroxide is required to change the color of the indicator. (USP 47)				

Diperiksa Oleh


Koordinator QC


Koordinator TS


Koordinator QA

Disetujui Oleh,

Manager QA