

ORIGINAL  Pakis Farma Raya		FORMULIR KERJA ANALISA PERMINTAAN BARANG		Halaman 1/1
Department HR&GS		No. Dokumen : FDR-HG.045		No. Rev : 00
Dibuat oleh : <i>ank 22/09</i> HR&GS Staff		Disetujui oleh : <i>[Signature]</i> HR&GS Manager		Tanggal Efektif : 23 SEP 2025

No	Nama Barang	Stok Saat Ini (kg)	Rencana Kebutuhan (kg)	Kekurangan (kg)	Pending Penerimaan		Jumlah Permintaan (sak)
					Purchase Request	Purchase Order	
1	Croscarmellose Sodium Ex : MINGTAI CHEMICAL CO.LTD. 1142, Shin Hang Rd, Bah-Der Distoct, Taoyuan City, Taiwan, R.O.C.	0,00	9,24	-9,24	-	-	1,00 <i>25 kg</i>

MOQ : 25 kg

Kebutuhan untuk produk
 - Pilot Paraltik Fast ✓

Kedatangan terakhir :
 N/A

Note : Kebutuhan produk baru

Dibuat Oleh
[Signature]
 Al Dhino
 Pelaksana PPIC

Diperiksa Oleh
[Signature]
 Lidhia Handayani
 Manager PPIC

[Signature]
 Paulianto Budi

Disetujui Oleh
[Signature]
 Suherman
 Plant Manager

Certificate of Analysis

Compendial name : CROSCARMELOSE SODIUM NF/USP/EP/BP/IP/CP

Type : Standard

Lot No. : D2604017

Date manufactured : April 18, 2026

Date of analysis : April 22, 2026

Test items	Units	Limits	Results
Characters		White, free-flowing, hygroscopic powder	Conforms
Identification A (Infrared Absorption)		To meet requirement	Conforms
Identification B,C'		To meet requirement	Conforms
pH		5.0-7.0	6.7
Degree of substitution		0.60-0.85	0.79
Na-chloride & Na-glycolate	%	Not more than 0.50	0.22
Water soluble substances	%	1.0-10.0	4.0
Heavy metals	ppm	Not more than 10	Conforms
Loss on drying	%	Not more than 10.0	2.2
Sulphated ash	%	14.0-28.0	20.0
Settling volume	ml	10.0-30.0	15.8
Particle size, on 200 mesh	%	Not more than 2.0	0.2
Particle size, on 325 mesh	%	Not more than 10.0	4.9
Residual solvents(Methanol)	ppm	Not more than 3,000	1,621
Solubility		Insoluble in acetone, ethanol, toluene	Conforms
Total aerobic microbial count*	cfu/g	Not more than 1000	Conforms
Total molds and yeasts count*	cfu/g	Not more than 100	Conforms
Escherichia coli*	/lg	Absence	Conforms

[MINGTAI Spec ref.C019]

Additional statement :

The product meets the requirement for Residual Solvents USP<467>

We certify herewith the above mentioned product is in conformity with the specification.

Jack Su
 QA Chief
 2026.04.28
 18:01:43 +08'00'



Note :

Re-evaluation date : April 2029

WE CERTIFY THAT ABOVE-MENTIONED PRODUCT MEETS CURRENT USP/NF,EP,BP,JP

AEO no. : 1.2.0.0.0.0.00029.ID

*Based on periodic test result

14/08 '26
 EFA
 untut pilot scale
 Paraffik Fast

A00026040171510MCH19DCMNH00

