

ORIGINAL

	FORMULIR KERJA		Halaman 1/1
	ANALISA PERMINTAAN BARANG		No. Rev : 00
Department HR&GS		No. Dokumen : FOR-HG.045	
Dibuat oleh :	Disetujui oleh :	Tanggal Efektif :	
 HR&GS Staff	 HR&GS Manager	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	Microcell 101 Ex : DFE Pharma , DFE Pharma GmbH & Co. KG, Goch, Germany	0,00	17,82	-17,82	-	-	1,00 25 kg

MOQ : 25 kg

Kebutuhan untuk produk
- Pilot Paraltik Fast ✓

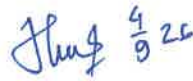
Kedatangan terakhir :
N/A

Note : Kebutuhan produk baru

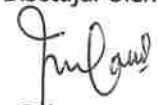
Dibuat Oleh


 Al Dhino
Pelaksana PPIC

Diperiksa Oleh


 Lidhia Handayani
Manager PPIC

Disetujui Oleh


 Suherman
Plant Manager

Certificate of Analysis

Customer number : 160560
 Customer name : PT Signa Husada
 Delivery number :
 Delivery Date :
 Material number : 0743678
 Material description : Pharmacel® 101
 Microcrystalline cellulose
 USP-NF, Ph. Eur., JP, IP
 Bag, PE liner, 25 kg net

Lot/ Batchnumber : 110078
 Date of production : 07.2025
 Retest date : 06.2029
 Order number : 18782747
 Your order number : PH250368

Analysis

Chemical & Physical

Characteristic	Method of analysis	Unit	Specification	Results
Identification B (USP, Ph.Eur.), 1 (JP)	USP-NF; Ph.Eur.		Pass	Pass
Identification C (IP)	IP		Pass	Pass
Organic impurity	IP		No red colour	Pass
Starch and dextrin	IP		Pass	Pass
Loss on drying	USP-NF; Ph.Eur.; JP	%	3.0-5.0	3.3
pH potentiometric	Pharmacopeia Harmonized Methods		5.5-7.0	6.3
Identification C (USP, Ph.Eur.), 3 (JP)	USP-NF; Ph.Eur.; JP		0-350	174
Identification A (USP, Ph.Eur.), 2 (JP)	Ph. Eur.		Pass	Pass
Conductivity	USP-NF; Ph.Eur.; JP	µS/cm	0-75	41
Residue on ignition	USP-NF; Ph.Eur.; JP	%	0.00-0.05	0.01
Water soluble substances	USP-NF; Ph.Eur.; JP	%	0.00-0.20	0.15
Ether soluble substances	USP-NF; Ph.Eur.; JP	%	0.00-0.05	0.01
Heavy metals	USP-NF		max 10 mg/kg	Pass
Arsenic	IP		Max. 2ppm	Pass
Assay	IP	%	97.0-102.0	98.6
Solubility (amm. cop. tetramine)	Ph. Eur.		Pass	Pass

Microbiological

Characteristic	Method of analysis	Unit	Specification	Results
Total aerobic microbial count	Pharmacopeia Harmonized	cfu/g	0-100	<100
Yeasts and Moulds	Pharmacopeia Harmonized	cfu/g	0-20	<20
Escherichia coli (10g)	Pharmacopeia Harmonized		Negative	Negative
Staphylococcus aureus (10g)	Pharmacopeia Harmonized		Negative	Negative
Pseudomonas aeruginosa (10g)	Pharmacopeia Harmonized		Negative	Negative
Salmonella (10g)	Ph.Eur; USP-NF; JP; IP		Negative	Negative



DFE
pharma

DFE Pharma GmbH & Co. KG / PO Box 20 21 20 / D-47568 Goch

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0743678-10G6RP3-20250916-161027-2006-3420-IN_01-000001

Characteristic	Method of analysis	Unit	Specification	Results
Shigella (10gr)	IP		Negative	Negative

OTHERS				
Characteristic	Method of analysis	Unit	Specification	Results
Bulk density	USP-NF; JP	g/cm ³	0.26-0.31	0.30
Particle size d10	Internal, laser diffraction dry	µm	14-30	23
Particle size d50	Internal, laser diffraction dry	µm	40-75	61
Particle size d90	Internal, laser diffraction dry	µm	90-156	118
Particle size <250 µm	equal to ISO 4610	%(m)	>=99.0	100.0
Particle size <75 µm	equal to ISO 4610	%(m)	70.0-90.0	79.3

Remarks

Product description: Microcrystalline Cellulose

Identification: conforms to USP-NF, Ph.Eur, JP, IP current at time of manufacture.

Characteristics: A white or almost white fine crystalline or granulated, slightly hygroscopic powder having fluidity, odorless. Practically insoluble in water, acetone, anhydrous ethanol, toluene, diethyl ether, dilute acid and swells with 50 g/L sodium hydroxide solution.

Production Site:

Material numbers: 0743678, 0743679, 0743842, 1141099
1141100, 1251208, 1251206, 1251205
Produced by DFE Pharma India Private Limited, Cuddalore, India.

Material numbers: 0733317, 0733326, 1165073, 1165074, 1177333
Produced exclusively for DFE Pharma India Private Limited by
Chemfield Cellulose Pvt. Ltd., Nagpur, India.



By qa at 8:39:43 AM, 9/25/2025

Seeley 14/08 '26
EFA
untuk Pilot Scale
Paraffin Fast

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This document has been produced electronically and is valid without signature.

Manufacturer: DFE Pharma GmbH & Co. KG, Goch, Germany (formerly named "DMV-Fonterra Excipients GmbH & Co. KG")