



DFE
pharma

DMV-Fonterra Excipients GmbH & Co KG / PO Box 20 21 20 / D-47568 Goch

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0743624-1059DWG-20191219-113446-2006-3420_IN_01-000001

Certificate of Analysis

Customer number : 160560
Customer name : PT. Sigma Husada
Delivery number : 4502052100
Delivery Date : 31.12.2019
Material number : 0743624
Material description : Pharmacopeia 101
Microcrystalline cellulose
USP-NF, Ph. Eur., JP, IP
Bag, PE liner, 25 kg net

Lot/ Batchnumber : 100823
Date of production : 11.2019
Retest date : 10.2023
Order number : 10580620
Your order number : PH190654

Analysis

Chemical & Physical

Characteristic	Method of analysis	Unit	Specification	Results
Identification A (Iodine $ZnCl_2$)	USP-NF; Ph. Eur.		Pass	Pass
Identification C (dispersion)	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	4.0
pH potentiometric	Pharmacopeia Harmonized methods		5.5-7.0	6.3
Degree of polymerization	USP-NF; Ph. Eur.; JP		0-350	239
Conductivity	USP-NF; Ph. Eur.; JP	$\mu S/cm$	0-75	46
Residue on ignition	USP-NF; Ph. Eur.; JP	%	0.00-0.05	0.02
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	0.02
Heavy metals	USP-NF		max 10 mg/kg	Pass
Arsenic	IP		Max. 2ppm	Pass
Assay	IP	%	97.0-102.0	99.4
Solubility (amyl. 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. 2.6.13.; USP <62>, JP 4.05 (3.3)		Negative	Negative

Manufacturer: DMV-Fonterra Excipients GmbH & Co. KG, Goch, Germany





0-436-R1-10590W6-20191219-113446-Z006-3420_IN_01-000001

OTHERS

Characteristic	Method of analysis	Unit	Specification	Results
Bulk density	USP-MF; JP	g/cm ³	0.26-0.31	0.27
Particle size d10	Internal, laser diffraction dry	µm	Report value	23
Particle size d50	Internal, laser diffraction dry	µm	Report value	61
Particle size d90	Internal, laser diffraction dry	µm	Report value	124
Particle size <250 µm	equal to ISO 4610	%(m)	>=99.0	99.9
Particle size <75 µm	equal to ISO 4610	%(m)	70.0-90.0	76.1

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

Produced by DFE Pharma India LLP, Cuddalore, India.

Material numbers: 0733317, 0733326

Produced exclusively for DFE Pharma India LLP by
Chemfield Cellulosics Pvt. Ltd., Nagpur, India

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Verified By :

QA Dept
PT SIGNA MUSADA

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Manufacturer: DMV-Fonterra Excipients GmbH & Co. KG, Goch, Germany

