Evonik Operations GmbH - D-63403 Hanau

Evonik India Private Limited
Mumbai Nashik Highway
Building B 600,K Square Industrial and
421101 MAHARASHTRA-BHIWANDI-THANE
INDIA

Inspection Certificate 3.1 according to EN 10204

Date	09.06.2023
Delivery Number / Item	3009486470 / 900003
Order Number / Item	46325955 / 000010
Silica	
Customer Number	503898

Sold-to
Evonik India Private Limited
Mumbai Nashik Highway
Building B 600,K Square Industrial and
421101 MAHARASHTRA-BHIWANDI-THANE
INDIA

Product	AEROSIL® 200 Pharma 18 x 10 KG / 22.00 lbs Paper Bag - / CP3 Wood pallet
Material	99133084
Quantity	3.600 KG = 360 BAG
Batch	233040220
Production date	02-Apr-23
Expiration date	01-Apr-25
Delivery date	09-Jun-23
Spec. No.	K00, Vers. 24.04.2020
Container/Railcar	HLXU 541125-9
Seal Text	VM029160

Delivery date = Estimated time of dispatch / departure

Property	Test Method	Unit	Value	Target	Min	Max
Specific surface area	ISO 9277, modified	m²/g	204	200	175	225
Identification	tested acc. to Ph.Eur.		Conforms	pass		
Assay (SiO2 content)	tested acc. to Ph.Eur.	%	99.8		99.0	100.5
pH value	tested acc. to Ph.Eur.		4.4		3.5	5.5
Chlorides <=250ppm	tested acc. to Ph.Eur.		Conforms	pass		
Loss on ignition	tested acc. to Ph.Eur.	%	0.7			5.0
Identification (1),(2) and (3)	tested acc. to JP		Conforms	pass		
Loss on drying	tested acc. to JP	%	0.9			7.0
Loss on ignition	tested acc. to JP	%	0.6			12.0
Al content	tested acc. to JP		Conforms	pass		

Product	AEROSIL® 200 Pharma 18 x 10 KG / 22.00 lbs Paper Bag - / CP3 Wood pallet		
Material	99133084	Date	09.06.2023
Batch	233040220	Delivery Number / Item	3009486470 / 900003

Property	Test Method	Unit	Value	Target	Min	Max
Fe content <=500ppm	tested acc. to JP		Conforms	pass		
Ca content	tested acc. to JP		Conforms	pass		
As content <=5ppm	tested acc. to JP		Conforms	pass		
Cl content <=0,011%	tested acc. to JP		Conforms	pass		
Heavy metals <=40ppm	tested acc. to JP		Conforms	pass		
Assay (SiO2 content)	tested acc. to JP	%	99.2		98.0	
As content <=8ppm	tested acc. to USP/NF		Conforms	pass		
Loss on drying	tested acc. to USP/NF	%	0.3			2.5
Loss on ignition	tested acc. to USP/NF	%	0.4			2.0
Identification, A and B	tested acc. to USP/NF		Conforms	pass		
pH value	tested acc. to USP/NF		4.2		3.5	5.5
Assay (SiO2 content)	tested acc. to USP/NF	%	100.0		99.0	100.5
As content (E551)	SOP AE_FQ01	ppm	Conforms			3.0
Pb content (E551)	SOP AE_FQ02	ppm	Conforms			5.0
Hg content (E551)	SOP AE_FQ03	ppm	Conforms			1.0
Na2SO4 content (E551)	SOP AE_FQ06	%	Conforms			5.0
Identification	tested acc. to IP		Conforms	pass		
Assay (SiO2 content)	tested acc. to IP	%	99.8		99.0	100.5
pH value	tested acc. to IP		4.4		3.5	5.5
Loss on ignition	tested acc. to IP	%	0.7			5.0
As content <=8ppm	tested acc. to IP		Conforms	pass		
Heavy metals <=25ppm	tested acc. to IP		Conforms	pass		
Chlorides <=250ppm	tested acc. to IP		Conforms	pass		

Product	AEROSIL® 200 Pharma 18 x 10 KG / 22.00 lbs Paper Bag - / CP3 Wood pallet		
Material	99133084	Date	09.06.2023
Batch	233040220	Delivery Number / Item	3009486470 / 900003

AEROSIL® 200 Pharma:

Colloidal Silicon Dioxide tested according to Ph.Eur., USP/NF, JP and IP (current Version).

TAMC (total aerobic microbial count) , TYMC (total combined yeast and mould count) and Gram-negative bacteria are tested on a regular basis acc. to USP .

Manufactured and packaged in a dedicated closed production system according to GMP guidelines established for bulk pharmaceutical excipients by the International Pharmaceutical Excipients Council (IPEC/GMP).

Material manufactured applying an HACCP system which fulfills the requirements of the following regulation of the European Union: (EC) No 852/2004.
Purity criteria for E 551 according to (EU) 231/2012 (specifications for food additives regarding (EG) 1333/2008 Annex II and III) are met.

White, fine, amorphous powder.

Typical sieve residue (Grit, 45 µm) is < 0.025 % (according to ISO 787-18).

Elemental Impurities:
Elemental Impurities are not intentionally added to the production process.
The elemental impurities of the ICH Q3D are tested on a regular basis acc. to USP 233 and Ph. Eur. 5.20.

Residual solvents:
No organic solvents are used in the manufacture of above mentioned product. For this reason, constitutionally no residual solvents as cited in recent versions of the European Pharmacopoeia, (class 1, 2 and 3 or other solvents, USP chapter 467), 2008 and amendments are present in concentration about the control limits quoted in USP. For above mentioned product class 1 residual solvents are tested on a regular basis according to USP/NF: Carbon tetrachloride, 1,2 Dichlorethane, 1,1 Dichlorethene, 1,1,1 Trichlorethane and Benzene.

TSE/BSE and materials of plant origin:
No raw materials of animal or plant origin (as mentioned in EMEA/410/01, current version) are used in the production process of AEROSIL® Pharma products. AEROSIL® Pharma products have not been in contact with and constitutionally do not include any material of animal or plant origin. We generally do not use any material of animal or plant origin in our production facilities. AEROSIL® Pharma products are not contaminated with material of animal or plant origin when they leave our production and warehouses.

Tests according to Ph.Eur., USP/NF, JP and IP and for specific surface area are performed in the laboratory of Evonik Operations GmbH, Rheinfelden, Germany.

This product is manufactured in Site Antwerp,
Tijsmanstunnel West, B-2040 Antwerpen, Belgium.

Product	AEROSIL® 200 Pharma 18 x 10 KG / 22.00 lbs Paper Bag - / CP3 Wood pallet		
Material	99133084	Date	09.06.2023
Batch	233040220	Delivery Number / Item	3009486470 / 900003

Leontine Van der Linden
Inspector,
Antwerp site, Belgium
Tijsmanstunnel west, B-2040 Antwerpen
+32 3 560 3154
leontine.van-der-linden@evonik.com

This document is computer printed and therefore without signature. All warranty claims in respect to the conformity of our product are subject to our General Terms and Conditions of Sale and Delivery. The data listed above reflects the results of our internal quality tests. We do not hereby make any express or implied warranty, whether for specific properties or for fitness for any particular application or purpose. All values are valid for the product when despatched from the works.

*** End ***