Product specification

Material AEROPERL® 300 Pharma
Spec.Code K00

Evonik Resource Efficiency GmbH

Business Line Silica

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Inspection Characteristics	Method	Limits	Units	Z
Specific surface area	ISO 9277, modified	260-320	m²/g	X
Identification	tested acc. to Ph.Eur.	pass		C
Assay (SiO2 content)	tested acc. to Ph.Eur.	99.0-100.5	%	X
pH value	tested acc. to Ph.Eur.	3.5-5.5		X
Chlorides <=250ppm	tested acc. to Ph.Eur.	pass		C
Loss on ignition	tested acc. to Ph.Eur.	<=5.0	%	X
As content <=8ppm	tested acc. to USP/NF	pass		C
Loss on drying	tested acc. to USP/NF	<=2.5	%	X
Loss on ignition	tested acc. to USP/NF	<=2.0	%	X
Identification, A and B	tested acc. to USP/NF	pass		C
pH value	tested acc. to USP/NF	3.5-5.5		X
Assay (SiO2 content)	tested acc. to USP/NF	99.0-100.5	%	X

Report on inspection certificate: X = specific/actual value, C = unspecific value/conformity, T = not reported

AEROPERL® 300 Pharma:
Colloidal Silicon Dioxide tested according to Ph.Eur. and USP/NF (current Version)
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).

White, fine, amorphous powder.

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 AEROPERL® Pharma products. AEROPERL® 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. AEROPERL® Pharma products are not contaminated with material of animal or plant origin when they leave our production and warehouses.

This product is manufactured in Site Rheinfelden, Untere Kanalstrasse 3, 79618 Rheinfelden, Germany.

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The Standard Test Methods can be obtained from specialized publishers. Evonik's test methods are available on request.