## Product specification

**Material** **AEROSIL® 200 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 | 175-225 | 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 |
| Identification (1),(2) and (3) | tested acc. to JP | pass | | C |
| Loss on drying | tested acc. to JP | <=7.0 | % | X |
| Loss on ignition | tested acc. to JP | <=12.0 | % | X |
| Al content | tested acc. to JP | pass | | C |
| Fe content <=500ppm | tested acc. to JP | pass | | C |
| Ca content | tested acc. to JP | pass | | C |
| As content <=5ppm | tested acc. to JP | pass | | C |
| Cl content <=0.011% | tested acc. to JP | pass | | C |
| Heavy metals <=40ppm | tested acc. to JP | pass | | C |
| Assay (SiO2 content) | tested acc. to JP | >=98.0 | % | 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 |
| As content (E551) | SOP AE_FQ01 | <=3.0 | ppm | C |
| Pb content (E551) | SOP AE_FQ02 | <=5.0 | ppm | C |
| Hg content (E551) | SOP AE_FQ03 | <=1.0 | ppm | C |
| Na2SO4 content (E551) | SOP AE_FQ06 | <=5.0 | % | C |
| Identification | tested acc. to IP | pass | | C |
| Assay (SiO2 content) | tested acc. to IP | 99.0-100.5 | % | X |
| pH value | tested acc. to IP | 3.5-5.5 | | X |
| Loss on ignition | tested acc. to IP | <=5.0 | % | X |
| As content <=8ppm | tested acc. to IP | pass | | C |
| Heavy metals <=25ppm | tested acc. to IP | pass | | C |
| Chlorides <=250ppm | tested acc. to IP | pass | | C |

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

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.

This product is manufactured in Site Antwerp,

Tijsmanstunnel West, B-2040 Antwerpen, Belgium.

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