

## Specification

### AEROSIL® 200 Pharma

Evonik Industries AG  
 Inorganic Materials  
 Dr. Martin Reisinger  
 Tel. 49-(0)6181/59- 2839  
 martin.reisinger@evonik.com

Spec. no.:	1365/1
Material number, Bulk:	23.8014.0001.00
Valid for all forms of packaging	

Standard

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 date of print: 16.12.2011  
 valid from: 01.05.2011

### Product specification

Properties and Test Methods	Units	Target Values (Spec. Limits)
663/DA07 <b>AEROSIL® 200 Pharma</b> <b>Colloidal Silicon Dioxide</b> <b>tested according to</b> <b>Ph.Eur., USP/NF and JP</b>		
663/DA07 USP 34 - NF 29 (2011) Ph.Eur. Edition 7.0 (2011) JPXV 2006		
663/0100 <b>Specific surface area (BET)</b>	m <sup>2</sup> /g	200 (175 - 225)
663/DA05 <b>Fine, white, amorphous powder</b>		
663/DA10 <b>Identification</b>		pass
663/DA10 tested according to Ph.Eur.		
663/DA40 <b>pH</b>		3,5 - 5,5
663/DA40 tested according to Ph.Eur.		
663/DA50 <b>Chlorides</b>	ppm	<= 250
663/DA50 tested according to Ph.Eur.		
663/DA60 <b>Heavy metals</b>	ppm	<= 25
663/DA60 tested according to Ph.Eur.		
663/DA70 <b>Loss on ignition</b>	%	<= 5,0
663/DA70 tested according to Ph.Eur.		
663/DA20 <b>Assay (SiO<sub>2</sub>-content)</b>	%	99,0 - 100,5
663/DA20 tested according to Ph.Eur.		
663/NF40 <b>Identification, A and B</b>		pass
663/NF40 tested according to USP/NF		
663/NF50 <b>pH</b>		3,5 - 5,5
663/NF50 tested according to USP/NF		
663/NF20 <b>Loss on drying</b>	%	<= 2,5
663/NF20 tested according to USP/NF		
663/NF30 <b>Loss on ignition</b>	%	<= 2,0
663/NF30 tested according to USP/NF		
663/NF10 <b>Arsenic</b>	µg/g	<= 8
663/NF10 tested according to USP/NF		
663/PHA1 <b>Residual Solvents</b>		
663/PHA1 There are no organic solvents		

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### Properties and Test Methods

### Units

### Target Values (Spec. Limits)

#### 663/JP91 TSE / BSE and materials of plant origin

663/JP91 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.

#### 663/JP93 Residual solvents

663/JP93 No organic solvents are used during the production process of AEROSIL® Pharma products. For this reason, constitutionally no residual solvents (as cited in CPMP/ICH/283/95, Ph. Eur., USP/NF and their amendments) are present.

All warranty claims in respect of the conformance of our product are subject to our terms of contract and General terms and Conditions of Sale and Delivery. The data listed above reflects the criteria for 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 plants.