

Certificate of Analysis

1.20610.9015 Candurin® Gold Lustre
Batch W240500X10

	Spec. Values		Batch Values		Method
Assay (E 555 Mica)	49.0 - 60.0	%	58.1	%	In-house
Assay (E 171 Titanium dioxide)	35.0 - 43.0	%	36.5	%	In-house
Assay (E 172 Iron oxide red)	5.0 - 8.0	%	5.4	%	In-house
pH (10% aqueous suspension)	8.0 - 11.0		10.1		ISO 787-9
Loss on Drying (105 °C)	≤ 0.5	%	≤ 0.5	%	ISO 787-2
Particle Size Distribution (80% within the range 10.0 - 60.0 µm)	conforms		conforms		laser diffraction
Particle Size (d50)	18.0 - 25.0	µm	23.5	µm	laser diffraction
Heavy metals (As)	≤ 3	ppm	≤ 3	ppm	In-house
Heavy metals (Ba)	≤ 25	ppm	≤ 25	ppm	In-house
Heavy metals (Cd)	≤ 0.5	ppm	≤ 0.5	ppm	In-house
Heavy metals (Cr)	≤ 100	ppm	≤ 100	ppm	In-house
Heavy metals (Cu)	≤ 25	ppm	≤ 25	ppm	In-house
Heavy metals (Hg)	≤ 1	ppm	≤ 1	ppm	In-house
Heavy metals (Ni)	≤ 50	ppm	≤ 50	ppm	In-house
Heavy metals (Pb)	≤ 4	ppm	≤ 4	ppm	In-house
Heavy metals (Sb)	≤ 1	ppm	≤ 1	ppm	In-house
Heavy metals (Zn)	≤ 25	ppm	≤ 25	ppm	In-house
Visual and Colorimetric Evaluation	conforms		conforms		In-house
Microbial Purity (Total Viable Aerobic Count)	≤ 1·10 ²	CFU/g	< 1·10 ¹	CFU/g	USP, Ph.Eur.
E.coli	absent in 1 g		passes test		USP, Ph.Eur.
Pseudomonas aeruginosa	absent in 1 g		passes test		USP, Ph.Eur.
Staphylococcus aureus	absent in 1 g		passes test		USP, Ph.Eur.
Salmonella species	absent in 10 g		passes test		USP, Ph.Eur.
Candida albicans	absent in 1 g		passes test		USP, Ph.Eur.

The product conforms to the applicable requirements in Regulation (EU) No 231/2012 and 21 CFR Part 73.

Manufactured and released by Merck Surface Solutions GmbH, 64579 Gernsheim, Deutschland, an affiliate of Merck KGaA, Darmstadt, Germany

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Minimum shelf life (DD.MM.YYYY) 31.01.2030

Dr. Martin Blömkör

Responsible laboratory manager quality control

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By/On: *RP* 20/03/25