

Evonik Operations GmbH - D-64275 Darmstadt

PT IMCD Indonesia
 Blugreen-Boutique Office, Tower C-D, 3rd
 Jl. Lingkar Luar Barat Kav. 88
 Puri Kembangan
 JAKARTA 11610
 INDONESIA

Product EUDRAGIT® E PO
 0.25 KG Bottle 3H1
 Quantity 2,5 KG = 10 EA
 Batch G230931015
 Production date 09/2023
 Stability at least until 09/2026
 end of

Certificate of Analysis

Date	12.09.2024
Delivery Number / Item	3010786824 / 000012
Order Number / Item	2006599793 / 000012
Date	21.08.2024
Contact Person	Eva Schuler
Mail	eva.schuler@evonik.com
Customer no.	7250098713
Your purchase order	Sample Order Eudragit
Date	21.08.2024

Property	Unit	Value	Specification			
			Evonik	Ph.Eur.	NF	JPE
Dry substance / Residue on evaporation	%	99,5	min. 98.0	N/A	N/A	N/A
Loss on drying	%	0,6	max. 2.0	max. 2.0	max. 2.0	max. 2.0
Dimethylaminoethyl units, based on DS	%	22,5	20.8 - 25.5	20.8 - 25.5	20.8 - 25.5	N/A
Alkali value	mgKOH/gDS	175	162 - 198	N/A	N/A	N/A
Assay (% Nitrogen)	%	4,4	4.0 - 6.0	N/A	N/A	4.0 - 6.0
Particle size (d50v/v)	µm	11	< 50	N/A	N/A	N/A
Viscosity / Apparent viscosity	mPa·s	4	3 - 6	3 - 6	3 - 6	N/A
Viscosity	mm²/s	3,5	2.5 - 5.5	N/A	N/A	2.5 - 5.5
Monomers	ppm	357	< 2500	N/A	N/A	N/A
Butyl methacrylate	ppm	74	< 1000	max. 0.1 %	max. 0.1 %	max. 1000
Methyl methacrylate	ppm	9	< 500	max. 0.1 %	max. 0.1 %	max. 500
Dimethylaminoethyl methacrylate	ppm	274	< 1000	max. 0.1 %	max. 0.1 %	max. 1000

Test methods are as prescribed in Evonik Operations GmbH Specification or referenced pharmacopoeias. Tests not listed above are performed on selected lots. Relevant data are available on request. The customer is not released from the obligation to conduct careful inspection and testing of incoming products.

This Product conforms to:

"Specifications and test methods for EUDRAGIT® E 100, EUDRAGIT® E PO and EUDRAGIT® E 12,5"
 "Basic Butylated Methacrylate Copolymer" Ph. Eur.
 "Amino Methacrylate Copolymer" NF
 "Aminoalkyl Methacrylate Copolymer E" JPE

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Manufacturer:

Evonik Operations GmbH
Site Darmstadt/Weiterstadt
Kirschenallee
64293 Darmstadt
Germany

GMP Compliance:

Compliance of manufacturing, testing, packaging, storage and release with the "EXCiPACT™ Standard for Pharmaceutical Excipient Suppliers: Good Manufacturing Practices" has been certified.

This product is manufactured according to current Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients as published by IPEC-PQG and in USP < 1078 >.

Residual Solvents Statement regarding Ph. Eur. 5.4 and USP < 467 >:

This product contains small amounts of 2-Propanol.

The concentration remains max. 4999 ppm.

Small amounts of Methanol may be detectable in the product within the minimum stability period.

The concentration remains max. 999 ppm.

Small amounts of Butanol may be detectable in the product within the minimum stability period.

The concentration remains max. 4999 ppm.

BSE/TSE Confirmation:

No animal based material is used in the manufacture of this product.

Genetically Modified Materials:

This product is manufactured by chemical process. None of the ingredients are of natural origin.

Evonik Operations GmbH

Michael Kübitz
(Head of Global Sales Support
Health Care)
(Written by computer and therefore not signed)

Dr. Christian Brämer
(Head of Quality Darmstadt/Weiterstadt
Health Care)

*** End ***