

METAPHARMACEUTICAL

N DE LOTE:

0100625

Ngondro

Date

2025-03-26

(YYYY-MM-DD)

Time

12:16:26

(Greenwich Mean Time)

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DOW FRANCE S.A.S.



Ship From: Antwerp H Essers 1097 Whse
Wilrijk
Belgium

Certificate of Analysis

Product Number 00000166998
Product Name
CARBOWAX™ SENTRY™ Polyethylene Glycol 4000 NF
Powder (Uninhibited); Macrogol 4000 Ph. Eur.
Delivery No. 829367484 / 000010
Order Number 117033924
Date Shipped 2025-03-26 (YYYY-MM-DD)
Shipment No. 46123145

Customer Information

Customer Product Code 000000000001015106
Customer Product Name CARBOWAX SENTRY PEG 4000 U
PDR 22.68K BG
Container ID ON04ZR
Vehicle# 81BVJ9
Specification Number 000000085563

Batch Number D6840CBBG1
Retest Date 2027-12-11 (YYYY-MM-DD)
Manufacturing Date 2024-12-11 (YYYY-MM-DD)

It is hereby certified that the material indicated above has been manufactured in accordance with current Good Manufacturing Practices Guide for Active Pharmaceutical Ingredients-ICH Q7 was inspected and tested in accordance with the conditions and the requirements of current monographs for National Formulary - Polyethylene Glycols; European Pharmacopoeia -MACROGOLS. The manufacturing facility and this product have been Kosher certified.

Test	Unit	Lower Limit	Upper Limit	Value	Method
Mole Weight, Average		3600	4400	4024	Current NF
Ethylene Oxide	ppm	-	10	0	Current NF
1,4-Dioxane	ppm	-	10	0	Current NF
pH		4,5	7,5	6,7	Current NF
25degC 5% aqueous solution					
Viscosity	cSt	110	158	134	Current NF
210degF					
Q Comp & Color of Soln	-	-	-	Pass	Current NF
5g/50mL less than slight haze					
Q Residue on Ignition	-	-	-	Pass	Current USP
less than 0.1%					
Appearance	-	-	-	Pass	Current EP
white solid with a waxy appearance					
Identification: a	-	-	-	Pass	Current EP
Acidity	-	-	-	Pass	Current EP
less than 0.1mL of 0.1M NaOH					
Viscosity	mPa.s	110	170	121	Current EP
20degC 50% AQ					
Hydroxyl Value		25	32	28	Current EP
Ethylene Oxide	ppm	-	1	0	Current EP

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1 1,4-Dioxane	ppm	-	10	0	Current EP
Water	WT%	-	1,0	0,1	Current EP
Q Identification: b, c	-	-	-	Pass	Current EP
Q Appearance of Soln	-	-	-	Pass	Current EP
Q Freezing Point between 53 - 59 deg C	-	-	-	Pass	Current EP
Q Reducing Substances	-	-	-	Pass	Current EP
Q Formaldehyde less than 15 ppm	-	-	-	Pass	Current EP
Q Sulphated Ash less than 0.2%	-	-	-	Pass	Current USP
Appearance Neat	-	-	-	Pass	DOWM 101924
BHT	ppm	-	20	6	DOWM 102906
Color, Pt-Co 25% aqueous solution	-	-	18	4	ASTM D5386
Diethylene Glycol	ppm	-	300	< 21	DOWM 102369
1 Ethylene Glycol	ppm	-	300	< 27	DOWM 102369
2 Acetic Acid less than 5000 ppm	-	-	-	Pass	Current EP

1:Residual Solvents - Class 2 Solvent

2:Ph. Eur. 2.4.24 ID and Control of Residual Solvents Class 3

Q:Analyzed Quarterly

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Belgium

Kyle Levy

Kyle Levy
Quality Manager

Original Manufacture/Location of Manufacture: D684=The Dow Chemical Company, St. Charles Operations, E-Park Plant, 355 Highway 3142, Hahnville, LA 70057 (previously known as Taft), Phone: 800-331-6451

Bulk SENTRY- PEGs: The Dow Chemical Company, St. Charles Operations, E-Park Plant
Packaged SENTRY- PEGs: Manufacturing: The Dow Chemical Company, St. Charles Operations, E-Park Plant; Packaging: The Dow Chemical Company St. Charles Operations, E-Park Plant

For inquiries please contact Customer Service or local sales

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F&A PHARMA

B.V.