

METAPHARMACEUTICAL




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af 15/04/2024

Date 2024-02-13 (YYYY-MM-DD)

Time 12:36:02 (Greenwich Mean Time) Page 1 of 2

 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. 827046730 / 000010 Order Number 115679021 Date Shipped 2024-02-13 (YYYY-MM-DD) Shipment No. 44089159		Customer Information Customer Product Code 000000000001015106 Customer Product Name CARBOWAX SENTRY PEG 4000 U PDR 22.68K BG Container ID KCF631 Vehicle# kcf631 Specification Number 000000085563			
Batch Number D684NAVBG1 Retest Date 2026-10-31 (YYYY-MM-DD) Manufacturing Date 2023-10-31 (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	4000	Current NF
Ethylene Oxide	ppm	-	10	0	Current NF
1,4-Dioxane	ppm	-	10	0	Current NF
pH 25degC 5% aqueous solution		4,5	7,5	6,6	Current NF
Viscosity 210degF	cSt	110	158	135	Current NF
Q Comp & Color of Soln 5g/50mL-less than slight haze	-	-	-	Pass	Current NF
Q Residue on Ignition less than 0.1%	-	-	-	Pass	Current USP
Appearance white solid with a waxy appearance	-	-	-	Pass	Current EP
Identification: a	-	-	-	Pass	Current EP
Acidity less than 0.1mL of 0.1M NaOH	-	-	-	Pass	Current EP
Viscosity 20degC 50% AQ	mPa.s	110	170	124	Current EP
Hydroxyl Value		25	32	28	Current EP
Ethylene Oxide	ppm	-	1	0	Current EP

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<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 35%;">1,4-Dioxane</td> <td style="width: 10%;">ppm</td> <td style="width: 10%;">-</td> <td style="width: 10%;">10</td> <td style="width: 10%;">0</td> <td style="width: 25%;">Current EP</td> </tr> <tr> <td>Water</td> <td>WT%</td> <td>-</td> <td>1,0</td> <td>0,1</td> <td>Current EP</td> </tr> <tr> <td>Q Identification: b, c</td> <td>-</td> <td>-</td> <td>-</td> <td>Pass</td> <td>Current EP</td> </tr> <tr> <td>Q Appearance of Soln</td> <td>-</td> <td>-</td> <td>-</td> <td>Pass</td> <td>Current EP</td> </tr> <tr> <td>Q Freezing Point between 53 - 59 deg C</td> <td>-</td> <td>-</td> <td>-</td> <td>Pass</td> <td>Current EP</td> </tr> <tr> <td>Q Reducing Substances</td> <td>-</td> <td>-</td> <td>-</td> <td>Pass</td> <td>Current EP</td> </tr> <tr> <td>Q Formaldehyde less than 15 ppm</td> <td>-</td> <td>-</td> <td>-</td> <td>Pass</td> <td>Current EP</td> </tr> <tr> <td>Q Sulphated Ash less than 0.2%</td> <td>-</td> <td>-</td> <td>-</td> <td>Pass</td> <td>Current USP</td> </tr> <tr> <td>Appearance Neat</td> <td>-</td> <td>-</td> <td>-</td> <td>Pass</td> <td>DOWM 101924</td> </tr> <tr> <td>BHT</td> <td>ppm</td> <td>-</td> <td>20</td> <td>6</td> <td>DOWM 102906</td> </tr> <tr> <td>Color, Pt-Co 25% aqueous solution</td> <td>-</td> <td>-</td> <td>18</td> <td>3</td> <td>ASTM D5386</td> </tr> <tr> <td>Diethylene Glycol</td> <td>ppm</td> <td>-</td> <td>300</td> <td>< 21</td> <td>DOWM 102369</td> </tr> <tr> <td>Ethylene Glycol</td> <td>ppm</td> <td>-</td> <td>300</td> <td>< 27</td> <td>DOWM 102369</td> </tr> <tr> <td>2 Acetic Acid less than 5000 ppm</td> <td>-</td> <td>-</td> <td>-</td> <td>Pass</td> <td>Current EP</td> </tr> </table>		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	3	ASTM D5386	Diethylene Glycol	ppm	-	300	< 21	DOWM 102369	Ethylene Glycol	ppm	-	300	< 27	DOWM 102369	2 Acetic Acid less than 5000 ppm	-	-	-	Pass	Current EP
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2:Ph. Eur. 2.4.24 ID and Control of Residual Solvents Class 3 Q:Analyzed Quarterly 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 © ™ Trademark of The Dow Chemical Company ("Dow") or an affiliated company of Dow																																																																																					