

## METAPHARMACEUTICAL

N DE LOTE:




0030624

06/06/2024

Date

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

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

 DOW FRANCE S.A.S.		 Date: 08/06/24 Signature: [Signature] F&A PHARMA Senteles B.V.		 Ship From: Antwerp H Essers 1097 Whse Wilrijk Belgium	
<b>Certificate of Analysis</b>			<b>Customer Information</b>		
Product Number 00000166998			Customer Product Code 000000000001015106		
Product Name CARBOWAX™ SENTRY™ Polyethylene Glycol 4000 NF Powder (Uninhibited); Macrogol 4000 Ph. Eur.			Customer Product Name CARBOWAX SENTRY PEG 4000 U PDR 22.68K BG		
Delivery No. 827046730 / 000010			Container ID KCF631		
Order Number 115679021			Vehicle# kcf631		
Date Shipped 2024-02-13 (YYYY-MM-DD)			Specification Number 000000085563		
Shipment No. 44089159					
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		4,5	7,5	6,6	Current NF
25degC 5% aqueous solution					Current NF
Viscosity	cSt	110	158	135	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	124	Current EP
20degC 50% AQ					
Hydroxyl Value		25	32	28	Current EP
Ethylene Oxide	ppm	-	1	0	Current EP

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



DOW FRANCE S.A.S.



Ship From: Antwerp H Essers 1097 Whse  
Wilrijk  
Belgium

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	-	-	-	Pass	Current EP
between 53 - 59 deg C	-	-	-	Pass	Current EP
Q Reducing Substances	-	-	-	Pass	Current EP
Q Formaldehyde	-	-	-	Pass	Current EP
less than 15 ppm	-	-	-	Pass	Current EP
Q Sulphated Ash	-	-	-	Pass	Current USP
less than 0.2%	-	-	-	Pass	Current USP
Appearance	-	-	-	Pass	DOWM 101924
Neat	-	-	-	Pass	DOWM 101924
BHT	ppm	-	20	6	DOWM 102906
Color, Pt-Co	-	-	18	3	ASTM D5386
25% aqueous solution	-	-	18	3	ASTM D5386
Diethylene Glycol	ppm	-	300	< 21	DOWM 102369
Ethylene Glycol	ppm	-	300	< 27	DOWM 102369
2 Acetic Acid	-	-	-	Pass	DOWM 102369
less than 5000 ppm	-	-	-	Pass	Current EP

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

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