## **METAPHARMACEUTICAL**

N DE LOTE: 0030624

Date

2024-02-13

(YYYY-MM-DD)

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

Customer Information



DOW FRANCE S.A.S.



F&A PHARMA

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. Order Number

827046730 / 000010

44089159

115679021

Customer Product Code

Customer Product Name

CARBOWAX SENTRY PEG 4000 U

PDR 22.68K BG

000000000001015106

Date Shipped

Shipment No.

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

Vehicle#

Container ID

KCF631 kcf631

Specification Number

000000085563

Batch Number

Manufacturing Date

Retest Date

D684NAVBG1

2026-10-31 (YYYY-MM-DD)

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	n	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 h	- naze		-	Pass	Current NF
Q Residue on Ignition less than 0.1%	=		=	Pass	Current USP
Appearance white solid with a waxy ap	- opearance	-	2	Pass	Current EP
Identification: a	_	::	- ·	Pass	
Acidity less than 0.1mL of 0.1M Na	- OH	:	5.	Pass	Current EP
Viscosity 20degC 50% AQ	mPa.s	110	170	124	Current EP
Hydroxyl Value		25	32	28	Φ.
Ethylene Oxide	ppm	=	1		Current EP
	FF		1	0	Current EP



DOW FRANCE S.A.S.



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			1,0110		
			Be:	lgium	
1,4-Dioxane	ppm	-	10	0	Current EP
Water	WT%	1 <del>.5</del>	1,0	0,1	Current EP
Q Identification: b, c	=	S <del></del>	<u>200</u> 4	Pass	The same of the sa
Q Appearance of Soln	· <del>***</del>	7-	<u>=</u> ;	Pass	Current EP
Q Freezing Point between 53 - 59 deg C	5=3	12	=	Pass	Current EP
Q Reducing Substances	-	-	8 <b>—</b> 8	Pass	Current EP
Q Formaldehyde less than 15 ppm	-	-	_	Pass	Current EP
Q Sulphated Ash less than 0.2%	<del>(</del>	-	:=	Pass	Current USP
Appearance Neat	-	=	-	Pass	DOWM 101924
BHT	ppm	-	20	60	DOWM 102906
Color, Pt-Co 25% aqueous solution		-	18	3	ASTM D5386
Diethylene Glycol	ppm	-	300	O< 21	DOWM 102369
Ethylene Glycol	ppm	124	300	< 27	DOWM 102369
2 Acetic Acid less than 5000 ppm		-	- Y	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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