



IC LOGISTICS
INDUSTRIEWEG 118/5
B-9032 WONDELGEM

Certificate of Analysis/Conformity

Shipment date 29.12.2022		
Truck / Trailer / Container OK 26 BJ		
Delivery item 91346437 000010	Shipment 3241927	Delivery item date 02.01.2023
Order item 2662378 000010		Order item date 29.11.2022
Customer number 50207		Reference from Customer PO231056333
Customer variant UP200 50207 01		

Date format used = dd.mm.yyyy or mm.yyyy

Material UP200251107	Our reference MERISORB 200 PHARMA SORBITOL	PACKED	Your reference 149958 MERISORB 200 PHARMA /
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Produced by : 1411 TSS Europe SAS - 80190 MESNIL-SAINT-NICAISE - France - FR

Batch F2K324602 Quantity 10,000 TO

Production date 20.11.2022 Expiry date 19.11.2024

Inspection lot number 100001273947 Inspection date 27.12.2022

Test	Unit of measure	Test result	Specification	Test Method	Remark
D-sorbitol	%/ds	99,1	97,0 - 102,0	239	Analysis
Identification A		conform	conform	239	Analysis
Appearance of solution		conform	conform	209	Analysis
Conductivity	$\mu\text{S}/\text{cm}$	11	≤ 20	1203	Analysis
Reducing sugars	%/cp	0,1	$\leq 0,2$	212	Analysis
Reducing sugars	mL	18,1	$\geq 12,8$	212	Analysis
Related substances - total	%/ds	1,4	$\leq 3,0$	239	Analysis
Impurity A	%/ds	$< 2,0$	$\leq 2,0$	239	Analysis
Impurity B	%/ds	$< 2,0$	$\leq 2,0$	239	Analysis
Impurity C	%/ds	$< 2,0$	$\leq 2,0$	239	Analysis
Water	%	0,1	$\leq 1,5$	115	Analysis
TAMC	n/g	< 100	≤ 1000	1995	Analysis
TYMC	n/g	< 10	≤ 100	1995	Analysis
Escherichia coli (/g)		absent	absent	1996	Analysis
Salmonella (/10g)		absent	absent	1996	Analysis

For parameters not appearing on the CoA/CoC or when no result is reported, we certify that the product contained in this shipment meets and conforms to all requirements of the agreed specification.

Compliance: Ph. Eur. and USP-NF monographs in force.

METAPHARMACEUTICAL

N DE LOTE:

0310623

29 JUN. 2023

Mrs. Christine Caseiro, Quality Manager Tereos Starch & Sweeteners Europe SAS, 80190 Mesnil-Saint-Nicaise, France. Acting on behalf of Tereos Starch & Sweeteners Belgium NV. Tel. +33 (0) 322 87 76 76

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