

REF:80688272/900001/1152068

Certificate of analysis / Compliance

Manufacturing site

ROQUETTE Frères, 1 Rue de la Haute Loge, 62136, LESTREM, France

References

Product name PEARLITOL® 200 SD - MANNITOL Ph.Eur. - USP/NF

GTIN/EAN

Material Code 450 320 113 P

Batch Number 1152068

Manufacturing Date 2025/06/16

Expiry Date 2030/06/15

Sales Order / Item

Delivery / Item

Your Reference

Product description

Aspect Powder

Colour White or almost white

Results of Analysis / Compliance

Parameter	Specification range	Result	Unit	Status
IDENTIFICATION TEST A (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST C (EP)	Conform	Conform		Guaranteed
IDENTIFICATION TEST 1 (JP)	Conform	Conform		Guaranteed
LOSS ON DRYING	<= 0,5	0,1	%	Inspected
REDUCING SUGARS (AS IS)	<= 0,1	Conform	%	Guaranteed
MANNITOL (ON DS)	97,0 - 102,0	99,9	%	Inspected
SORBITOL (ON DS)	<= 2,0	0,8	%	Inspected

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Parameter	Specification range	Result	Unit	Status
MALTITOL AND ISOMALT (ON DS)	<= 2,0	0,0	%	Inspected
ANY UNSPECIFIED IMPURITY (ON DS)	<= 0,10	0,0	%	Inspected
TOTAL IMPURITIES (ON DS)	<= 2,0	0,2	%	Inspected
CONDUCTIVITY AT 20% (W/W)	<= 20	3.6	µS/cm	Inspected
APPEARANCE IN SOLUTION (CONFORMITY)	Conform	Conform		Guaranteed
NICKEL CONTENT	<= 1,0	Conform	mg/kg	Guaranteed
HEAVY METALS	<= 5	Conform	mg/kg	Guaranteed
MELTING POINT	165 - 170	166 - 168	°C	Inspected
LASER > 300 MIC	<= 10,0	0,9	%.	Inspected
LASER > 140 MIC	>= 45	53	%.	Inspected
LASER > 30 MIC	>= 90,0	93,0	%.	Inspected
DIAMETER D10	<= 100	63	µm	Inspected
MEDIAN DIAMETER	120 - 180	145	µm	Inspected
DIAMETER D90	<= 280	231	µm	Inspected
TOTAL COUNT	<= 1000	< 10	/g	Inspected
YEASTS AND MOULDS	<= 100	< 10	/g	Inspected
ESCHERICHIA COLI IN 1g	Not detected	Conform		Guaranteed
SALMONELLAE IN 10g	Not detected	Conform		Guaranteed

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Other batch compliance:

Meets the requirements of the current monograph of:

- European Pharmacopoeia : MANNITOL (0559)
- USP-NF Pharmacopoeia : MANNITOL
- Japanese Pharmacopoeia : D-Mannitol

When tested accordingly, this product complies with relevant monograph requirements. The compliance to the general chapters depends on plant manufacturing standards. This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharmaceutical GMPs. Please contact us for further information.

Notes:

All the dates are formatted like YYYY/MM/DD.

This document was issued from a controlled electronic document management system. Date of approval and contact identity: see below.

2025/06/25

BARON Alexandre
PLANT QUALITY MANAGER

