

REF : 80614215 / 900002

**Certificate of analysis /
Compliance**

Manufacturing site

ROQUETTE Frères, Rue de la Haute Loge, 62136, LESTREM, PAS-DE-CALAIS, France

References

Product name	PEARLITOL® PF - MANNITOL PYROGEN FREE
GTIN/EAN	03604740016948
Material Code	5900000008
Batch Number	596757
Manufacturing Date	2023/03/26
Retest Date	2026/03/25
Sales Order / Item	10601928 / 10
Our Reference	1/4
Delivery / Item	80614215 / 900002
Your Reference	4500251267//1/4
Customer reference	10001769

Product description

Aspect	Crystalline 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
MANNITOL (ON DS)	97,0 - 102,0	99,5	%	Inspected
APPEARANCE IN SOLUTION (CONFORMITY)	Conform	Conform		Inspected
CONDUCTIVITY AT 20% (W/W)	<= 20	1	µS/cm	Inspected

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Parameter	Specification range	Result	Unit	Status
MELTING POINT	165 - 170	167	°C	Inspected
REDUCING SUGARS (AS IS)	≤ 0,1	< 0,1	%	Inspected
SORBITOL/MANNITOL RATIO (<2.0%)	Conform	Conform		Inspected
MALTITOL AND ISOMALT (<2.0%) ON DS	Conform	Conform		Inspected
ANY UNSPECIF. SINGLE IMPURITY (< 0.10%)	Conform	Conform		Inspected
TOTAL IMPURITIES (<2.0%) ON DS	Conform	Conform		Inspected
HEAVY METALS	≤ 5	Conform	mg/kg	Guaranteed
NICKEL CONTENT	≤ 1,0	Conform	mg/kg	Guaranteed
LOSS ON DRYING	≤ 0,5	< 0,1	%	Inspected
TOTAL COUNT	≤ 100	0	/g	Inspected
YEASTS AND MOULDS	≤ 100	0	/g	Inspected
ESCHERICHIA COLI IN 1g	Not detected	Conform		Guaranteed
SALMONELLAE IN 10g	Not detected	Conform		Guaranteed
BACTERIAL ENDOTOXINS (eu/g)	≤ 2,40	< 0,15	eu/g	Inspected

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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

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

2023/05/31

BARON Alexandre
PLANT QUALITY MANAGER

