



SORBITOL POLVO PURO (EUR. PH. / E 420 / FU)

PRODUCT CODE: 1596	CAS Nº: 50-70-4	ANALYSIS Nº: 039/25
MANUFACTURER BATCH: 967505	CERTIFICATE ID: 45.274	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 07/08/2024	
METAPH BATCH: 0130225	EXPIRY DATE: 06/08/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Identification A	Complies	Complies (*)
Appearance of solution	Clear and colourless	Complies
Conductivity	=< 20 $\mu\text{S}\cdot\text{cm}^{-1}$	0.3 $\mu\text{S}\cdot\text{cm}^{-1}$
Reducing sugars	=< 0.2 %	< 0.1 %
Related substances		
Any impurity	=< 2.0 %	< 2.0 % (#)
Total impurities	=< 3.0 %	< 3.0 %
Water	=< 1.5 %	0.3 %
Microbial contamination		
TAMC	=< 1000 CFU/g	Complies
TYMC	=< 100 CFU/g	Complies
Escherichia coli	Absence	Complies
Salmonella	Absence	Complies
Assay	97.0 - 102.0 %	99.2 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Impurities detailed underneath:

Iditol = 0.4 %

Maltitol = 0.2 %

Mannitol = 0.6 %

It shows polymorphism.

Product intended for pharma applications.

(*) Data controlled by Metapharmaceutical Industrial SL.

STORAGE

Keep the container tightly closed. Protect from direct sunlight, humidity and water.

Analysis date: 22/04/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Manufacturer: 40000323