

FRUCTOSE SODIUM DIPHOSPHATE

PRODUCT CODE: 95	CAS N°: 81028-91-3	ANALYSIS N°: 244/24
MANUFACTURER BATCH: 231110	CERTIFICATE ID: 43.593	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 10/11/2023	
METAPH BATCH: 0270924	EXPIRY DATE: 30/10/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
pH	5.5 - 6.5	6.2
Water	24 - 27 %	26.1 %
Heavy metals	=< 10 ppm	< 10 ppm
Free phosphate	=< 0.4 %	< 0.4 %
Chlorides	=< 0.03 %	< 0.03 %
Sulfates	=< 0.05 %	< 0.05 %
Ferric Iron	=< 0.001 %	< 0.001 %
Arsenic	=< 0.0001 %	< 0.0001 %
Protein	Complies	Complies
Related substances	Complies	Complies
Visible foreign matter	Complies	Complies
Assay	96.3 - 103.0 %	97,39 %

COMPLIES WITH

China Pharmacopoeia 2020

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Fructose Sodium Diphosphate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the container tightly closed, in a dry and well-ventilated place.

Analysis date: 19/11/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies

Manufacturer: 40000921

