



MONOSODIO DIHIDROGENOFOSFATO DIHIDRATADO (EUR. PH.)

PRODUCT CODE: 002728	CAS Nº: 13472-35-0	ANALYSIS Nº: 285/24
MANUFACTURER BATCH: 103851	CERTIFICATE ID: 44.107	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 19/12/2023	
METAPH BATCH: 0101124	RETEST DATE: 19/12/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder or colourless crystals	Colourless crystals (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Identification C	Complies	Complies (*)
Appearance of solution	Clear and colourless	Complies
pH	4.2 - 4.5	4.4
Reducing substances	Complies	Complies
Chlorides	=< 200 ppm	< 5 ppm
Sulfates	=< 300 ppm	< 30 ppm
Iron	=< 10 ppm	2 ppm
Loss on drying	21.5 - 24.0 %	22.4 % (*)
Assay	98.0 - 100.5 %	99.9 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Sodium Hydrogen Phosphate Dihydrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data controlled by Metapharmaceutical Industrial SL.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, 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

Store in a cool and dry place. Do not freeze and protect from light and heat.

Analysis date: 05/12/2024

Signature: Albert Sanchez Lopez (QP)

Conclusion: Complies

Manufacturer: 40000221