METAPHARMACEUTICAL

SODIO BICARBONATO (SODIO HIDROGENOCARBONATO) (EUR. PH.)

PRODUCT CODE: 001319	CAS Nº: 144-55-8	ANALYSIS Nº: 350/25
MANUFACTURER BATCH: 1000007868	CERTIFICATE ID:	49.037
SUPPLIER BATCH: 4557565020	MANUFACTURING DATE:	13/10/2025
METAPH BATCH: 0031125	EXPIRY DATE:	13/10/2027

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 (*)
Appearance of solution	Clear and colourless	Clear and colourless (*)
Carbonates		
pH	=< 8.6	8.4
Chlorides	=< 150 ppm	< 150 ppm
Sulfates	=< 150 ppm	< 150 ppm
Ammonium	=< 20 ppm	< 20 ppm (*)
Calcium	=< 100 ppm	< 100 ppm (*)
Iron	=< 20 ppm	0.3 ppm
Assay	99.0 - 101.0 %	99.9 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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

(*) Data controlled by Metapharmaceutical Industrial SL.

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

In tightly closed container, protected from light and heat.

Relase date: 24/11/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies

Original certificate available upon request