

**SACARINA SODICA (EUR. PH.)**

PRODUCT CODE: 1534	CAS Nº: 6155-57-3	ANALYSIS Nº: 219/22
MANUFACTURER BATCH:	CERTIFICATE ID:	36.161
SUPPLIER BATCH: U0146701	MANUFACTURING DATE:	31/03/2021
METAPH BATCH: 0031022	EXPIRY DATE:	31/03/2026

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals, efflorescent in dry air	White crystalline powder (*)
Solubility	Freely soluble in water, sparingly soluble in ethanol (96 %)	Complies
Identification B	Complies	Complies (*)
Identification E	Complies	Complies (*)
Appearance of solution	Clear and colourless	Complies (*)
Acidity or alkalinity	Complies	Complies
o-and p-toluensulfonamide		
o-toluenesulfonamide	=< 10 ppm	< 0.10 ppm
p-toluenesulfonamide	=< 10 ppm	< 0.10 ppm
Readily carbonisable substances	Complies	Complies
Water	=< 15.0 %	14.0 %
Assay	99.0 - 101.0 %	100.5 % (*)

**COMPLIES WITH**

European Pharmacopoeia 10.0

**REMARKS**

Active ingredient permitted as food additive in compliance with specifications for food additives (Reg. EU n. 231/2012).

Saccharin Sodium 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.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

**STORAGE**

Store in the original container in a cool and dry place.

Analysis date: 19/10/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Manufacturer: 40000740