ROQUETTE
Offering the best of nature™

PRODUCT SPECIFICATION SHEET

SODIUM GLUCONATE PHARMA

Definition

Product Identifier

Product name: SODIUM GLUCONATE PHARMA

Sodium gluconate.
CAS no. : 527-07-1

Specifications

A) CHARACTERS		
APPEARANCE		Crystalline, yellowish powder.
B) IDENTIFICATION		
IDENTIFICATION TEST - A(*)	USP-NF	COMPLIES
IDENTIFICATION TEST - B(*)	USP-NF	COMPLIES
C) TESTS		
ASSAY	USP-NF	98.0 - 102.0 %
CHLORIDE	USP-NF	0.07 % max.
SULPHATE	USP-NF	0.05 % max.
LEAD	USP-NF	10 ppm max.
REDUCING SUBSTANCES	USP-NF	0.5 % max.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT		100 CFU/g max
- BACTERIAL ENDOTOXINS		25 EU/g max.

Comments

Methods used by Roquette may be the Pharmacopoeia methods or internal validated methods which have been compared to the Pharmacopoeia methods.

Conformity

Conforms to the current edition of

- US Pharmacopeia (USP)

Please contact us for any statement regarding compliance to the General Chapters (elemental impurities, residual solvents, organic

volatile impurities, metal catalyst, metal reagent).

Storage

Retest Date

Manufacturing date + 3 years, in its unopened packaging.

We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity.

- * Compliance data - Tests not performed

Disclaimer

The information provided in this Product Specification Sheet relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process.

All information and instructions provided in this Product Specification Sheet are based on the current state of our knowledge at the latest revision date indicated. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.

Notes : All the dates are formatted like YYYY/MM/DD.