

PRODUCT SPECIFICATION SHEET
GLUCONO DELTA LACTONE PL

Definition

Product identifier

Product name: GLUCONO DELTA LACTONE PL

Specifications

Description (characters)

Glucono-delta-lactone

Aspect
Colour

Crystalline powder
White

Identification

Identification test A	USP	Complies
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Physical and chemical values (tests)

Reducing substances (ml)	USP	16,1 ml max.
Gluconolactone	USP	99,0 - 101,0 %(w/w)
Lead	USP	10 mg/kg max.
Sieve grain size fraction		
- Residue on 250 µm		10 % max.
- Residue on 75 µm		80 % min.

Additional data

Comments

Methods used by ROQUETTE may be the Pharmacopoeia methods or alternative validated methods.
Not intended for use in manufacture of parenteral dosage forms.
Caption :
- USP stands for US Pharmacopoeia

Conformity

Legislation / specific regulations

Meets the requirements of the current monograph of:
- National Formulary from USP-NF : GLUCONOLACTONE

When tested accordingly, this product complies with relevant USP monograph requirements. The compliance to USP general chapters depends on plant manufacturing standards. This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs . Please contact us for further information.

Storage

Storage conditions The product durability may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.

Storage conditions for PACK material We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity. Upon opening, use the product as quickly as possible to prevent moisture regain.

Expiry date of the packed product Manufacturing date + 5 years, in its unopened packaging.

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. Analytical criteria are tested either on each batch or monitored or guaranteed, based on the Product Risk Analysis. For each batch, the status of the analysis may be indicated in the Certificate of Analysis. 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.

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