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PRODUCT SPECIFICATIONS SHEET

PEARLITOL® CR-H-EXP-HYPROMELLOSE-MANNITOL

Definition

Product Identifier

Product name: PEARLITOL® CR-H-EXP-HYPROMELLOSE-MANNITOL

Powder for direct compression composed of 30% of Mannitol and 70% of Hypromellose type 2208.

Specifications

A) CHARACTERS

APPEARANCE	White to yellowish-white, powder or granules.

B) TESTS

LOSS ON DRYING	4,0 % max.
pH	5,0 - 8,0
D-MANNITOL (as is)	25 - 35 %
HYPROMELLOSE (as is)	65 - 75 %
SULFATED ASH	1,0 % max.
PARTICLE SIZE(laser)	
- PART. > 500 microns	5 % max.
- PART. > 315 microns	25 % max.
- PART. > 40 microns	90 % min.
MICROBIOLOGICAL VALUES:	
- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.
- ESCHERICHIA COLI	Not detected in 1g
- SALMONELLA	Not detected in 10g

Indicative Values

BULK DENSITY	300-500 g/l approx.

Comments

This product should be considered as an experimental product. Product specifications and relative analytical methods may evolve with product development.

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Conformity

Meets the requirements of the current monograph of

- European Pharmacopoeia MANNITOL (0559) and HPMC

- USP-NF Pharmacopoeia MANNITOL and HPMC

- Japanese Pharmacopoeia D-MANNITOL and HPMC

- Chinese Pharmacopoeia MANNITOL and HPMC

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.

-These dates are indicative and may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.

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

-Upon opening, use the product as quickly as possible to prevent moisture regain.

Disclaimer

SPECIFIC DISCLAIMER:

Not intended for use in manufacture of parenteral dosage form, nor preparation for dialysis.
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.

GENERAL 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. The ultimate use of this Product in any finished product is the responsibility of the purchaser.
This Product may have restrictions with respect to its use and/or usage levels, and such may vary on a country-by-country basis. The purchaser is responsible for its use of the Product and for its finished product, and that any claims made regarding its use of the Product and/or the finished product comply with applicable laws and regulations.