

PEARLITOL® FLASH

Definition

Product Identifier

Product name: PEARLITOL® FLASH

PEARLITOL FLASH IS A COMPOUND OF :

- MANNITOL (CAS : 69-65-8 - EINECS : 200-711-8)
- MAIZE STARCH (CAS : 9005-25-8 -EINECS : 232-679-6)

Specifications

A) CHARACTERS

APPEARANCE	WHITE POWDER
TASTE	SWEET
ODOUR	NEUTRAL

B) PHYSICO-CHEMICAL VALUES

D-MANNITOL /COM.	78.0 - 82.0 %
MAIZE STARCH /D.S.	15.0 - 19.0 %
LEAD	0.5 ppm max.
NICKEL (*)	1 ppm max.
LOSS ON DRYING	3.0 % max.
SULFATED ASH	0.2 % max.
SO ₂	10 ppm max.
OXIDISING SUBSTANCES (*)	20 ppm max.
IRON (*)	10 ppm max.
PARTICLE SIZE	
- RESIDUE ON 100 MIC.	80 % min.
- RESIDUE ON 315 MIC.	20 % max.

C) MICROBIOLOGICAL VALUES

TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.
ESCHERICHIA COLI(**)	Absence in 10g.
SALMONELLA(**)	Absence in 10g.

Comments

PEARLITOL® FLASH

IDENTIFICATION

- **MANNITOL** Retention time of HPLC peak.

identification test 1 and 2 (JP)

- **MAIZE STARCH** identification test A (EP/USP)

identification test C (EP/USP) identification test 1, 2 and 3 (JP)

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

Conformity

Current pharmacopeias

- **MANNITOL** EP - USP/NF - JP

- **MAIZE STARCH** EP - USP/NF - JP

- **PEARLITOL FLASH** JPE 2018

Regarding any compliance referred to in the General Chapters of the Pharmacopoeias (elemental impurities, residual solvents, organic volatile impurities, metal catalyst, metal reagent), statements are available on request.

Storage

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

EXPIRY DATE Manufacturing date + 3 years, in its unopened packaging.

- * Compliance data - Tests not performed

- ** Monitoring plan

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.