

PRODUCT SPECIFICATIONS SHEET

**STARLAC®**

Definition

Product Identifier

**Product name:** STARLAC®

SPRAY DRIED COMPOUND:

- 85 PARTS LACTOSE MONOHYDRATE
- 15 PARTS GMO FREE EXTRA WHITE NATIVE MAIZE STARCH

Specifications

A) CHARACTERS

APPEARANCE	White or almost white odourless powder.
SOLUBILITY	Partially soluble in cold water, practically insoluble in ethanol 96%.

B) IDENTIFICATION

STARLAC® :

- IR-Spectroscopy COMPLIES

MAIZE STARCH:

- Test identification B EP COMPLIES

- Test identification C EP COMPLIES

C) PHYSICO-CHEMICAL VALUES

LACTOSE (on DS)	HPLC(*)	82.0 - 88.0 %
MAIZE STARCH (on DS)	Polarimetric(*)	12.0 - 18.0 %
LOSS ON DRYING	EP(*)	3 % max.
SULPHATED ASH	EP(*)	0.2 % max.
<b>PARTICLE SIZE (Sieve)</b>		
- Residue on 32 microns		85 % min.
- Particle size under 160 microns		35 - 65 %
- Residue on 250 microns		20 % max.

D) MICROBIOLOGICAL VALUES

- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.

PRODUCT SPECIFICATIONS SHEET

**STARLAC®**

- <b>ESCHERICHIA COLI</b>	Not detected in 1g
- <b>SALMONELLA</b>	Not detected in 10g

Comments

---

**Caption**

-(\*) See analytical monograph STARLAC, available on request.

Conformity

---

**EACH COMPONENT CONFORMS TO THE CURRENT EDITION OF**

- European Pharmacopoeia (EP), LACTOSE MONOHYDRATE / MAIZE STARCH
- USP-NF Pharmacopoeia (USP/NF), LACTOSE MONOHYDRATE / CORN STARCH
- Japanese Pharmacopoeia (JP), LACTOSE HYDRATE / CORN STARCH

Storage

---

**Retest date**

Manufacturing date + 3 years.

- This date is 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

---

**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.