

## PRODUCT SPECIFICATION

## ARMOR PHARMA™ lactose monohydrate 450M

MANUFACTURING SITE: Armor protéines S.A.S., Loudéac, France

PRODUCT NAME: ARMOR PHARMA™ lactose monohydrate 450M

Conforms to USP - NF, Ph. Eur., JP lactose monohydrate

monographs, current versions at time of manufacture.

PRODUCT DESCRIPTION: White, crystalline powder; Freely soluble in water, practically

insoluble in ethanol (96 per cent).

RESIDUAL SOLVENTS

(CPMP/ICH/283/95 + CVMP/VICH/502/99):

No class 1, 2, 3 solvents are used during production.

## **SPECIFICATION**

Appearance White, crystalline powder
Solubility Freely soluble in water
Identification Complies with pharmacopoeia

Water (KF) 4.5% to 5.5% Loss on drying max. 0.5% Specific optical rotation, [ $\alpha$ ]20D, anhydrous substance + 54.4° to + 55.9°

Residue on ignition/ Sulphated ash max. 0.1 %

Absorbance: proteins and light-absorbing impurities

[A] 1%, 1 cm at 210 to 220 nm max. 0.25 [A] 1%, 1 cm at 270 to 300 nm max. 0.07 [A] 10%, 1 cm at 400 nm max. 0.04

Appearance of solution (Ph. Eur.)

Clarity and Colour of Solution (USP, JP)

Clear and not more coloured than ref. BY<sub>7</sub>

Clear and colourless or nearly colourless

Acidity or Alkalinity (ml 0.1 M NaOH) max. 0.4 Heavy metals (USP) max. 5 ppm

Particle size distribution (Air jet sieve)

% < 45  $\mu$ m ≥ 90 % < 63  $\mu$ m ≥ 98 % < 150  $\mu$ m 100

Total aerobic microbial count max. 100 CFU/g
Total yeast and moulds count max. 50 CFU/g

Total yeast and moulds count max. 50 CFU/g
Escherichia coli neg. in 1 g
Salmonella neg. in 10 g

Frédérique GREAULT Pharmacist Quality Manager

## **STORAGE**

Store in original unopened packaging, in a dry and odour-free place. Shelf life: 36 months

**Edition No.: 4** 

Issue date: 07 Sept. 2018

Valid until: 06 Sept. 2022

Document No.: QUA 08 FT 405\_E

Page: 1/

This version annuls and replaces all previous versions.

ARMOR PHARMA™ is a brand of Armor Protéines S.A.S.

• Sales and Administration: 19 bis, rue de la Libération, Saint-Brice-en-Coglès 35460 Maen Roch, FRANCE

• Head office : 50890 Condé-sur-Vire, FRANCE

• E-mail : <u>contact@armor-pharma.com</u> • Tel : +33 (0)2 99 18 39 29