

PRODUCT SPECIFICATION

EXCIPURE™ DPI 111

MANUFACTURING SITE:	Armor Protéines S.A.S., Loudéac, France
PRODUCT NAME:	EXCIPURE™ DPI 111 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
Purity (HPLC)	>99.7%
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.)	Clear and not more coloured than ref. BY ₇
Clarity and Colour of Solution (USP, JP)	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 (Laser diffraction – Sympatec, Dry dispersion)	
X ₁₀	60 – 110 µm
X ₅₀	170 – 230 µm
X ₉₀	270 – 380 µm
Total aerobic microbial count	max. 10 CFU/g
Total yeasts and moulds count	max. 10 CFU/g
Escherichia coli	neg. in 10 g
Salmonella	neg. in 10 g
Bile tolerant gram negative bacteria	absence / 10 g
Staphylococcus aureus	absence / 10 g
Pseudomonas aeruginosa	absence / 10 g
Burkholderia cepacia	absence / 10 g
Endotoxins	≤5 EU/g

Frédérique GREAULT
Pharmacist Quality Manager



STORAGE

Store in original unopened packaging, in a dry and odour-free place.
Shelf life: 12 months

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 : contact@armor-pharma.com
- Tel : +33 (0)2 99 18 39 29