

## PRODUCT SPECIFICATION

### EXCIPURE™ DPI 223

|  |   |
|--|---|
| MANUFACTURING SITE:  | Armor Protéines S.A.S., Loudéac, France   |
| PRODUCT NAME:  | <b>EXCIPURE™ DPI 223</b><br>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<br>(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 <sub>7</sub> |
| 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<br>(Laser diffraction - Sympatec, dry dispersion) |   |
| X <sub>10</sub>  | 4 – 10 µm   |
| X <sub>50</sub>  | 35 – 65 µm  |
| X <sub>90</sub>  | 110 – 160 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  |

Frédérique GREAULT  
Pharmacist Quality Manager



### STORAGE

Store in original unopened packaging, in a dry and odour-free place.  
Shelf life: 24 months

This version annuls and replaces all previous versions.

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

- Sales and Administration: Le pont, 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](mailto:contact@armor-pharma.com)
- Tel : +33 (0)2 99 18 39 29