



# EXCIPURE™

## LACTOSE FOR INHALATION





## Product development

We offer an extensive range of pharmaceutical grade lactose, with the added ability to customize bespoke products to fulfill your exact specifications and meet formulation challenges.

- All products conform to **Ph. Eur., USP-NF, JP**
- Accurate control of batch-to-batch consistency through **on-line Malvern laser diffraction PSD analysis**
- Full traceability from raw material
- Certified animal Rennet-free raw materials
- ICH Q3D Elemental Impurities analysis results available
- Excipient Information Package available



## Manufacturing facilities

Our products are manufactured in a dedicated, purpose built facility based in Brittany, France.

- EXCIPACT certified (GMP)
- ISO 9 001 and ISO 22 000 certified
- Following IPEC cGMP
- On-site Batch testing & Batch release





# A range of lactose grades from coarse crystals to fine powders for Dry Powder Inhalers:

## COARSE LACTOSE



Coarse sieved lactose carrier with good flow properties which can be blended with micronized or fine lactose.

**DPI 111**

PSD (Laser diffraction Sympatec, dry dispersion)	Specifications (µm)
X <sub>10</sub>	60 to 110
X <sub>50</sub>	170 to 230
X <sub>90</sub>	270 to 380
Flowability	<div style="width: 80%; background-color: #00a68f;"></div>
SSA	0.05 m <sup>2</sup> /g

**x<sub>10</sub> : 88 µm | x<sub>50</sub> : 206 µm | x<sub>90</sub> : 333 µm \***

\*PSD laser diffraction (Sympatec, dry), indicative.

## BROAD LACTOSE



Broad lactose suitable for blister's devices formulation. Can also be blended with micronized or fine lactose for adjustment of fines content.

**DPI 231**

PSD (Laser diffraction Sympatec, dry dispersion)	Specifications (µm)
X <sub>10</sub>	5 to 30
X <sub>50</sub>	50 to 120
X <sub>90</sub>	130 to 200
Flowability	<div style="width: 80%; background-color: #00a68f;"></div>
SSA	0.2 m <sup>2</sup> /g

**x<sub>10</sub> : 10 µm | x<sub>50</sub> : 73 µm | x<sub>90</sub> : 172 µm \***

\*PSD laser diffraction (Sympatec, dry), indicative.

## FINE LACTOSE



Very finely milled cohesive lactose powder. Enables the adjustment of fines content when blended with a broad or coarse lactose.

**DPI 222**

PSD (Laser diffraction Sympatec, dry dispersion)	Specifications (µm)
X <sub>10</sub>	1 to 5
X <sub>50</sub>	10 to 20
X <sub>90</sub>	30 to 45
Flowability	<div style="width: 80%; background-color: #00a68f;"></div>
SSA	1.4 m <sup>2</sup> /g

**x<sub>10</sub> : 2 µm | x<sub>50</sub> : 16 µm | x<sub>90</sub> : 39 µm \***

\*PSD laser diffraction (Sympatec, dry), indicative.

Finely milled cohesive lactose powder.

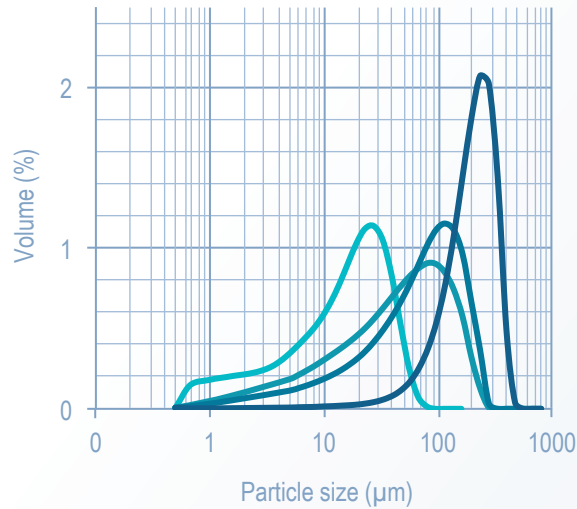
**DPI 223**

PSD (Laser diffraction Sympatec, dry dispersion)	Specifications (µm)
X <sub>10</sub>	4 to 10
X <sub>50</sub>	35 to 65
X <sub>90</sub>	110 to 160
Flowability	<div style="width: 80%; background-color: #00a68f;"></div>
SSA	0.8 m <sup>2</sup> /g

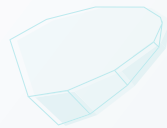
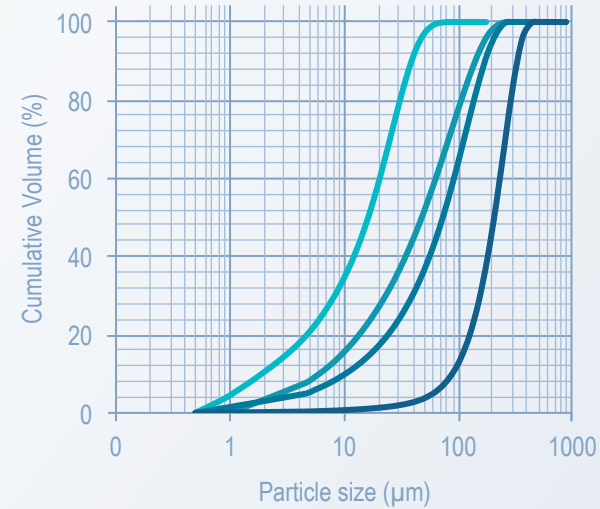
**x<sub>10</sub> : 6 µm | x<sub>50</sub> : 48 µm | x<sub>90</sub> : 142 µm \***

\*PSD laser diffraction (Sympatec, dry), indicative.

# PSD Comparison (Laser diffraction, Sympatec, Dry dispersion)



DPI 222  
 DPI 223  
 DPI 231  
 DPI 111



**Reservoir**



**Capsule**



**Blister**

**Expected properties**

Good flow  
 Constant density

Good flow  
 Cohesive powder

Cohesive powder

**Available Grades**

**EXCIPURE™**

DPI 111

DPI 111 + DPI 222  
 DPI 223  
 DPI 231

DPI 223  
 DPI 231  
 DPI 231 + DPI 222

# Customization possibilities:

Much more than these marketed EXCIPURE Coarse & Fine Lactoses, we offer a full range of customization capabilities

- Particle size/shape/surface customization through process adjustment
- Blending of several products
- Joint product development
- Functionality related characteristics testing
- Low, medium and high volume manufacturing scales
- Additional microbial & physical properties testing
- Packaging in cartons drums/Plastic boxes/Carton with aluminium foil...



## Any specific requirements?

Simply tell us... How you would like your lactose!



[contact@armor-pharma.com](mailto:contact@armor-pharma.com)



[www.armor-pharma.com](http://www.armor-pharma.com)





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