

## Most important things you would like to know about lactose

## Introduction:

Lactose is a sugar naturally present in mammal's milk. It has been used in the pharmaceutical industry for several decades as an excipient. It is either used as a Diluent in oral solid dosage forms (OSDF) such as tablets, capsules, sachets or as a Carrier for dry powder inhalers (DPI) because pure active substances need excipients to produce a final dosage form.

An excipient has no medicinal properties but it helps the API (Active Pharmaceutical Ingredient) to reach its target in the body and facilitates physiological absorption of the drug.

Several properties such as cost effectiveness, a bland taste, its availability and the compatibility with active ingredients and other excipients contribute to the popularity of lactose as an excipient. Further advantages of lactose are its water solubility, its low hygroscopicity, as well as the excellent physical and chemical stability.

Armor Pharma is part of the Savencia Group, a world-leading specialty cheese company. As a family owned international company, sustainability, longevity and quality are part of the heritage. Despite being a large group with around 20,000 co-workers, the family business philosophy to put the interest of customers and employees first is being maintained.

Armor Pharma was set-up in 2014 after completion of a brand new, purpose built manufacturing site for pharma-grade lactose. The new pharma-lactose plant is based on more than 40 years of manufacturing experience serving the infant formula market with high quality lactose. Thanks to exceptional product quality and client service ARMOR Pharma is slowly but surely becoming an important actor in the business of pharmaceutical excipients.

The manufacturing facility is EXCIPACT (GMP), ISO 9001 and ISO 22000 certified and is being audited regularly. Batches are tested and released on-site.

## **Types of lactose:**

Various processes such as milling, sieving, spray drying etc. enable the obtention of lactose particles with different functionality related characteristics such as flowabillity or particle size distribution allowing to select the most suitable grade for a particular need.

Armor Pharma grades meet all the pharmacopoeia requirements of Ph. Eur., USP-NF and JP monographs. Accurate control of lactose granulometry through on-line Malvern laser diffraction ensures batch to batch consistency.

Armor Pharma offers various grades of lactose from oral solid dosage forms to dry powder inhalations.

### LACTOSE MONOHYDRATE SIEVED

Sieving process gives coarse particles with a narrow particle size distribution enabling very good flowability. It is suitable for capsules and sachets formulation.

Available grades: 80M



## LACTOSE MONOHYDRATE MILLED

Milling process produces fine lactose particles with good compaction and blending properties. This range of cohesive powders is mostly used for tablet manufacturing using wet and dry granulation, but also for blends or premixes.

Available grades: 150M, 200M, 350M, 201, 450M, 231



## **EXCIPRESS™** for Direct Compression

#### **GRANULATED**



Granulated lactose consists of agglomerates of primary lactose fine particles bound in a matrix of non amorphous lactose. It combines high compaction properties of fine lactose crystals as well as good flowability of coarse particles. EXCIPRESS<sup>TM</sup> GR150 is a granulated lactose typically used for Direct Compression.

#### **SPRAY DRIED**



Spray-dried lactose consists of fine primary lactose particles bound in a matrix of amorphous lactose. It combines high compaction properties of fine lactose crystals and amorphous lactose as well as very good flowability of spherical particles. EXCIPRESS<sup>TM</sup> SD2 is a spray-dried lactose typically used for Direct Compression.

## **EXCIPURE**<sup>™</sup> Lactose for Inhalation

EXCIPURE<sup>™</sup> is a range of lactose grades from coarse particles to fine powders for Dry Powder Inhalers. Depending on the device used, Armor Pharma has a starting range of products to propose.



Armor Pharma offers as well a full range of customization capabilities and joint product development to ensure the right outcomes.

Medicines containing lactose can be taken by lactose intolerant people considering the small amount of lactose in tablets and capsules (<1g). Lactose intolerance is caused by ingestion of high quantity of lactose greater than 7 to 10g of lactose per day in one single dose.

### **Conclusion**

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

# Simply tell us... how you would like your lactose!

Do not hesitate to contact us in order to receive an overview of product applications, characteristics & functionalities, our brochures or any other information.





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