

# From Milk to Medicine

## The Journey of Lactose as a Pharmaceutical Excipient

This infographic illustrates the transformation of lactose - from its origin in milk to its crucial role as a pharmaceutical excipient in oral solid dosage forms.

### From Lactose to Pharmaceutical Grade Alpha-Lactose Monohydrate Powder

MANUFACTURED IN COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICES



#### From Raw Milk to Whey Serum - milk coagulation

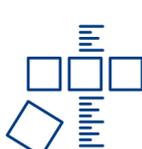


Raw milk is first **pasteurized** and then **subjected to coagulation** to separate casein for cheese production or casein powder from the liquid whey which is collected.

The collected liquid whey is to **ultrafiltrated**, that removes proteins and other high-molecular-weight components, allowing only **lactose** and **minerals** to pass through. The resulting filtrate, known as **whey permeate**, is mainly composed of lactose.



#### From whey to whey permeate - Ultrafiltration



#### Whey permeate purification (active charcoal)



**Active charcoal** adsorbs residual organic compounds, pigments, and trace contaminants, thereby **enhancing the purity** of the lactose precursor.

Whey permeate is pasteurised and concentrated by evaporation under controlled temperature and solution conditions to **increase lactose content** and **ensure microbiological safety**.



#### Liquid Whey permeate Concentration



#### Crystallization (~36 hours)



**Controlled cooling** in temperature-controlled tanks to grow **lactose crystals**.

**Multiple rinsing steps** to eliminate impurities and residues (protein, minerals).



#### Lactose Crystal Purification & decantation



#### Fluid Bed Drying



The process promotes the **conversion** of beta-lactose into the alpha form, ensuring the desired crystalline structure. To initiate **crystallization** of pure **alpha-lactose monohydrate**, the concentrated lactose solution is cooled and maintained **below 93.5 °C**. Above this temperature, beta-lactose tends to form anhydrous crystals instead.

### From Milled & Sieved Pharmaceutical-Grade Lactose to Functional Excipients

- Particle size reduction**  
→ improves compressibility.
- Precise fractionation**  
→ achieved through calibrated mesh screens.
- Controlled particle size distribution (PSD)**  
→ ensures uniform powder density.
- Optimization of particle shape and size**  
→ enhances downstream performance.



**Milling & Sieving:** Engineering particles with controlled characteristics: shape, particle size distribution (PSD)



#### Packaging



Following **quality approval**, lactose is **hygienically packaged** regarding lactalpa range from 50, 100, 150 or 200 mesh size.

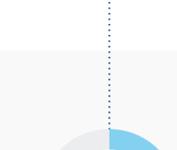
Rigorous testing ensures lactose meets **pharmaceutical standards for purity, safety, and performance**, in accordance with major pharmacopoeias including **Ph. Eur., USP-NF, and JP**.



#### Quality Control



#### Storage & Distribution



Packaged lactose is stored under **controlled conditions** and **distributed to pharmaceutical manufacturers** in compliance with **Good Distribution Practices**, such as those outlined in the **EXCiPACT** certification framework.

Lactose is incorporated as an **excipient in tablets, sachets and capsules**, supporting drug processability, stability and delivery.

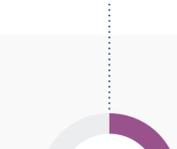
	PROCESS	GALENIC APPLICATIONS	LACTOSE PROPERTIES
Lactalpa 50 50 mesh sieved lactose	Dry blending		Diluent/Good flowability
Lactalpa 100 100 mesh milled lactose	Dry blending		Diluent/Good flowability
Lactalpa 150 150 mesh milled lactose	Wet and dry granulation		Tablet binder/ Diluent/ Good Mixing
Lactalpa 200 200 mesh milled lactose	Wet and dry granulation		Tablet binder/ Diluent/ Good Mixing



#### Integration into Medications



#### Quality Assurance



Finished medications undergo **final quality checks** before reaching patients, **ensuring safety and efficacy**.

Lactose's journey from milk to medicine underscores its vital role in pharmaceutical formulations, ensuring efficacy and safety in drug delivery.

For high-quality pharmaceutical lactose, trust Lactalis Ingredients Pharma.

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