IIEPL

INTERNATIONAL INGREDIENTS & EXCIPIENTS PVT LTD

VISION

- To become a Global Excipients Manufacturing Company and to be recognized as a world class integrated superior healthcare Organization through innovation, production, quality, competence and veneration for human life.

MISSION

- The deepest Mission and Purpose as an organization is helping, supporting the health, wellbeing and nurturing of both people- Customer, team members and business organization in general along with Mother Nature.
- To create a great value to humanity and our stakeholders.
- To exceed our customer expectations in service standards, quality, delivery and cost through continuous improvement and customer interaction.
- To maintain a superior level of integrity in interactions with business partners and associates, now and forever.

ABOUT PLANT

The plant site was awarded by APIIC for constructing our facility at Madanapalem, Chittoor district, Andra Pradesh. This is a strategic location keeping in mind the infrastructure, connectivity and habitat of the locality. The Site is connected by Road ,5 Sea Ports , Air and Rail.

The plant will be producing complete range of Pharmaceutical grades of Lactose. It is a state-of-the-art facility having fully automated Skada controlled system.

The Quality management systems in place are meant to calibrate and produce high quality grades of Lactose. Our plant meets global pharmacopeia certification and norms.

ABOUT PHARMACEUTICAL LACTOSE

Lactose is the most important carbohydrate of the milk of most species. Its biosynthesis takes place in the mammary gland. Lactose is the first and only carbohydrate every newborn mammal (including human) consumes in significant amounts. Bovine milk contains 45 – 50 grams lactose per liter. Industrially lactose is produced from bovine milk exclusively, or rather from milk derivatives like cheese whey or ultra filtration permeate. Lactose is also known as milk sugar.

Lactose is disaccharide. One molecule of lactose consists of one molecule each of galactose and glucose. The galactose and glucose moieties are linked together through a so called beta-(1,4) glucosidic linkage.

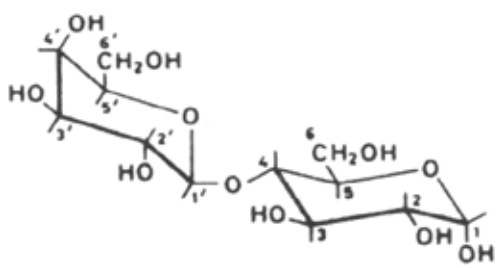
The official chemical name of lactose is 4-O-β-D-galactopyranosyl, D-glucopyranose.

In milk, lactose exists in two isomeric forms, called α- and β- lactose respectively. The molecular structures of α- and β -lactose differ in the orientation of a hydrogen- and a hydroxyl group on carbon atom no.1 in the glucose moiety, as is shown in figure 1. Both forms change into one another continuously, by a phenomenon called mutarotation. The velocity of mutarotation is determined by factors like temperature, concentration and pH (acidity) of the solution. At room temperature the equilibrium results in a ratio of about 40% α-lactose and 60% β-lactose.

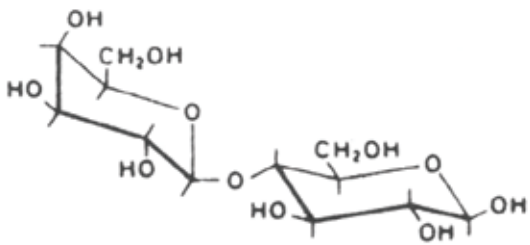
The two forms of lactose affect various properties of lactose such as crystallization behavior, crystal morphology, solid state properties and solubility.

Lactose in solid form can either be in a crystalline state or in an amorphous state. Crystalline lactose can exist in several distinct forms. Most well known are α-lactose monohydrate and β-lactose. Also, two crystalline anhydrous α-lactose types are known, a stable and an unstable (hygroscopic) form.

FIGURE 1 CHEMICAL STRUCTURE



(a)
α-lactose



(b)
β-lactose

PHARMACEUTICAL GRADE - ALFONOLAC™ (LACTOSE MONOHYDRATE)

The most common way to obtain lactose in solid form is crystallizing from solution. When crystallization is performed at temperatures below 93.5°C, exclusively α-lactose monohydrate is obtained. α-Lactose has the peculiarity that in the crystalline state each lactose molecule is associated with one molecule of water, i.e. monohydrate. The water is incorporated in the crystal lattice and forms an integral part of it. It is not removed by normal drying processes. Due to this water of crystallization the normal water content of α-lactose monohydrate is around 5%. Only at temperatures as high as 140°C, the crystal water will be removed completely.

FIGURE 2
ALFONOLAC™ -LACTOSE MONOHYDRATE

In the pharmaceutical industry this lactose is used chiefly as an excipient in the production of solid dosage forms, e.g. tablet production by wet granulation and direct compression and for encapsulation. In dry powder inhalers α-lactose monohydrate is used as a carrier.

PHARMACEUTICAL LACTOSE: ANHYLAC™ - (LACTOSE ANHYDROUS)

When a highly concentrated solution of lactose is crystallized at high temperatures crystals of β-lactose are exclusively formed. Particles with crystalline β-lactose are more brittle than α-lactose monohydrate crystals and they do not contain crystal water. β-Lactose is often referred to as anhydrous lactose.

The isomeric purity is approximately 80% β-lactose, the remaining 20% being anhydrous α-lactose. Crystals of β-lactose in this product are very small

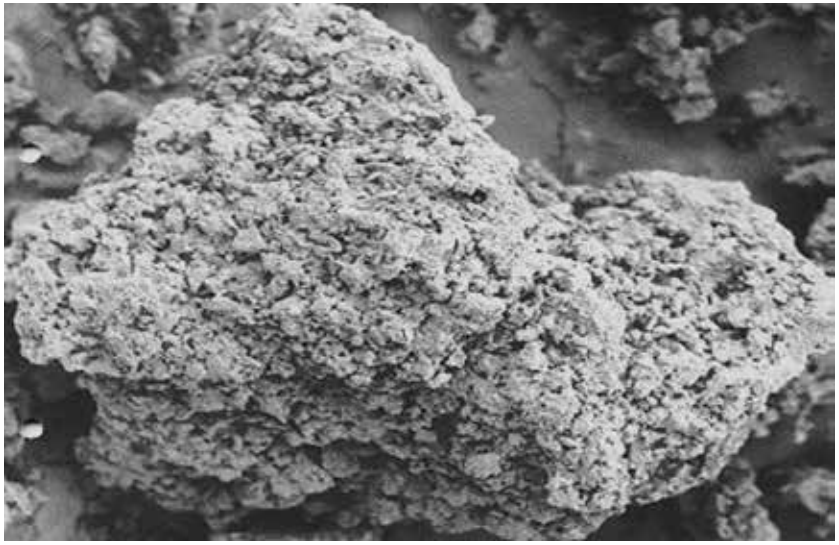


FIGURE 3
ANHYLAC™ - LACTOSE ANHYDROUS

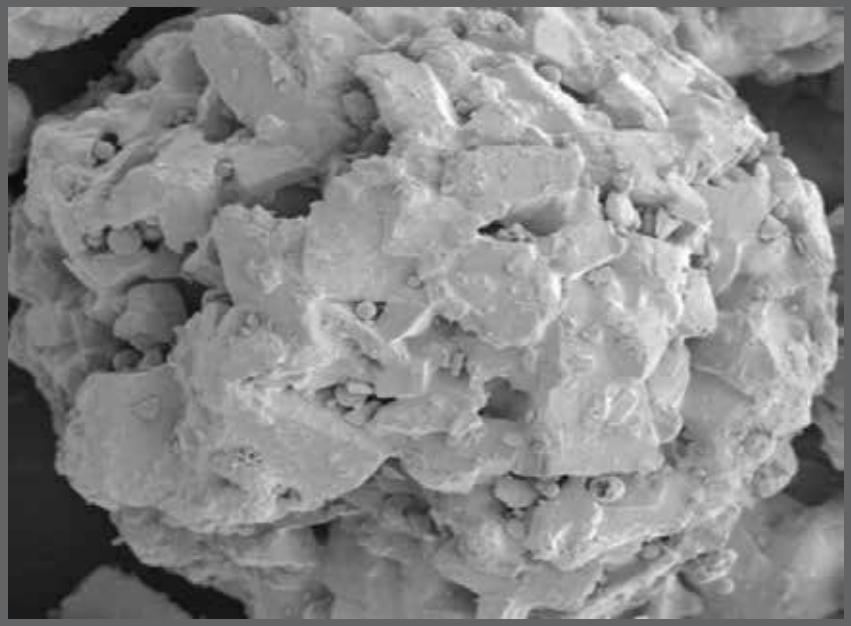
This type of lactose is used mainly as filler-binder for tablet production by direct compression.

PHARMACEUTICAL LACTOSE SPRAYLAC™ (SPRAY DRIED)

When a highly concentrated lactose solution is spray dried, a glassy, amorphous lactose mass is obtained. This amorphous mass contains both α- and β-lactose, the ratio being approximately the same as the equilibrium ratio of the original lactose solution. Lactose glass is very hygroscopic . Although dry lactose glass can appear very hard, it lacks the brittleness of crystalline α-lactose monohydrate and anhydrous lactose. The material is plastically deformable under high pressure.

The spray dried product consists of a matrix of lactose glass in which lactose monohydrate crystals are embedded. A typical ratio crystalline/amorphous lactose is around 85/15.

FIGURE 4
SPRAYLAC™ – LACTOSE SPRAY DRIED



Spray dried lactose is used mainly for tablet manufacture by direct compression processes.

PHARMACEUTICAL LACTOSE PRODUCT SUMMARY

SIEVED GRADES

- ALFONOLAC™ 40M
- ALFONOLAC™ 80M
- ALFONOLAC™ 100M
- ALFONOLAC™ 125M

MILLED GRADES

- ALFONOLAC™ 70M
- ALFONOLAC™ 140M
- ALFONOLAC™ 150M
- ALFONOLAC™ 200M
- ALFONOLAC™ 300M
- ALFONOLAC™ 400M

ANHYDROUS GRADES

- ANHYLAC™ 40M
- ANHYLAC™ 120M

INHALATION GRADES

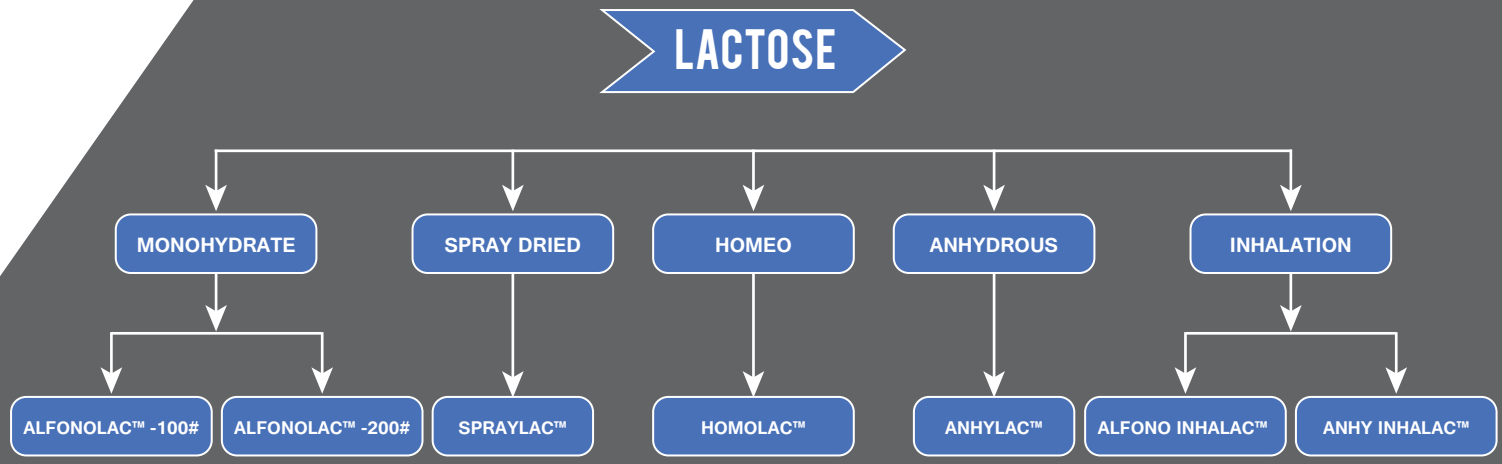
- ALFONO INHALAC™60S
- ALFONO INHALAC ™80S
- ALFONO INHALAC ™120S
- ALFONO INHALAC ™160S
- ALFONO INHALAC ™140M
- ALFONO INHALAC ™300M
- ALFONO INHALAC ™400S
- ALFONO INHALAC ™500S

ADVANTAGES

- Good compressibility
- Good blending properties
- Narrow particle size distribution
- High storage stability
- High batch-to-batch consistency

APPLICATIONS

- Wet granulation
- Dry granulation
- Premixes
- Powder blends
- Fermentation
- Odour absorbent



CERTIFICATION

LACTOSE MONOHYDRATE
(CRYSTALLINE & SPRAY DRIED) IP/BP/EP/JP/USP

US DMF : 037688

IIEPL LACTOSE
COMPLYING WITH BELOW PHARMACOPIA

IIEPL

CORPORATE OFFICE

Chesney Nilgris Apts,37-D, Ground Floor
Commander - In - Chief Road, Egmore
Chennai 600008, Tamilnadu, INDIA
T : + 91-44 24992298
+ 91-44 28250982
E : admin@iiepl.in
E : customersupport@iiepl.in
W : www.iiepl.in

PLANT

UDL-6,7 & 7A, Industrial Park,
Madanapalem, (Mandal - Satyavedu)
Tirupati District,
Andhra Pradesh - 517 646
Land Mark: (Near Hero Motors Factory)