



**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 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, Andhra 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.

“Our plant excels at producing a complete range of Pharmaceutical Grades of Lactose and have many more grades in the pipeline”

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.

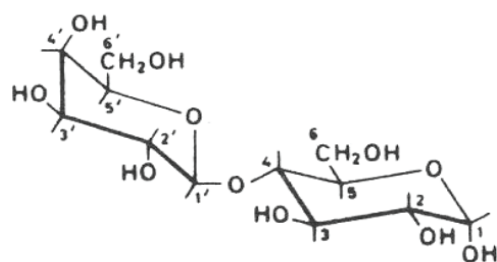
The official chemical name of lactose is 4-O- β -D-galactopyranosyl, D-glucopyranose.

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 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.

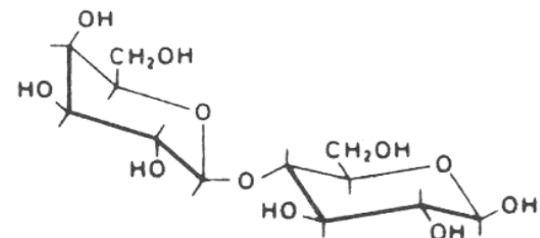
The two forms of lactose affect various properties of lactose such as crystallization behavior, crystal morphology, solid state properties and solubility.

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.

CHEMICAL STRUCTURE



(a)
 α -lactose



(b)
 β -lactose

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 140°C, the crystal water will be removed completely.

ALFONOLAC™



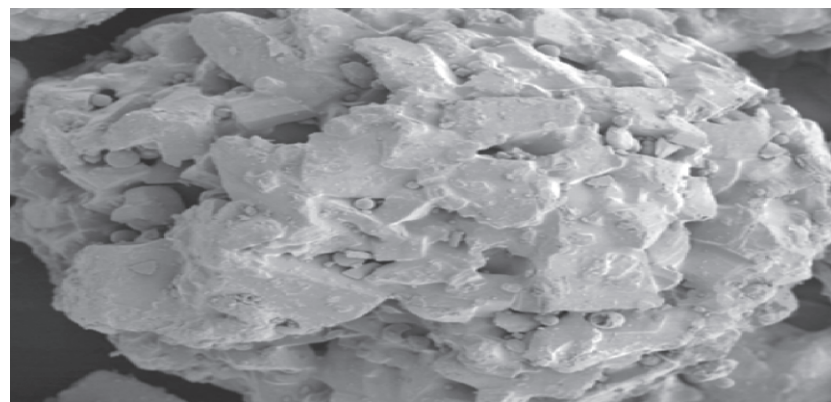
In the pharmaceutical industry this lactose is used chiefly as an excipient in the production of solid dosage forms, e.g. tablet production by wet granulation and direct compression and for encapsulation. In dry powder inhalers α -lactose monohydrate is used as a carrier.

SPRAYLAC™ – (LACTOSE MONOHYDRATE)

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.

SPRAYLAC™

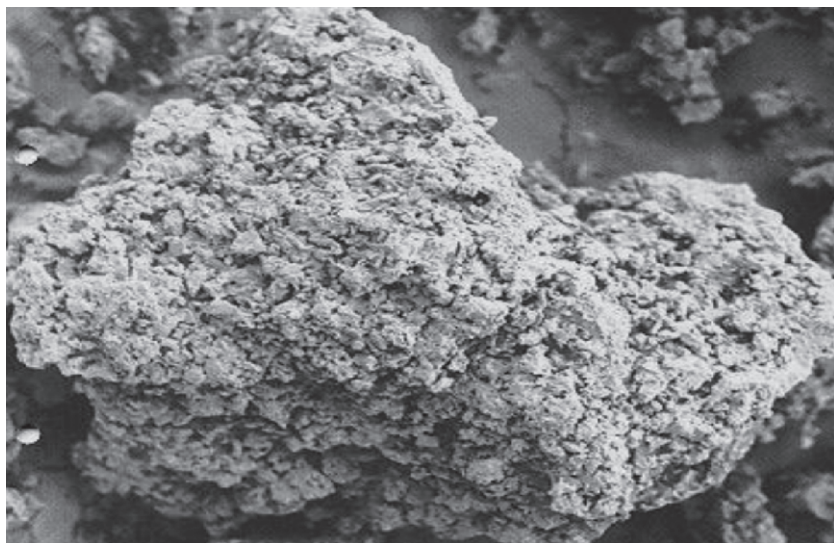


Spray dried lactose is used mainly for tablet manufacture by direct compression processes.

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.



ANHYLAC™

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

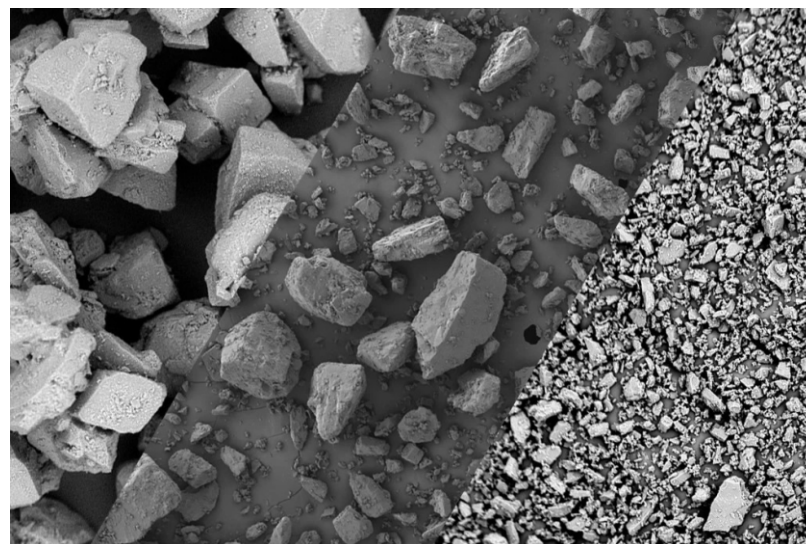
DIPLAC™ – (INHALATIONAL GRADE LACTOSE)

Inhalation lactose is a naturally occurring disaccharide, which is extensively purified to meet the strict requirements for use in an inhaled application. To obtain different functionalities for the inhalation formulation the lactose is further processed by techniques such as sieving, milling, micronization or air-classification. A dry powder inhaler formulation should contain drug particles with an aerodynamic particle size of less than 5 μm for an optimal pulmonary delivery. Due to the high surface area to mass ratio of the particulates, the powdered drug is highly cohesive. Therefore a larger carrier, such as lactose, is applied to de-agglomerate the drug particles and optimize the deposition of the drug in the lung.

We have launched **DIPLAC™** an Innovative solution as Inhalational powder for the fastest growing and most significant form of inhaled treatments; Dry Powder Inhalers (DPI).

The properties of the inhalation lactose are chosen based on the different parameters, like the device, filling platform, type of drug and how it is processed and the required drug release.

We at **IIEPL** provide a broad range of inhalation lactose grades – **DIPLAC™**, enabling tailored selection and blending to meet specific device and formulation requirements.



IIEPL LACTOSE PORTFOLIO – IIEPL is not restricted to the below list

ALFONOLAC™ (LACTOSE MONOHYDRATE)	SPRAYLAC™ (SPRAYDRIED)	ANHYLAC™ (LACTOSE ANHYDROUS)	DIPLAC™ (INHALATIONAL GRADE LACTOSE)
ALFONOLAC - 70M	SPRAYLAC - 35	ANHYLAC - 005	DIPLAC - 0011
ALFONOLAC - 80M	SPRAYLAC - 45	ANHYLAC - 006	DIPLAC - 0031
ALFONOLAC - 90M	SPRAYLAC - 50	ANHYLAC - 009	DIPLAC - 0101
ALFONOLAC - 100M	SPRAYLAC - 65	ANHYLAC - 014	DIPLAC - 0601
ALFONOLAC - 150M	SPRAYLAC - 70	ANHYLAC - 016	DIPLAC - 1001
ALFONOLAC - 200M	SPRAYLAC - 85	ANHYLAC - IMPALPABLE	DIPLAC - 2001
ALFONOLAC - 350M	SPRAYLAC - 90		DIPLAC - 2101
ALFONOLAC - 450M	SPRAYLAC - 95		DIPLAC - 2301
ALFONOLAC - IMPALPABLE	SPRAYLAC - 105		DIPLAC - 2311
ALFONOLAC - INJECTABLE			DIPLAC - 2511
			DIPLAC - 3001
			DIPLAC - 4001
			DIPLAC - 5001

QUALITY CONTROL LAB

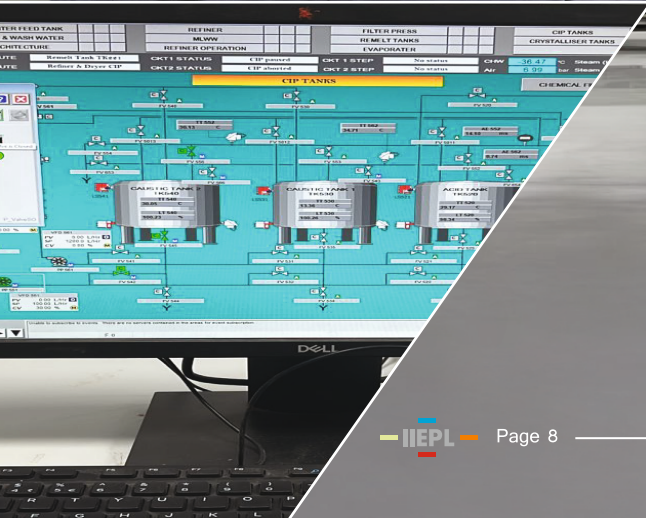




← SCADA ROOM



PACKING ROOM
↓





← **CRYSTALLISERS**

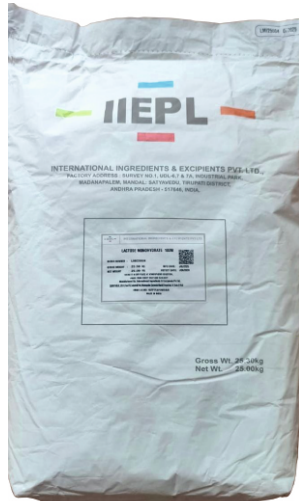
CIP TANKS



OUR WAREHOUSE



OUR PACKAGING



25KGS PAPER BAG



45KGS HDPE DRUM



25KGS HDPE DRUM



5KGS HDPE DRUM

CERTIFICATION



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

US DMF : 037688

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

US DMF : 041438



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