

PROMOTING NEW POSSIBILITIES FOR HEALTHY LIFE



BULK API AND CONTRACT MANUFACTURER'S- TABLETS, LIQUID ORALS
AND EXCIPIENTS



YOUR EXPERT PARTNER

FORMULATING NEW

POSSIBILITIES FOR HEALTHY LIFE

LACTOSE INDIA LIMITED

Lactose India Limited is your full service CMO partner in the Contract Manufacturing of pharmaceutical Drug Products, Excipients & with our own Bulk manufacturing of Active Pharmaceutical Ingredients (APIs)- Lactulose . At Lactose India Limited, our experts are taking care to follow your needs every step of the way

We understand that behind every successful pharmaceutical project are the people, from the chemists and operators to the QA/QC teams, project managers, and most importantly customers, working together who make it possible. At Lactose India Limited, our experts are committed to providing you with inspired global service, regulatory support and dedicated management at all points.

COMPANY PROFILE

We have earned our name & reputation with our Brand product “Lactose Monohydrate” (an Excipient). Since its inception in 1991, the company has delivered unsurpassed product value to our customers who have benefitted with a high quality (100 % Import substitute) product backed by unparalleled service, technical support and formulation customization capabilities.

Lactose India Limited has stood for perfection, quality, constant innovation and complete dedication to their clients. Over the years, Lactose India Limited has broadened its horizons to enter into Contract Manufacturing of Tablets, Liquid Orals & Manufacturing of Pharmaceutical formulations.

We are Contract / Toll Manufacturers for companies like, Kerry Ingredients Pvt Ltd (Kerry, USA), Sanofi (Sanofi Group), International Pharmaceuticals Generic – Canada, UCB Belgium, Eurolife Healthcare Pvt Ltd. Products from these units are exported to Russia, Kazakhstan, Belarus, Nigeria, Sri Lanka, Pakistan, Bangladesh, Korea, Myanmar, Ghana, Mexico, Columbia, Iran, Egypt, Kuwait, Australia, Canada and several other countries.

Lactose India Limited is a WHO – cGMP and ISO: 9001: 2008 certified Company giving you uncompromising quality standard Products. Our products are available in different Segments like Liquid dosage Form, Solid dosage Forms, Excipients & API's. The packaging is available as per buyer's requirements or as per Industry requirement.

Our new innovative & market driven Finished Pharmaceutical Formulations division is intended to nurture alternatives & help curtail challenges from global market prices & existing competitive products.

For the first time ever in Asia, we have launched the production of Lactulose USP with a State of the Art Manufacturing facility. The plant produces both, Lactulose Concentrate and Lactulose Solution USP / EP in Commercial Drum packs of 280 Kgs.

The strategic location of our Vadodara Plant in Gujarat 250 Km from Port of Nhava Sheva will nurture our customers of Southeast Asian -Pacific Region, Middle East, North Africa & Europe along with our domestic clients in India.

Lactose India Limited help leading pharmaceutical companies achieve their product success for their market driven products. Solving Your Complex Problems Through our long-standing experience in top big pharmaceutical companies, we understand the pharmaceutical industry's ever-changing variables - such as under-utilized capacity, fierce price competition, and growing regulatory pressures - which affect your pharmaceutical drug development. As your partner, we draw upon that insight to solve complex problems early-on and bring efficiency throughout the process.

From Excipient Manufacturing to Bulk APIs – Lactulose in Commercial Packing..

Lactose India Limited provides a broad range of capabilities in manufacturing of APIs and Contract Manufacturing of Tablets & Liquid Orals. Our network of fully-inspected cGMP facilities with adaptable volumes, state-of-the-art technologies and stringent quality systems provides flexible solutions to overcome the challenges.

API's

OUR CAPABILITIES IN MANUFACTURING BULK API'S- LACTULOSE & TECHNOLOGY SUPPORT BY GERMANY

Lactose India has pioneered the manufacturing of Disaccharide Lactulose, a versatile bulk API. It is a one of a kind plant in the whole of Asia with a capacity to manufacture 2400 MT / Annum. Lactulose is used in the treatment of Constipation, Hepatitis Encephalopathy, Intestinal Micro flora, Dental Care, Diabetes, and Chronic Liver Disease & as an effective Prebiotic.

A clear, viscous liquid, colour less or pale brownish -yellow, miscible with water. It may be a supersaturated solution or may contain crystals which disappear on heating. Chemical name: 4-O- β D-galactopyranosyl-D-fructofuranose

LACTULOSE MANUFACTURING

Specialized in our state-
of- the-art facilities

Lactulose, how does it work?

Lactulose reaches the colon unchanged, where the bacteria of the intestines metabolise it, producing a number of short chain fatty acids. This process initiates a large number of effects in the gastrointestinal tract:

Laxative-osmotic

Ammoniac binding

Pre-biotic

Lactulose as a drug: quality and application spectrum

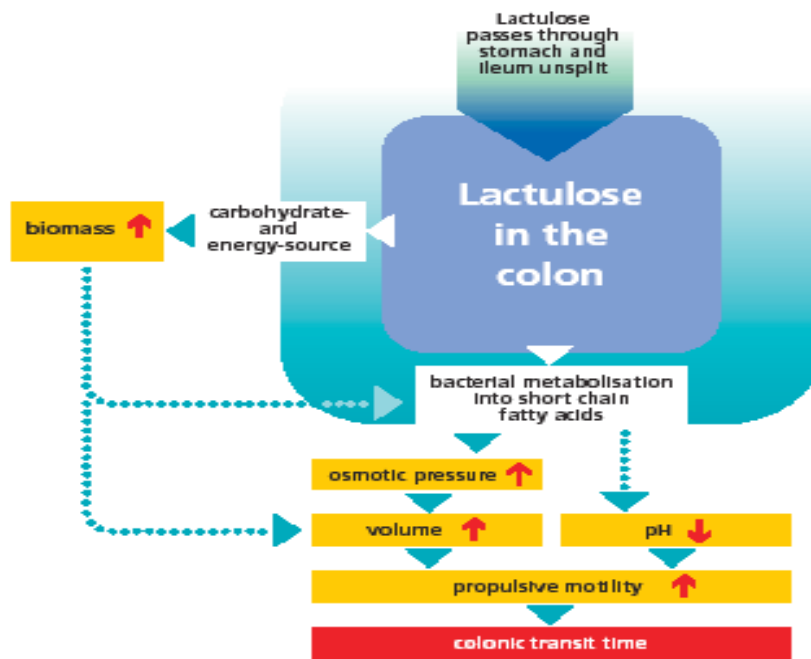
In humans, the gastrointestinal tract is a highly complex eco-system which reacts sensitively to its interior and exterior environment. An intact intestinal barrier, guarantees, together with a well functioning immune system, the integrity of the body's interior. A number of influencing factors, such as stress, incorrect nutrition and lifestyle, as well as unusual hygienic conditions and food (e.g. on holiday) can upset this delicate system and lead to health difficulties. If used correctly, the prebiotic effect of lactulose can play a major role in ensuring that equilibrium is stabilized or re-established. In human medicine, lactulose has a long track record as a successful therapy against constipation, portal hepatic encephalopathy and salmonella, or as a complementary measure.

Constipation

Hepatic Encephalopathia

Salmonellose

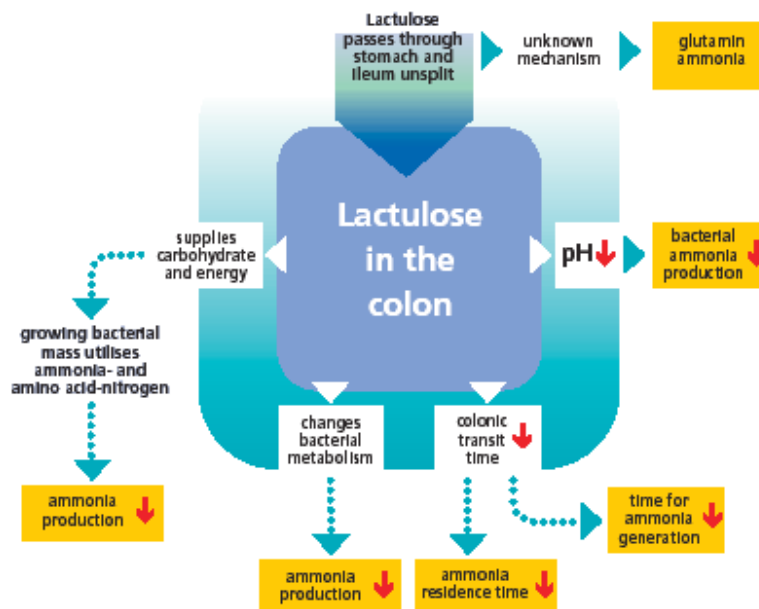
Physiological therapy for constipation Lactulose has been successfully applied in the treatment of constipation since 1959. Lactulose has proven its efficacy as a gentle as well as highly effective medication in the regulation of intestinal activity and regular bowels. It can also play an important role to support intestinal activities in the pre- and post-operative phases.



Mechanism of action in constipation

Golden Standard in Portal - Systemic Encephalopathy

Lactulose has been the Gold Standard in PSE therapy since 1966. Lactulose has an inhibiting action on ammonia production in the ileum and reduces the ammonia level in portal circulation.



Mechanism of action in hepatic encephalopathy

Salmonella infections

Lactulose has been applied in the treatment of intestinal infections since 1975. Lactulose reduces the pH value to make the milieu less favourable for salmonella and expedites transit time. Both actions are important pre-conditions for the regeneration of intestinal flora.

Lactulose as a logical food additive

Lactulose in prophylactic therapy

Pre-biotic Effect

The food design trend

Health Care needs health food

Lactulose in the food industry

Lactulose in prophylactic therapy

It is now known that many bowel irritation symptoms and illnesses are closely related to the living and eating habits common in modern society. On the other hand, fitness and health are also part of our present day lifestyles. Health has therefore more than simple medicinal aspects. Our mobility and our enjoyment of travel, sport etc. depends on personal well-being, for which we must each play our part.

Food, metabolism and the immune system must be seen as an interactive process. If we can balance our food and digestion with this background in mind, we can contribute to stabilising health.

Pre-biotic effect

The pre-biotic effect of lactulose can play its part not only in therapy but also as a sensible preventive agent in order to maintain the health of the immune system, the gastro-intestinal tract and hence to underpin and enhance general well-being. In the future, lactulose will therefore be increasingly added to foods as a nutritional supplement because of its preventive actions.

The food design trend

The trend in the food industry is moving towards clearly defined ingredients, put together according to nutritional/scientific food design specifications as a sensible nutrition supplement. Obviously, the safety of the product in both its effect and its interaction are of primary importance. Lactulose has a very high safety profile even over long ingestion periods. Food design is feasible for individual target groups and market niches: For children and young people of various ages, for expectant and breast-feeding mothers, for high-performance sportsmen and women and more cerebral workers as well as for senior citizens: each with their specific and special requirements. The ability to positively influence the digestive and immune systems makes lactulose a key player in food design, as an agent between nutrition and health.

Health Care needs health food

In food production, health aspects are gaining in importance. Today the gastrointestinal tract has been identified as a central organ of the immune system, and consequently food research and production have gained more significance. Growing health awareness and the desire and the will for illness prevention are broad-based social movements. The prevention of illnesses in the gastrointestinal tract is the field in which

lactulose plays an outstanding role: in its liquid form it can be easily and unproblematically added to many food to promote overall health and quality of life.

Lactulose in the food industry

Following the successful introduction of minerals, electrolytes and vitamins as nutritional supplements in the production of health food, lactulose, with its high safety profile and its health-promoting pre-biotic effects can also now become a very interesting product for the industry.

ADVANTAGES OF LACTULOSE:-

- Maintains the healthy good bacteria in the colon.
- It is non- toxic and non-habit forming.
- It does not develop a tolerance so no need for increase in dosage,
Can be safely used by and recommended to:
 - Pregnant women
 - Elderly Patients
 - Nursing mothers
 - Children
 - Patients with Chronic Liver Disease & Post Surgical Patients

**WE FOCUS
ON YOU**

Active Customers which have Global
Presence

CONTRACT MANUFACTURING, We draw upon a combination of facilities equipped to manufacturing of both Wet Granulation & Dry Granulation of solid dosage, Liquid Orals & pouch filling.

OUR STRENGTH

- ❖ Technocrats as Promoters
- ❖ Over a decades of experience in manufacturing and International Marketing
- ❖ Excellent Quality Standards
- ❖ Major Multinational Companies as clients
- ❖ Established track record as a manufacturer
- ❖ Adequate capabilities
- ❖ Sound Infrastructure

Lactose India Limited is one amongst the fastest growing contract manufacturing companies in Finished Formulation Products, Nutritional / Dietary Supplements APIs & Excipients. LIL develops long-term strategic partnerships with clients, responds quickly and effectively to market demand, and develops tailored solutions for specific needs. Our vision is to become the best known manufacturers of Nutritional, API and Formulated Products to the Pharmaceutical industry.

Lactose India Limited is a certified FDA & WHO-GMP approved facility, and produces products for exports to South East Asian Pacific Regions, West African & CIS Countries.

Our corporate Quality Assurance Department, Regulatory Affairs and Audited In-House Laboratory Testing Facility is a reassurance to our global clients. We are heading towards EU GMP and MHRA Certifications.

As a Toll Manufacturer, we are continuously upgrading our facilities to help our CMOs develop new products and improve their existing product line in the market and to fulfill upcoming regulatory regulations.

The Tablet production lines ensure high levels of productivity, clearly differentiating it from competition. By improving the efficiency of the production processes, Lactose India Limited is capable of reducing processing times and increase production volumes.

With over 25 years of production experience using state-of-the-art equipment and technologies with stringent quality systems. Our combined legacy becomes your value when choosing Lactose India Limited as your preferred partner.

This combination of expertise, state-of-the-art equipment and stringent quality systems creates strong value in quality, efficiency and price for your outsourcing needs. Full-Service CMO for a Global Market. Our manufactured is marketed in a global market in more than 20 countries worldwide.

Lactose India Limited employs over 650 employees in production serving as a CMO. Fully-Inspected Facilities Our facilities are fully-inspected by all relevant health agencies including the FDA & WHO-GMP approved facility as well as audited by numerous customers. Lactose India Limited is a preferred supplier. Key Facility Capacities for APIs. Our API manufacturing sites is going to produce 2400 MT/Annum of Lactulose Solution & Lactulose Concentrate.

OUR FORMULATIONS FOR EXPORTS

Competitive Markets

Drug manufacturing for International markets in a highly competitive markets and only the very best to survive. It takes a strong infrastructure with a great precision in manufacturing expertise to bring out finest quality finished formulations. At, Lactose India Limited, we have long track record of manufacturing pharmaceuticals oral & Liquid / Solid dosage forms for Sanofi , Dr Reddy's / UCB Ltd, Euro life Healthcare Pvt

Ltd and for Excipients Kerry Ingredients, a Kerry Group USA. We are proud to be able to provide high quality products that can improve Health and Quality of Life of many people across the globe at reasonable prices. We have manufacturing infrastructure consisting of modern WHO-GMP Certified facilities. We use state of art facility equipment's and have team of qualified professionals who ensure the rolls out of our factory that will meet the WHO-GMP Guidelines and other world class standards. This allows us to bring out finest quality finished formulations to cater to your needs.

Surpassing Standards Successfully Inspected by the FDA, Audited by 8 out of the Top 10 Pharma

QUALITY

- Assuring product quality, purity, efficacy and safety
- Committed for continuous improvement
- Quality assured through a highly qualified and competent workforce
- Committed towards total customer satisfaction

QUALITY ASSURANCE AND QUALITY CONTROL

- Well equipped laboratory with Chemical and Microbial Testing and Instrumentation.
- Approved and experience Technical Chemists for testing of Raw material, In Process Quality Checks for Primary & Secondary packaging material as well as Finished Product.
- Strong QA system based on Quality Policy, Training, Change Control, Self
- Inspection, Batch Deviation & Failure Investigation, OOS Investigation and Market Complaint Investigation.

Lactose India Limited, experts understand a continuous commitment to compliance with worldwide Health Agencies and customers via audits, inspections and a code of ethics. We bring over 2 decades of combined years of acquired facility experience with the highest industry standards to excel in meeting the requirements of compliance for your pharmaceutical product success.

We maintain a culture of continuous improvement to optimize and enhance quality systems and ensure operational excellence. This culture extends beyond our facilities to their surrounding communities with a commitment to local environmental and regulatory responsibilities as well. Lactose India Limited experts receive on-going training to guarantee customers benefit from the highest levels of compliance.

In addition, Codes of Ethics & Conduct Lactose India Limited responsibly conducts business through a Code of Ethics and Compliance which communicates to employees and suppliers the importance their actions and decisions have, in a legal and ethical sense, on maintaining both compliance and trust with customers.

Training on our Code of Ethics and Compliance is regularly conducted.



Lactose India Limited.

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