
Esri
Industries &
Chemicals Pvt Ltd

OVERVIEW AND HISTORY

Industries & Chemicals Pvt Ltd

Overview

We have over 30 years of experience in the Pharmaceutical industry and have worked on a host of product categories with the biggest names in the business. Quality has been the cornerstone of our thinking and has helped us sustain as well as grow our business over this long period.

At Espi we intend to not only focus on quality but also be dynamic and adapt to the environment around us. This attitude means that we not only deliver to our clients the discipline and consistent quality associated with contract manufacturing but also provide innovative solutions for new product development.

Our History

- Began as a bulk drug unit for supply of Antacid chemicals to Warner Hindustan Ltd who were having difficulty procuring this material
- Received a big contract from P&G in 1987 for manufacture of their prestigious brand "Oil of Olay". This familiarized the team with manufacturing practices followed internationally and the company grew exponentially from then on.
- Today manufactures a multitude of products for the biggest MNC's in the space with a special focus on Antacid manufacture
- Quality has been the watch word at Espi and the company's facilities are constantly audited by principals as well as various regulatory agencies from overseas and in India

Espi Industries & Chemicals Pvt Ltd

ESPI INDUSTRIES AND CHEMICALS PRIVATE LIMITED

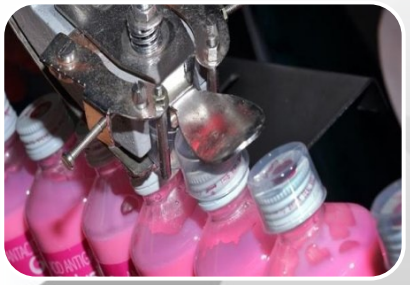
Espi Industries and Chemicals Pvt Ltd. set up in 1979 is the oldest of the three plants we currently operate. Spread over approximately 10,000 square meters the plant which started out with a total of 8 workmen involved in the manufacture of Aluminium and Magnesium Hydroxide paste has today developed into a facility primarily for manufacture of formulations and boasts of:

- Four state of the art oral liquid filling lines with a capacity of 50 million bottles annually
- A tablet manufacturing section with an installed capacity of over 250 million units annually
- A sachet packing section for liquids and dry powders with a capacity of 50 million sachets annually

All supported by a committed workforce of over 250 individuals.

Our GLP approved research center is spread over approximately 5000 square feet. While we continue to prioritize quality in manufacturing and attempt to reduce defects to zero, we have also been fine tuning capabilities such as formulation development, stability and release testing etc. We have successfully been able to develop and produce brands for the likes of Dr. Reddy's Labs and Sun Pharmaceuticals.

We currently produce API's at a separate facility in close proximity to our formulations plant in order to optimize the manufacturing process. Our API plant has an installed capacity of about 8000 kg per shift of Aluminium and Magnesium Hydroxide paste. This paste is the primary raw material for antacids which as a product category accounts for a majority of the produce in the liquids section of the formulations unit.



DEEPTI FORMULATIONS PRIVATE LIMITED

Espi Industries & Chemicals Pvt Ltd

History

- Incorporated in December 1990 with the intention of manufacturing Bulk Drugs
- Commercial production of the same began in the year 1993
- Adopted a change in strategy in the year 1998 and began manufacturing Betalactum products at the facility for some of the larger MNC's
- In the year 2006-07 most of the production for Betalactum was shifted to North India due to various incentives announced by the government in this region
- The company was hit hard and forced to revamp the facility for manufacture of non Betalactum products
- DFPL faced a tough period during the years 2007-2011
- The Management and Board was able to turn the fortunes of the company around in the year 2011 through a great deal of investment in infrastructure and facilities at the unit
- The company has grown from strength to strength over the last 5 years

Deepti Formulations Pvt Ltd. is spread over 2000 square meters and engages about 50 individuals. Non Betalactum formulations are manufactured. Infrastructure at the facility includes:

- A state of the art liquid filling line with a capacity of 9 million bottles annually, primarily utilized for the manufacture of liquid drops
- A tablet manufacturing section with an installed capacity of over 300 million units annually
- A capsule manufacturing section with an installed capacity of over 300 million units annually
- A dry syrup packing section for dry powders with a capacity of 6 million units annually
- A GLP approved research center and laboratory spread over approximately 3000 square feet for analysis, microbial testing and product development

ANALYTICAL CAPABILITIES

Industries & Chemicals Pvt Ltd

We offer a vast array of analytical services to the pharmaceutical industry. An experienced staff coupled with state-of-the-art instrumentation provides clients with the knowledge, skill, and assurance for sound results.

Development, Validation and Transfer/Evaluations of Test Methodologies

- Full method development
- Method transfer/ evaluation
- Optimization of existing methods
- Validation of developed and transferred methods

The facility possesses a full fledged GLP approved Analytical Lab which is sub-divided into

- Wet lab
- Instrumentation
- Microbiology

- All sections have state of the art equipment as per current industry requirements
- The HPLC and IR are connected through a central server to ensure data integrity
- Apart from routine analysis the lab is equipped to carry our Method Development and Analytical Method Validations including impurity profiling

Pre Formulation/Formulation Development

Pre Formulation/Formulation Development

Our scientists characterize, formulate, and develop drugs for oral delivery and have experience with a variety of liquid formulations (syrups or suspensions)

- Pre-formulation
- Formulation development
- Flavoring
- Manufacturing process development
- Stability and release testing
- Scale-up and technical transfer

A separate formulation development department of over 5000 square feet with lab scale prototype equipment is available on site. The exact production conditions of temperature, humidity and air changes can be replicated in this area (for product development). The equipment available can be used for liquid oral, tablet, capsule and dry syrup development.

We have developed products for companies like DRL and Sun Pharmaceuticals in this Lab and compiled the dossiers for registration in Russia, and many African and South East Asian countries.

STABILITY STUDIES

Espi Industries & Chemicals Pvt Ltd

Espi provides complete stability testing and storage services for your product as per required conditions. We also generate stability protocols, generate and compile stability data, evaluate data, and prepare reports for regulatory submissions. Apart from routine stability testing, we undertake stability testing for some of our principals to generate data for change in vendors, change in packing components etc.

Key Stability Studies

- New drug (R&D) stability
- Commercial stability
- Container and closure stability

Stability Storage

We have five stability chambers of which two are walk in. All the chambers are connected to a double power back up in case of a power break down. The chambers are also connected to a central computer to record all necessary data. Alarms are connected to all the systems to alert any excursions in the set limits.

ORAL SOLIDS

Espi Industries & Chemicals Pvt Ltd

Espi's state-of-the-art oral manufacturing facility in Hyderabad, India, has a capacity to manufacture 250 million tablets and capsules annually. This facility is approved as per WHO-GMP and NAFDAC – Nigeria standards, and has been supplying the said products since 1996. Stringent measures have been taken for environmental and contamination control, and materials management.

Manufacturing Services

- Tablets
- Capsules
- Commercial batch sizes from 50 kg to 800 kg
- Comprehensive analytical services and microbiology testing

Manufacturing Technology

Blending and granulation: – Wide range of blender types and sizes – Wet and Dry granulation – Roller compaction – Particle sizing – Directly-compressible formulation

Compression – Range of compression equipment with output up to 1000 tablets per minute per machine

Encapsulation – Range of capsule filling equipment with tooling – Powder fill, granule fill, pellet fill, tablet fill

Coating – Range of tablet coating equipment

Packaging Capabilities

- Strip
- Blisters
- Bulk packing

ORAL LIQUIDS

Espi Industries & Chemicals Pvt Ltd

Over the past 25 years, Espi has consistently developed its liquid manufacturing expertise. We are now one of the largest manufacturers (by volume) of antacids in Asia. As on date we have the ability to produce up to 50 million bottles per year in our manufacturing facility. Our facility is also approved to export to 17 African nations.

This plant has been designed to serve the needs of global markets. We believe that our oral liquid section represents our true strength and this department is where our experience and know how can add value. The product range and activities undertaken include:

- Solutions • Syrups • Suspensions
- Pilot scale and commercial manufacturing
- Comprehensive analytical services & microbiology testing
- Fill volumes from 15 mL to 350 mL

Packaging Capabilities

- Glass bottles
- Plastic bottles/ PET bottles

API's

At Espi we believe in focusing on our core competency, which today is the manufacture of oral liquids with an emphasis on Antacids. With this in mind, we have chosen to take the quality of our key raw material into our own hands. We not only manufacture the finished products i.e. antacid formulations, but also different grades of Aluminium and Magnesium Hydroxide paste (API's) which are key constituents in all antacids. The company has adopted this method of vertical integration since the year 1990.

API's are currently produced in an independent facility in Uppal, Hyderabad. The plant has a capacity of about 8000 kg per day. The finished product is utilized for internal consumption as well as for sale to external clients.

QUALITY AND COMPLIANCE

Espi Industries & Chemicals Pvt Ltd

Espi pushes relentlessly for consistency in quality. Our proven delivery model and impressive track record over 30 years is testament to our unwavering commitment to continuous improvement. Our key focus areas are:

- Delivering the highest quality products and services on time
- Creating transparent quality metrics and review systems
- Building compliance teams and quality review teams to maintain high compliance levels and monitoring the same for continuous improvement
- A clear distinction between Quality Assurance/Quality Control personnel and the Production Department. Ensuring that all personnel in Q.A. feel empowered and highlight concerns
- Arranging periodic discussions with employees on constantly evloving quality standards

Employee Welfare

Implementing EHS according to regulatory requirements

Comprehensive medical check-up for all employees at the plant once annually

Health insurance cover for employees and their immediate family members

Compliance

Our quality systems fulfill WHO GMP, NAFDAC (Nigeria) and 16 other African country requirements. We successfully complete audits every year by regulatory agencies as well as client quality teams

WHO-GMP

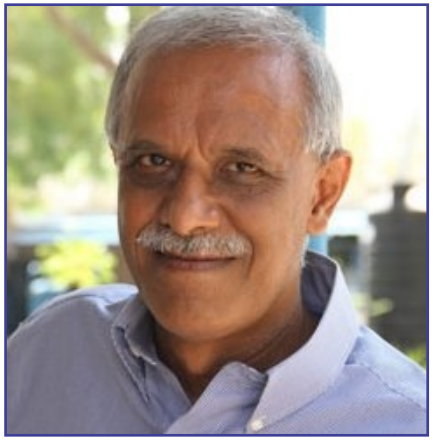
NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION & CONTROL
NAFDAC

OUR LEADERSHIP

Our management team has a total of over 250 years of experience in the pharmaceutical industry. We strictly believe in promoting from within the organization and therefore most of the personnel at senior positions today have grown through the ranks at the Espi.

Mr. Ashwini Chadda, an IIT Kanpur and IIM Calcutta graduate, is the brains behind what Espi is today. He founded the company with the support of 8 workmen and through ingenuity and hard work has been able to grow the firm exponentially. After a short stint with a firm called Deepak Nitrite in the year 1978, he decided it was time to spread his wings and thus created Espi in '79.

Mr. Chadda is responsible for formulating and executing long term strategies and is the key decision maker with regard to new initiatives to be undertaken by the company. Product quality and following ethical practices are his two major priorities and his thinking filters down and has a major influence on the way the firm is run.



Mr. Ashwini Chadda
Chairman & Founder

Our Clients

SUN PHARMA
Dr. Reddy's
Johnson & Johnson
P&G
Pfizer
Piramal knowledge action care
Veritaz Building Happier Life Through Medicare
East India Pharmaceutical Works Ltd Medicine for Millions
NOVARTIS

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