

**Bymaa Laboratories Private Limited**  
(A WHO-GMP Certified Company)



# BYMAA LABORATORIES PRIVATE LIMITED

## Company Overview



Bymaa Laboratories Private Limited is based in Pondicherry, a South Eastern coastal town of the Indian Peninsular, where the beauty of Mother Nature and the heritage of the French are preserved. It was established in 2015 as a Non-Beta Lactam Formulations unit and is an internationally accredited pharmaceutical company that provides healthcare solutions to address the evolving needs of clients worldwide. With its renowned quality standards, our company's mission is to be a global leader in discovering new ways to improve people's lives by continuously refining the manufacturing and distributions of medicines globally. We believe that our vision which is committed to develop, manufacture and supply the finest quality medicinal products, will lead to a healthier society all around the world.

### PRODUCT RANGE

- ▶ Antidiabetic
- ▶ Cardiovascular
- ▶ Gastroenterology
- ▶ Gynecology
- ▶ Multivitamins and Multiminerals
- ▶ Analgesic, Antipyretic & Anti-allergics
- ▶ Dietary & Health supplements
- ▶ Topicals





Bymaa Laboratories is dedicated towards achieving these objectives in line with our company's mission. Through continuous research coupled with technological advancement, our culture of strong values defines and assist us in executing our strategy to maintain optimal quality in developing medicines. Backed by a team of professionals we are continuously increasing our product range in oral dosage forms.

Close collaboration with leading global partners who share our vision and complement our strengths have been a catalyst to our constant growth. By capitalizing on key alliances for marketing and distribution, our aim to improve the health of patients worldwide include:

- ▶ **Continuous innovation in formulation**
- ▶ **Effective marketing**
- ▶ **State-of-the-art manufacturing facilities**
- ▶ **A wide product portfolio**
- ▶ **In-depth understanding of pharmaceutical regulations**



## QUALITY CONTROL POLICY

Right from inception, the company strongly believes and follows the principle “Quality - The Key to Success”.

## QUALITY POLICY

The Management and Staff at Bymaa Laboratories Private Limited are committed to consistently manufacture and deliver pharmaceutical products of quality that comply with International Quality Standards by strict adherence to:

- ▶ Good Manufacturing Practice (GMP)
- ▶ Quality Management System (QMS)
- ▶ Good Laboratory Practices (GLP).



## Key Elements for Effective Quality Controls

- ▶ Our state-of-the-art manufacturing facilities are cGMP compliant and conform to national and international standards. Our sophisticated industrial machineries are procured to achieve a high level of precision.
- ▶ Our quality control laboratories have the latest equipment that offer excellence at every stage of processing. We have a dedicated pool of talent that consistently adheres to the international safety standards.
- ▶ We maintain world-class quality for our products and services across domestic and overseas markets, thus ensuring that every person has access to the best medicines in the world.
- ▶ We are committed towards continuously upgrading our manufacturing facilities by adapting cutting-edge technological innovations in order to provide quality medicines at an affordable price.

## KEY STRENGTHS

- ▶ One of the fastest growing pharmaceutical companies in India
- ▶ Strict adherence to current Good Manufacturing Practices (cGMP)
- ▶ Driven by quality, integrity, and innovation
- ▶ Strongly committed to business ethics
- ▶ Well experienced and dedicated team with expertise in pharmaceutical manufacturing
- ▶ Wide range of products catering for the pharmaceuticals and healthcare sectors
- ▶ Customized packaging as per the customer and market requirements



## ACCREDITATIONS & RECOGNITIONS

We are a WHO-cGMP and ISO 9001:2015 certified company. Our facility is also designed and built to compliment with the standards of PICS/ USFDA/ UKMHRA/ TGA/ EUGMP etc. As a recognized WHO-cGMP approved manufacturer for pharmaceutical products, we strive not only to adhere but also exceed the WHO/PICS quality standards.

We have already initiated the process of obtaining various global recognitions and are in the process of exporting to more than 10 countries across the globe.

## FACILITY



## INFRASTRUCTURE

Our plant is located in the Union Territory of Pondicherry, one of the most popular tourist destinations in South India. Pondicherry is situated about 170 km south of Chennai on the East Coast Road and National Highway NH-45A connecting to Chennai and other major cities. Pondicherry is easily accessed by air, sea and land (road and railroad).

- ▶ Our manufacturing facility covers approximately over 45,000 square feet and is located at PIPDIC (Pondicherry Industrial Promotion Development and Investment Corporation Limited) -Electronic Park
- ▶ Uni-directional flow for men and material and process movement
- ▶ Eco-friendly design of the Building & Premises
- ▶ Highly advanced HVAC, Water and other Utility Systems
- ▶ Effective water and waste management systems
- ▶ Adheres to GMP Documentation and Records Guidelines
- ▶ Over 10,000 square feet area dedicated for Quality Control and Quality Assurance activities

## PRODUCTION FACILITY



Our plant is designed to manufacture pharmaceutical/nutraceutical formulations, such as Tablets, Hard Gelatin Capsules, Powders & Ointments (Topical). The Ointment & Lotion section, has additional facility for manufacturing Cream, Gel and Serum.

All production / formulation activities are conducted in the ground floor.

### The production area consists of the following section:

- ▶ Granulation Section  
Sieving | Lubrication | Mixing | Drying
- ▶ Blending Section
- ▶ Granule In-Process Storage
- ▶ Compression Sections
- ▶ Tablet Storage
- ▶ Coating Section
- ▶ Capsule Filling Section
- ▶ Powder Filling Section
- ▶ In - Process Quality Assurance
- ▶ Washing Area
- ▶ Ointment Section

## MANUFACTURING CAPACITY

Dosage Forms	Installed Capacity Per Shift Per Annum
Tablets	200 Million
Hard Gelatin Capsules	200 Million
Powders	100 Tonnes
Ointments, Lotions & Creams	100 Tonnes



### PACKAGING SECTION

Primary and Secondary Packing areas are separated in order to prevent contamination, mix-ups and cross - contamination. We have following packaging lines;

- ▶ PVC Blister Packing Lines
- ▶ Alu-Alu Packing Lines
- ▶ Strip Packing Line
- ▶ Pouch/Container/Jar Filling line
- ▶ Sachet Filling Line
- ▶ Tube Filling (Laminated & Aluminum Tubes)



### WARE HOUSE

We have a 4000 square feet Warehouse, that has been built complying to cGMP norms. The warehouse is temperature and humidity controlled so as to ensure quality of the materials throughout its shelf life. Sampling and dispensing of materials are carried out under laminar airflow in class 100 environment.



## RESEARCH & DEVELOPMENT

We have a dedicated Formulation R&D at the ground floor, where new products are developed and Lab Scale/Pilot Scale batches are taken. These batches are studied for its efficacy and stability. Based on the study the products are transferred to Commercial Production where the batches are upscaled to Commercial Volumes.

At our Analytical R&D section we develop methods for testing of Finished formulations. Once the methods are developed and approved the same is being mastered and transferred to Quality Control laboratory for inclusion into their testing procedures.



## QUALITY CONTROL

Our in-house state-of-the-art testing laboratory is fully equipped with the latest pharmaceutical lab apparatus. We have a highly qualified and experienced technical team, who use transparent, traceable and calibrated techniques to maintain high standards of quality at all stages of the manufacturing and delivery process. Our quality control (QC) laboratory plays a critical role in testing both in-process and finished products.

We at Bymaa not only monitor and control the quality of incoming APIs (active pharmaceutical ingredients), but other supplies used in the manufacturing process; QC Labs are also instrumental in the batch release process.

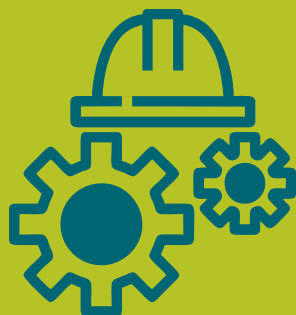


## WATER PLANT

The Purified Water required for the manufacturing process is generated by our in-house water purification plant. Municipality Supply Water is used as feed water to produce Purified Water. The purified water system was installed according to ISPE (International Society for Pharmaceutical Engineering) baseline pharmaceutical engineering guide. The purified water meets USP-24 specifications.

## AIR HANDLING SYSTEMS

Production, Stores and Microbiology areas are provided with Air Handling Units to maintain the required Room Condition with respect to the Temperature, Relative Humidity, Particulate Matter Count and Potential Risk of Airborne Contamination. A total number of 21 Double Skin Air Handling Units are in place. The core areas are supplied with dedicated AHU's to prevent cross contamination. Our AHU systems conform to ISO 14644-3 standard. All Air Handling Units are double skin type. The Ventilation System design is based on Recirculation of air at 90% and 10% of fresh air, with not less than 30 air changes per hour. We ensure that the air entering our air handling units undergoes these four stages of filtration process.



## ENGINEERING & MAINTENANCE

Our Engineering and Maintenance department are equipped to conduct maintenance and engineering activities round the clock. The team strictly adheres to the Preventive Maintenance schedule in order to reduce break down of machinery and equipments.

## Stability Studies & Documentation

We at Bymaa, have installed an 8,000 litres Walk in Stability Chambers for Real-Time Stability studies along with other Stability chambers for conducting Accelerated stability studies of our products at different temperature and humidity conditions. We are also equipped with Photo Stability chamber to conduct the light exposure testing for the products. We continuously study and document the product stability and efficacy.



## Regulatory Affairs (RA)

We have a seasoned Regulatory Department with qualified & experienced personnel who prepare dossiers as per the guidelines of the Ministry of Health of different countries and its regulatory bodies. Our Regulatory team is well updated with all the recent regulations of Drug and Food Administration agency of India and other countries.

## Quality Management & Assurance Systems (QMS)

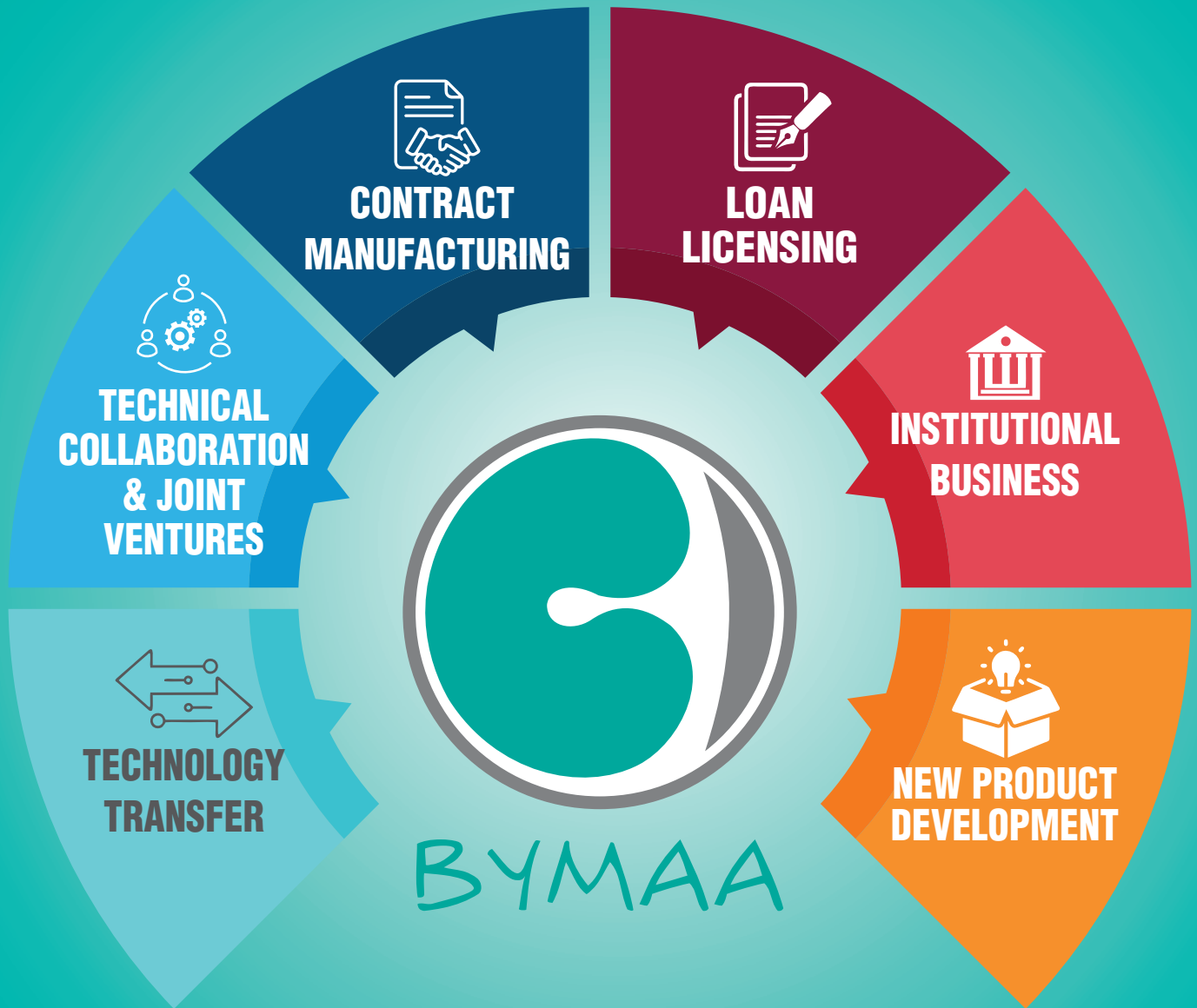
Our Quality Assurance (QA) Department adheres to strict operating procedures by maintaining the highest standards of safety and quality. Our QA team follows clear and precise working instructions for each process activities and operations of equipment by adhering to the Standard Operating Procedures (SOPs) that are written and reviewed by technically qualified personnel. Approved SOPs are available for all critical activities carried out at our manufacturing facility. Implementation and compliance are the responsibilities of individual department heads and Quality Assurance Department.

A team of Trained Chemists under the supervision of the Head of Quality Assurance carries out these activities. Specification and Analytical test methods for Raw Materials, Packaging Components, In-Process and Finished Products are written by Qualified Personnel. Control at all stages of the manufacturing and packaging processes is maintained by the Quality Assurance Department through strict enforcement of cGMP's standards. Similarly, all equipment and system qualification and validation are designed and reviewed by suitably trained and qualified personnel before the final approval by Quality Assurance Head.

## AUDIT PROGRAMMES

We have consciously designed our Audit programmes to keep upgrading our Quality Management Systems. We carryout extensive audit programmes in order to align with the Company's quality policy;

# BUSINESS VERTICAL



## DOMESTIC PRESENCE

Bymaa Laboratories is committed to improve the health of patients in India through development, production and marketing of innovative pharmaceutical products. We ensure the availability of globally accepted pharmaceutical products in India. Our strategy is complemented by key alliances with marketing and distribution partners throughout India. We have a comprehensive presence in the southern part of the country and are now spreading across the Nation.

We understand the need of our customers and customize our range of services accordingly. Our product portfolio includes a wide range of therapeutic areas, such as cardiology, gastroenterology, diabetology, dermatology, gynaecology and many more.

Bymaa Laboratories focuses on providing quality medicines on par with international standards to the domestic market. We undertake manufacturing on P2P Model, Loan Licensing Model and Contract Manufacturing Model. We ensure the availability of globally accepted quality of pharmaceutical products in India.

## INTERNATIONAL BUSINESS

At Bymaa, we strive towards better health for patients worldwide through leading innovation in medicine, distinctive marketing capabilities, state of the art manufacturing facilities, broad product portfolio, deep understanding of pharmaceutical regulations, and strong partnerships and affiliations.

We have initiated the process of partnering with various companies across the globe. Our dossier team are proficient in preparing required documents as per the requirement of different countries and its regulatory bodies.

Bymaa Laboratories have already initiated the process of partnering with various companies across the globe. Bymaa is currently exporting to Srilanka. We have obtained registrations from Cambodia. The registration in Myanmar, Vietnam and Maldives are under process. We are actively negotiating for other international markets in Middle East and Africa.



SRILANKA



CAMBODIA



MYANMAR



VIETNAM



MALDIVES



UAE



## BUSINESS DEVELOPMENT AND SUPPORT TEAM

We have a dedicated Business Development and support team. The BD team constantly stays in touch with our customers and understands their requirement and ensures the smooth delivery system. Our BD team has established a strong network in both Domestic and International market and continuously study the market and update our development team with new innovations in the market in order to increase our product portfolio and cater our customer with new products. Our BD team is well trained to offer a hassle-free experience right from the order execution to the delivery of products.



## WORKING AT BYMAA

At Bymaa we practice a strong culture of discipline. Our diverse and dynamic team work together to bring innovative products and ideas to life. The team at Bymaa is dedicated to become one of the world's leading pharmaceutical companies. We offer a rewarding professional environment that supports the mutual growth of the company and employees. We believe that effective communication and teamwork are essential in delivering success. At Bymaa we offer an environment that is fulfilling, both professionally and personally.

## WHY BYMAA?

- ▶ Wide range of products
- ▶ Best quality
- ▶ Competitive pricing
- ▶ On-time delivery
- ▶ Responsibility towards providing quality product
- ▶ Full technical/regulatory support to customer
- ▶ State-of-art manufacturing and R&D facilities
- ▶ Customized solutions for customer needs
- ▶ Support across the Pharma value chain – from development to commercial supplies
- ▶ Strong Group Network
- ▶ Compliance of cGMP throughout all manufacturing, packing and development processes.
- ▶ Competent personnel
- ▶ International Exposure



BYMAA



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