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An Industrial Internship Report Submitted in Partial Fulfillment of the Requirements for the Degree of Bachelor of Pharmacy from the Department of Pharmacy, Independent University, Bangladesh.

In-Plant Training at-

BEXIMCO PHARMA

Submitted By:

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Section: 05

Course Code: PHA-407

Department of Pharmacy

School of Pharmacy and Public Health

Independent University, Bangladesh

Submitted To:

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Independent University, Bangladesh

Training Period: 12-22 October, 2025

Semester: Spring-25

Submission-Spring-26

Declaration

I hereby declare that the internship report submitted in partial fulfillment of the requirements for the degree at Independent University, Bangladesh is entirely my own original work.

I further declare that:

- This report has been prepared by me based on my internship experience and has not been copied from any other source.
- No part of this report has been previously submitted to any university or institution for the award of any degree, diploma, or other qualification.
- All information, data, and materials collected from secondary sources have been properly acknowledged and cited through appropriate references.
- I have given due recognition to all authors, organizations, and sources whose works have been used in the preparation of this report.
- Any errors or omissions remaining in this report are solely my responsibility.

_____

Naimur Rahman
ID: 2030016

BEXIMCO PHARMA here's to life
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Date: 22-10-2025

TO WHOM IT MAY CONCERN

This is to certify that ***Naimur Rahman,*** a student at the **School of Pharmacy & Public Health, Independent University, Bangladesh** has successfully completed In-plant Training from October 12, 2025, to October 22, 2025.

During this period, he observed various activities performed in different departments, equipment used at respective functional units, and steps involved in the production, preparation, and packaging of oral dosage products, including tablets, capsules, oral liquids, and suspensions.

He has also gained an overall understanding of materials management, warehousing, equipment maintenance, environmental control systems necessary for the production process, workplace health and safety protocols, and the quality management systems in the pharmaceutical laboratory.

We are confident that this training experience will significantly contribute to his academic and professional growth.

Mohammed Lutfur Rahman
Director Manufacturing

BEXIMCO PHARMACEUTICALS LTD
Date 22.10.2025
TONGI

BEXIMCO PHARMA

Acknowledgement

First and foremost, I would like to express my deepest gratitude to Almighty Allah for granting me the strength, patience, and opportunity to successfully complete my industrial internship.

I would like to convey my sincere appreciation to our respected Dean, Associate Professor **Kamran ul Baset**, PhD, School of Pharmacy & Public Health (SPPH), Independent University, Bangladesh (IUB), for providing me with the invaluable opportunity to undertake this industrial internship as a part of the Bachelor of Pharmacy program.

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I would also like to extend my sincere thanks to the management and all the officials of Beximco Pharmaceuticals Ltd. for providing me with the opportunity to gain practical experience in a professional pharmaceutical manufacturing environment. Their cooperation, guidance, and willingness to share their knowledge greatly enhanced my understanding of pharmaceutical manufacturing practices and industrial operations.

Finally, I would like to express my heartfelt gratitude to everyone who directly or indirectly contributed to the successful completion of my industrial internship and this report.

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Aims and Objectives

For the last five years, we went through several courses of pharmaceutical Sciences to complete our graduation. We studied many topics theoretically and also did our practical classes with some basic equipment and machines but could not see their implementation in pharmaceutical industries. To enrich the practical knowledge of the students, the university insists the students to offer the in-plant training. Such in-plant training will provide an industrial exposure to the students as well as to develop their career in the high-tech industrial requirements. Reputed companies are providing in-plant training to the students.

For the development of our practical skills and techniques which are directly applicable to our careers such as:

To realize and know how a pharmaceutical company runs.

To know how its departments are interlinked and work together.

To identify how GMP or cGMP is applied in the plant.

To have an idea about Standard Operating Procedure (SOPs).

To get information about how a product runs smoothly and be a quality-based product.

To understand how pharmacist, manage the manufacturing problems. •

To see how quality is assured as well as controlled.

To learn about the documentation record practices.

To get general ideas about corporate environment and activities of an organization

Company Profile

Beximco Pharmaceuticals Ltd (BPL) is a leading manufacturer of pharmaceutical formulations and Active Pharmaceutical Ingredients (APIs) in Bangladesh. The company is the largest exporter of pharmaceuticals in the country and its state-of-the-art manufacturing facilities are certified by global regulatory bodies of Australia, Gulf nations, Brazil, among others. The company is consistently building upon its portfolio and currently producing more than 400 products in different dosage forms covering broader therapeutic categories which include antibiotics, antihypertensive, antidiabetics, antiretroviral, anti-asthma inhalers etc. among many others.

The company was incorporated in 1976 and commenced operations in 1980 with the manufacturing and marketing of products of Bayer AG, Germany and Upjohn Inc., USA under licensing arrangements.

In 1983, the company started manufacturing its own formulations and it launched export operation in 1992.

In 2005 Beximco Infusions Ltd, the company that produces intravenous fluids, was amalgamated with the parent company. In the same year it completed the state-of-the-art oral solid dosage plant in compliance with the US FDA and UK MHRA standards, which has been approved by major global regulatory bodies.

Today Beximco Pharmaceuticals Ltd. is the largest exporter of pharmaceuticals in the country and the only company to win National Export Trophy (Gold), the highest national accolade for export, for record three times.

The company is the largest producer of Metered Dose Inhalers (MDIs) in the country, and the first to produce CFC free inhalers. BPL is also the first company to produce anti-retroviral drugs (ARVs) locally.

During our training at the company, we took the notes on visiting different departments. This report will only represent what we have seen, what we have learnt & what we have been taught during our training. We hope this report will help us to implement our experience in our working field.

Mission and Vision

Mission

Beximco is committed to enhancing human health and well-being by providing contemporary and affordable medicines, manufactured in full compliance with global quality standards. We continually strive to improve our core capabilities to address the unmet medical needs of the patients and to deliver outstanding results for our shareholders.

Vision

The company will be one of the most trusted, admired and successful pharmaceutical companies in the region with a focus on strengthening research and development capabilities, creating partnerships and building presence across the globe.

Core Values

The core values define who we are; they guide us to take decisions and help realize our individual and corporate aspirations.

Commitment to quality

Beximco Pharmaceuticals LTD. adopt industry best practices in all our operations to ensure highest quality standards of our products.

People focus

This company give high priority on building capabilities of our employees and

empower them to realize their full potential.

Accountability

Beximco encourage transparency in everything we do and strictly adhere to the highest ethical standards. We are accountable for our own actions and responsible for sustaining corporate reputation.

Corporate Social Responsibility

Beximco actively take part in initiatives that benefit our society and contribute to the welfare of our people. We take great care in managing our operations with high concern for safety and environment.

Achievements

Received GMP (Good Manufacturing Practices) accreditation from Austrian regulatory authority (for the European Union) and GMP clearance from MCC (South Africa) both for new Metered Dose Inhaler (MDI) facility.

Registered 38 new products in 11 countries.

Achieved multiple landmark achievements for Bangladesh in the pMDI portfolio: became the first Bangladeshi company to launch Salbutamol HFA Inhaler in Singapore, commenced inhaler exports to South Africa, and launched pMDI products for the first time in Bangladesh with integrated dose counter device.

Introduced 19 new products including dosage forms and strengths. Launched 3 products for the first time in Bangladesh.

US FDA Approval

- Beximco Pharmaceuticals Limited becomes the first Bangladeshi pharmaceutical company to be approved by the US Food and Drug Administration (FDA).
- The approval came following successful inspection of its oral solid dosage facility at Tongi during 19- 22 January 2015.
- The company says it has received the establishment inspection report (EIR) from the US drug regulatory authority stating that the audit is formally concluded.
- This approval, it said, is based on the comprehensive audit encompassing all the systems of drug manufacturing including quality, facilities and equipment, materials, production, packaging and labeling and laboratory controls.
- Remarkably, there was no 483-observation issued by the US regulatory authority. A 483 form is issued when FDA has observations of non-compliance or deviation from good manufacturing practices (GMP).

Units Of Beximco Pharmaceutical Limited

TRACK – 1

- Human Resource Department
- Production Planning
- Solid Dosage Formulation
- Quality Assurance and Quality Control
- LCO & Suppository Unit
- Infusion Unit
- ION (Injectable, Ophthalmic & Nebulizer)
- Unit Power Plant & Engineering Department

TRACK – 2

- Solid Dosage Formulation
- QA&QC

TRACK – 3 (Under Construction)

Human Resource Department

Beximco Pharmaceuticals Limited is one of the leading corporate houses of the country. It has a handsome amount of work force led by the HRD. Different jobs are done by this department for a smooth running of the industry.

Duties & Responsibilities

- Organizing & controlling of routine activity in the factory.
- Prepare & maintain ISO-9001 documentation.
- Supervise shift wise sectional activities.
- Shift wise manpower distribution.
- Recruit and Organize employees

Environment, Health and Safety (EHS) Department

The EHS Department of BEXIMCO Pharmaceuticals Limited (BPL) is concerned with Personal Safety, that is, safety of the employees. They arrange annual check-up for the existing employees and pre medical check-up for the newly joined employees. This check-up is required for the regular audit and satisfaction of the employees.

Activities of EHS Department:

- Collection of Medical Safety Data Sheet (MSDS)
- Identification of hazardous area and taking preventative measures.
- Preparation of SOPs for handling chemicals.
- Identification of criticalities od machineries and providing awareness and safety Providing Personnel Protective Equipment (PPE)
- Providing First Aid and it using procedure.
- Arranging yearly Medical Checkup programs.
- Identification of pipelines by using different colors on them according to the standards.
- Identification of dangerous goods by using different symbols on them according to the standards.
- Providing automatic fire alarm system with smoke and head detector.
- Providing training for using alternative exit in case of emergencies.

Warehouse

A warehouse is a commercial building for storage of goods. Warehouses are used by manufacturers, importers, exporters, wholesalers, transport businesses, customs, etc. They are usually large plain buildings in industrial areas of cities, towns and villages. They usually have loading docks to load and unload goods from trucks. As a biggest leading pharmaceutical industry Beximco Pharmaceuticals Ltd. has a large, well decorated & well controlled warehouse. They follow some standard operating procedure to maintain warehouse activity.

Main functions of warehouses:

- Exhibition and Selling: Another incidental service which warehouses offer is exhibition and selling the goods on behalf of their customers.
- Storage: This is the main purpose of a warehouse as we have already seen.
- Financing: one of the functions of a warehouse is to advance money to the owners of the goods up to the value of the goods deposited. The owners of the goods can also borrow from banks on the security of warehouse receipts.
- Sorting, Packing, Weighing, Labeling- These are some of the incidental services, for preparing the goods for the market, which warehouses render to merchants.

Warehouse of BEXIMCO Pharmaceuticals:

1. **Central warehouse:** Temperature is maintained at 25 degrees with 45% relative humidity.
    - Quarantine area
    - Released area
    - Dispensing area
    - Finished product area

- Packaging product area
- Special area
- QC sampling room

2. **Infusion warehouse**: The temperature is around 25 degree Celsius and the relative humidity is around 45%
3. **Pharma Tek warehouse**
4. **Track 2 warehouse**

Quarantine Area: The quarantine area is used for storing raw and packaging materials before Quality Control (QC) approval. Materials remain isolated until testing and inspection are completed. This area helps prevent the use of unapproved materials in production.

Released Area: The released area stores materials that have been approved by the Quality Control department. These materials are ready for use in manufacturing and packaging operations. Proper environmental control ensures product quality and stability.

Dispensing Area: The dispensing area is used for weighing and measuring raw materials according to production requirements. Accuracy and cleanliness are strictly maintained.

Finished Product Area: Finished pharmaceutical products are stored in this area before distribution to the market. Products are organized systematically to maintain quality, safety.

Packaging Product Area: This area stores packaging materials such as cartons, labels, bottles, and foils used for pharmaceutical products. Proper storage conditions protect packaging.

Special Area: The special area is used for storing sensitive, hazardous, or controlled materials that require extra care and restricted access. This section follows strict safety and monitoring procedures.

QC Sampling Room: The QC sampling room is used by Quality Control personnel to collect samples of raw materials and packaging materials for laboratory testing. The room is maintained under controlled conditions to avoid contamination during sampling.

Production Unit

Solid Dosage Form

Areas of Solid dosage Department: Solid Department is one of the most important sections in any pharmaceutical company. Solid department is the largest unit of Beximco Pharmaceutical LTD where they formulate tablet, capsule, & powder for suspension. About 70% of the total turnover per year is manufactured in this section. That's why this department plays a key role in the financial aspects of this company.

Tablet

Tablets are most commonly used solid dosage form. Tablets are solid dosage forms usually prepared with the aid of suitable pharmaceutical excipients. They may vary in size, shape, weight, hardness, thickness, disintegration, and dissolution characteristics and in other aspects depending on their intended use and method of manufacture. Most tablets are used in the oral administration of drugs. A polymer coating is usually applied to hide the taste of the tablet's components, to make the tablet smoother and easier to swallow, and to make it more resistant to the environment, extending its shelf life.

Steps involved in solid dosage formulation:

Dispensing UNIT Manufacturing Packaging UNIT

Dispensing Unit:

Dispensing is the first step in any pharmaceutical manufacturing process. Dispensing is one of the most critical steps in pharmaceutical manufacturing; as during this step, the weight of each ingredient in the mixture is determined according to dose. Dispensing unit receive required raw materials which are approved by QC for tablet preparation. It supplies materials to the granulation and coating unit after accurate weighing according to dispensing order sheet and return the remaining materials to store.

Main function of dispensing department:

- Ensures specific raw material are stored in specified area with proper documentation Dispensing of raw material both for sampling and for manufacturing. The dispensing area of solid department is called central dispensing area.
- All the raw materials (solid and liquid) and packaging materials are dispensed and stored. The dispensing tag is attached to respective bags before dispensing.

Parameters to be checked during dispensing:

- Humidity Check Line Clearance Check gross weight
- Check code number of Raw materials and Packaging materials
- Check R-number of raw materials
- Check P-number of packaging materials.

Cleaning of equipment, booths and others in the Dispensing Area: In the dispensing area, there are two booths facilitated with:

- Avery Balance
- Sartorius Balance
- Temperature & humidity detector

Different filters: Pre filter**,** Fine dust filter**,** HEPA filter

Granulation Unit:

Granulation refers to the act or process in which primary powder particles are made to adhere to form larger, multiparticle entities called granules making them physically stronger and larger agglomerates in order to facilitate compression for the production of tablets.

Pharmaceutical granules typically have a size range between 0.2 and 4.0 mm, depending on their subsequent use. For suitable granulation, 30-40% powder and 60-70% granules are essential and also 1-5% moisture in compressing particles.

Dry Granulation:

By the dry granulation method, the powder mixture is compacted in large pieces and subsequently broken down or sized into granules. There are two main processes: either a large tablet (known as a 'slug') is produced in a heavy-duty tableting press (a process known as 'slugging') or the powder is squeezed between two rollers to produce a sheet of material ('roller compaction'). Dry granulation is widely used for achieving the desired particle size to make the appropriate dose of a medicine. Dry Granulation requires machines to conduct the process. For this purpose, several types of machines are used in Beximco Pharmaceuticals which are discussed below.

Machineries used in Granulation Unit:

In Beximco Pharmaceuticals, there are five granulation unit. At these units, there are following machineries thar are being used for dry granulation. The following machines are only for the purpose of granulation of the medicine ingredient.

Name of the machines	Purpose
Planetary mixer-60 kg, Gansons, India.	To mix the active ingredient and binder to form granules.
FBD-400 kg, Alliance Eng. Co. India.	To Dry granules.
Multi mill-1, RPM 1400- 2700 India and Bangladesh.	To reduce the size of granules.
Double cone Blender, 250 kg, rpm 18-20, Bangladesh.	To mix uniformly all the excipients.

Blending

Blending is the process of mixing lubricants, glidants and colorants with the granules prior to compression (in case of granules containing the active Ingredients) or mixing of active ingredient/s along with lubricants, glidants and colorant with the placebo granules (in case of granules without the moisture sensitive active ingredients) prior to compression. So, the process is often-called lubrication or remixing.

Blending critical parameters:

1. Blending time
2. RPM (Rotation Per Minute)

Compression Unit:

After granulation, the granules are compressed to form tablets of definite Shape, size, hardness, weight & thickness. Compression unit of solid Department of BEXIMCO Pharmaceutical has 8 compression machines. Two types of compressions are seen in the tablet press units of the factory; they are-

1. Compression of previously made granules

2. Direct Compression

There are nine compression unit in Beximco Pharmaceuticals Limited. Machineries used in those units are given below:

Rapid Mixture Granulator 60 kg, Saral ENG. Company LTD.	To mix the active ingredient and binder to form granules, to Dry granules.
Y-cone and Double cone blenders.	To mix the processed granules with lubricating agents.
Paste Preparation Vessel (TB-PPv60)	To bind with hot water
Stirrer (TB-S57)	For stirring
Powder Transfer system (TB-PT70)	To transfer powder
Flow tech flameproof Peristaltic pump	For pumping the binder
IBC (Intermediate Bulk Container)	Used for blending
Fette P3 100	594000 tablets per year
Sejong	Imported from South Korea

Compression Process

1. Removed the equipment cleaned label and set up the compression machine
2. Update the logbook with details of this product and display
3. Fit new flat tubing to the IBC discharge cone
4. Verify that the instrument to be used is within their calibration period
5. Ensure the compression machine is set up with the following tooling

Coating

Coated tablets are tablets covered with one or more layers of mixtures of various substances such as natural or synthetic resins, gums, gelatin, inactive and insoluble fillers, sugars, plasticizers, ploys, waxes, coloring matter authorized by the competent authority and sometimes flavoring substances and active substances. The substances used as coatings are usually applied as a solution or suspension in conditions in which evaporation of the vehicle occurs. When the coating is a very thin polymeric coating, the tablets are known as film- coated tablets.

Coated tablets have a smooth surface which is often colored and may be polished; a broken section, when examined under a lens, shows a core surrounded by one or more continuous layers with a different texture. Coated tablets are intended to avoid the gastric environment because some drugs are degraded by the stomach acid as a result it is not absorbed effectively in the intestine. However coated tablets bypass the the stomach acid and release the medicine in the intestine where it is thoroughly absorbed

Tablet Coating Principles: The application of coating to tablets, which is an additional step in the manufacturing process, increases the cost of a product; therefore, the decision to coat a tablet is usually based on one or more of the following objectives:

- To mask the taste, odor, or color of the drug.
- To provide physical and chemical protection for the drug.
- To protect the drug from the gastric environment of the stomach with an acid-resistant enteric coating.
- To improve the pharmaceutical elegance by use of special color and contrasting printing.
- To control the release of the drug from the tablet.

Conditions for Tablet Coating:

Distance between spray gun and tablet bed should be as follows:

- For aqueous coating – (3-4) inch and for organic coating- 8 inch
- Rotating pan rpm must be within 3-15/hr
- Air pressure must be within 1.5-4 kg

Steam temperature should be as follows:

Coating	Inlet	Exhaust
Aqueous	(45-75) ^{o} C	(35-55) ^{o} C
Organic	(35-65) ^{o} C	(30-50) ^{o} C

Solid Packaging:

The terminal stage of the production is packaging. This is the terminal stage at which a finished product gets a shape for marketing purpose. Proper packaging maintains the integrity of the pharmaceuticals. It should preserve drug efficacy as well as its purity, identity, potency and quality for its entire shelf life.

Packaging Materials: Two types of packing materials are used here.

Primary Packing Materials: These materials actually come into the contact of products; such as:

1. For Blister packing Aluminum foil and PVC film
2. For Strip packing Aluminum foil only
3. Alu foil for moisture sensitive drug-Alu.

Secondary Packing Materials: These materials do not come into the contact of the product rather they provide extra protection and facilities for transport and use. These materials include-

- Printed cartoon
- Fiberboard outer
- Filament partition
- Liner
- Cellulose tap

There are two types of Packaging

1. Blister Packing
2. Strip Packing

At Beximco Pharmaceuticals Ltd, two types of combination are used depending on the upper & lower layers as well as product requirement. They are:

1. PVC/PVDC- Alu Blister

2. Alu -Alu Blister

Besides blister packaging, at Beximco Limited, other packaging includes:

⇒ Striping

⇒ Filling of tablets &capsules in bottles

⇒ Labeling of bottles

⇒ Secondary Packaging (Both on-line & off-line)

⇒ Packaging of Ampoules

Capsule

Capsules are solid dosage forms in which medicinal agents are enclosed within hard or soft soluble shell. The shells are generally formed from gelatin. The capsule is regarded as container drug delivery system that provides a tasteless/ odorless dosage form without need for secondary coating step.

Types of capsules: Capsule may classify depending on nature of shell. Two types are,

⇒ Hard gelatin
⇒ Soft gelatin capsules, also called as soft gels

There are 4 different sizes of empty hard gelatin capsule shells used in BEXIMCO - Pharmaceuticals Ltd. for general production, which include:

1. Capsule shell size 0
2. Capsule shell size 1
3. Capsule shell size 2
4. Capsule shell size 4

Polishing of Capsules after Encapsulation:

Not all but most capsules need polishing specially those is filled with powder. Polishing is done first by Capsule Polishing machine which removes dust, adherent powder and gives a shiny appearance.

Packaging Unit:

A product is packaged for its safe delivery to the target customers. It should be safe, compatible to the product contained and robust enough to resist the hazards met during the overall transaction and shell-life. It should be economic and the labels contained on it should be informative, meeting the requirements of the regulatory authorities.

Packing Forms: The following forms of packs available in this company:

⇒ Blister pack, used for tablet, capsule.
⇒ Strip pack, used for tablet and capsule

Blister Packing: A blister package is excellent form of unit dose packing. It provides excellent environmental protection, coupled with an esthetically pleasing and efficacious, appearance. It also provides user functionally in terms of convenience, child resistance and now temper resistance and now temper resistance.

Steps in blister packaging:

1. Forming of pocket (By hydraulic pressure and temperature
2. Filling station (Channel/ feeder/ dosage channel)
3. Sealing (temp station)
4. Cooling
5. Code embossing
6. Slitting
7. Punching
8. Rejection of empty blister pack
9. Collection of blister pack

Strip packaging: A strip package is a form of unit dose packaging that is commonly used for the packaging of tablets and capsules. A strip is formed by feeding two webs of a heat seal able flexible film through either a heated crimping roller or a heated reciprocating platen. The product is dropped into the pocket formed prior to forming the final set of seals. A continuous strip of packets is formed, which is cut to the desired number of packets in length.

Steps of strip packaging:

1. Aluminum foils (2 ways)
3. Pocket formation
4. Sealing (Temp. station)
5. Cooling
6. Batch no. & exp. Date
7. Slitting of strip

Secondary Packaging:

1. Strip & blister pocket check

2. Coding check
3. Label check

In Process Control for Packaging: For strip packaging,

- ➢ Leak test
- ➢ Coding
- ➢ Appearance
- ➢ Stoppages/Adjustments

LCO (Liquid, Cream & Ointment) Department

The production department of liquid, cream & ointment (LCO) is the second largest manufacturing unit in BEXIMCO Pharmaceuticals Limited (BPL). This production area is highly maintained to minimize the risk of serious medical hazard due to cross-contamination, dedicated and self-contained facilities are available for the production of pharmaceuticals products.
There are eight types of dosage forms produced in the LCO department of BPL which are listed as follows:

1. Syrup (e.g. Napa)
3. Suspension (e.g. Lactameal)
4. Nasal spray (e.g. Decomit)
5. Pediatric drops (e.g. Deflux Pediatric drops)
6. Suppositories (e.g. Napa)
7. Cream (e.g. Neosten cream)
8. Ointment (e.g. Anustat ointment)
9. Gel (e.g. Ultrafen gel)

Instruments use:

⇒ Inner mixer & Transfer pump
⇒ Filtering M/C Millipore
⇒ Vertical Ultrasonic cleaning machine
⇒ FAR Infrared sterilizing and drying tunnel
⇒ Filling & Plugging machine
⇒ Vacuum emulsifier
⇒ Oil phase tank
⇒ Water phase tank
⇒ Auto filling, sealing, Bottle washing & labeling machine
⇒ Auto-tube filling & sealing machine

General Manufacturing Process of Oral liquids:

The general manufacturing of oral liquids in the liquid section of Beximco Pharmaceuticals Ltd. is given below:

- Weighing of active ingredients and excipients
- Mixing of excipients with certain amount of purified water as specified in the Batch Manufacturing Record (BMR) by the aid of the mechanical stirrer
- Addition of active ingredients and mixing
- Volume adjusted and passed through a pump to the storage vessel 5. The solution is then transferred through cartridge filter to the filling vessel
- Filling, Flushing of Nitrogen (N2) and sealing of bottles containing oral liquids.

Conditions for manufacturing oral liquids:

- Relative Humidity: Not more than 55%
- Temperature: Below 30°C

Machines used in the Oral Liquid Manufacturing unit:

Name of the Machine	**Function**	**Capacity**
Charge vessel	Manufacturing	2000 Liter
S.S Storage VAT	Storage	2000 Liter
Cartridge Filter	Filtration	
Bottle filling and sealing machine	Filing and Sealing of oral liquids	2300 bottles per hour
Homogenizer	Mixing and Miling	1200 Liter
Steam Jacketed Manufacturing Vessel (Origin: China)	Mixing	1000 Liter

Mixing tank Origin: China	Mixing	1000L
Double head filling machine (Origin: India)	Filling	38-44/min
Mono-block rotary volumetric filling machine. Origin: India	Filling	6000/hour
Automatic liquid filling and sealing machine (Origin: India)	Filling and Sealing	5000/hour
Cartridge filter dry	Drying	

Suspension

Suspension has the advantage of superior bioavailability. The finer the powder in the suspension, the better the absorption. Hence, to facilitate this, often surfactants or suspending agents are used. Particularly for very fine powders, suspension is a must to prevent caking or sedimentation.

Steps involved in Suspension Preparation:

Dispersion of suspending agent

↓

Transfer to manufacturing vessel containing sucrose solution

↓

Addition of active ingredients and excipients

↓

Mixing with continuous stirring

↓

Adjustment of final volume with purified water

↓

Filling and sealing

Creams and Ointments

Topical medications are applied to body surfaces to treat conditions via creams, foams, gels,

lotions and ointments. The widest used are Topical Creams & Ointments. These are the main topical preparations manufactured at BEXIMCO PHARMA LTD.
Creams and ointments are dosage forms for local application or rubbing on the skin. Here, generally O/W creams are prepared. Ointment is an O/O preparation.

Creams: A dosage form comprising a viscous semisolid emulsion, primarily o/w emulsion bases but can apply to any semisolid emulsion.

Ointments: A viscous oleaginous polymeric semisolid dosage form in which primarily drug substances are incorporated in a suitable base. Un-medicated ones are used for their physical effects as protectants, lubricants and emollients.

Equipment Used for Manufacturing Topical Preparation:

Machine Name	Specification and Origin	Capacity
Double headed tube filling machine	Practice industries, India	1000-2000 products/hr
Charging vessel	Myth industries, Bangladesh	100L
Vacuum emulsifying mixer	China Wenzhou T-zone machinery manufacturing co. ltd	160L
Homogenizer	China	-
Transfer pump	USA	-
Automatic labelling machine	Korea	6000/hr
Automatic tube filling and Sealing machine	China	6000/hr
ROPP-cap Sealing Machine	India	1000-2000 products/hr

Sterile Product

Formulation development and product manufacture of quality sterile dosage forms that meet or exceed expected good manufacturing practice requirements. Sterile products are the top most specialized formulations for the benefit of the mankind.

Sterile means free from bacteria or other living microorganisms, that is totally clean. By sterilization; Sterilization (or sterilization) is a term referring to any process that eliminates (removes) or kills all forms of life, including transmissible agents (such as fungi, bacteria, viruses, spore forms, etc.) present on a surface, contained in a fluid, in medication, or in a compound such as biological culture media.

BEXIMCO sterile department:

Class 100 Clean Room: The specification of class 100 clean room is that airborne particle ≥0.5 µm in size do not exceed 100 in number per cubic feet area. This is essential for sterile production. The clean room is maintained by HEPA filter & laminar air flow.

HEPA (High Efficiency Particulate Air) filters: HEPA (high efficiency particulate air) filter is installed at terminal points so that only HEPA filtered air can enter the clean area. HEPA filters can remove at least 99.97% of airborne particles of 0.3 µm in diameter.

Laminar Air Flow: It is generally defined as airflow in which the entire body of air within a confined area and moves in essentially unidirectional velocity along parallel flow lines. The filtered air may be directed vertically or horizontally across the work area. This laminar flow of clean air protects materials in the work area from particulate and cross contamination.

Room Construction: All walls & ceiling of the plant are made of Sandwich panels giving a smooth & easily cleanable surface free of cracks or crevices. The floors are coated with Self levelling Epoxy (SLE) to provide a hard impact & chemical resistant surface. All corners between the floor, walls & ceiling are finished with PVC coving to prevent the accumulation of debris & moistures.

Uninterrupted Power Supply: An automatic gas generator is installed in this plant, which provides uninterrupted power supply to maintain smooth operations of HVAC and machineries of this ultramodern plant.

Products made in sterile department:

1. Eye drops
2. Eye gels
3. Eye ointments
4. Injectable products
5. Powder for injection
6. Lyophilized injection

7. Prefilled syringe

Generally, the products are manufactured by two ways:

⇒ Aseptically Sterilized
⇒ Terminally Sterilized

Infusion Units: Large Volume Parenteral Formulations

Infusion is a very sophisticated product where highest purity & quality is maintained because this is introduced into patient's systemic circulation. A micro corruption may lead to death. In BEXIMCO Pharmaceuticals the quality & purity of infusion products are maintained strictly. They mainly produce dextrose saline.

The infusion preparation involves 2 main operations-

- Preparation of WFI
- Preparation of solution

Steps of preparing WFI in BEXIMCO:

Step 1: Natural water collection
Step 2: Removal of iron
Step 3: Chlorination
Step 4: Removal of bad odor & pyrogen
Step 5: Removal of minerals.
Step 6: Removal of Pyrogen
Step 7: Temperature minimization

Solution Preparation room

↓

Cleaning with citric acid weekly

↓

Flushing with DM water

Sterilization at 121℃ 1.2 base for 30 minutes with moist steam

↓

Buddle point test to ensure the integrity of sterile filter

↓

Drain the WFI (300L) taken for bubble test

↓

Mixing (1.5-2.0mm)

↓

Pre filter (1.9 nm)

↓

Final filter

Step of bottle pack Operations:

Polyethylene granules are given to hopper of blow fill & sealing machine

↓

Extraction by extruder

↓

Molding

↓

Blowing & filling

↓

Sealing

↓

Punching

↓

Capping wielding

Filling and Sealing in Aseptic Area:

Vial (Dry Powder): Raw materials and the packaging materials are received in aseptic area by pass them through dynamic pass box under laminar air flow. Once inside the room, the filling and sealing is done in aseptic condition.

Vial (Liquid): In the aseptic area, solution is charged and then passed through cartilage filter (0.2 µm) and collected into storage vessel. Solutions are collected by the pipe of filling and sealing machine. Vials are placed on nozzle manually. Using the first hopper, solutions are filled in vials. Then plugging and capping is done automatically using the second and third

hopper. The vials are sealed and packaged after terminal sterilization.

Ampoule: In the aseptic area, solution is charged and then passed through cartilage filter (0.2 µm) and collected into storage vessel. Using the pipe of auto filling and sealing machine, inject able solutions or WFI is collected. Ampoules are placed on feed pan which are moved towards nozzle by the help of conveyer system. Ampoules are flashed using Nitrogen gas, followed by filling and then sealing using heat. The ampoules are then sealed and packaged after terminal sterilization. Ampoules should be checked for visual inspection which includes: Fiber (black background), glass particle, inadequate volume, printing, faulty filling & sealing, satisfactory appearance, clarity of solution, sealed integrity & leakage.

Water for Injection (WFI) Preparation by Distillation: At first, demineralized water is stored in a vessel and pre-heated at 60ºC. The water moves into Steam Jacketed tank and undergoes continuous condensation and evaporation. Water is stored in a Steam Jacketed vessel at a temperature of 80-90ºC. The water is continuously circulated to and this water is then used in parenteral preparation. The heating process helps to maintain the microbiological quality of the water by inhibiting microbial growth. Continuous circulation prevents water stagnation within the distribution system. The entire system is designed to comply with current Good Manufacturing Practice (cGMP) requirements. Temperature, pressure, and conductivity are continuously monitored throughout the process. The steam jacket provides uniform heating and ensures process efficiency. The generated water is transferred through stainless steel pipelines to the designated production areas. These pipelines are constructed using pharmaceutical-grade stainless steel to prevent contamination and corrosion. Regular sanitization procedures are carried out to maintain the integrity of the system. Samples are collected periodically for microbiological and physicochemical analysis. The quality parameters are maintained according to pharmacopeial specifications. Water intended for parenteral products requires stringent quality control due to its direct administration into the body. Any deviation in water quality may compromise product safety and efficacy. Therefore, routine monitoring and validation of the water system are essential. The system is also equipped with control instruments to detect any operational abnormalities. Proper documentation is maintained for all process parameters and quality control results. This highly purified water plays a critical role in ensuring the quality and safety of sterile pharmaceutical products.

Machineries in infusion unit:

Machine Name	Capacity	Origin
Insert folding machine	1000/hr	China
Automatic labelling machine	3000-3500/hr	India
Blister machine	2160/hr	Korea

Quality Control (QC) Department

Quality control, or QC for short, is a process by which entities review the quality of all factors involved in production. ISO 9000 defines quality control as "A part of quality management focused on fulfilling quality requirements. Controls include product inspection, where every product is examined visually, and often using a stereo microscope for fine detail before the product is sold into the external market. Inspectors will be provided with lists and descriptions of unacceptable product defects such as cracks or surface blemishes for example.

QC in Pharmaceutical Industry

Validation of analytical procedures is imperative in demonstrating that a drug substance is suitable for a particular purpose. Common validation characteristics include: accuracy, precision (repeatability and intermediate precision), specificity, detection limit, quantitation limit, linearity, range, and robustness. In cases such as changes in synthesis of the drug substance, changes in composition of the finished product, and changes in the analytical procedure, revalidation is necessary to ensure quality control.

All analytical procedures should be validated. Identification tests are conducted to ensure the identity of an analyte in a sample through comparison of the sample to a reference standard through methods such as spectrum, chromatographic behavior, and chemical reactivity.

Impurity testing can either be a quantitative test or a limit test. Both tests should accurately measure the purity of the sample. Quantitative tests of either the active moiety or other components of a sample can be conducted through assay procedures. Other analytical procedures such as dissolution testing or particle size determination may also need to be validated and are equally important.

Activities of the Quality Control Department

- Method development for analysis.
- Receiving of the samples to be tested from QA department
- Giving RR (receiving record) number
- Issuing release, rejecter quarantine advice for each batch of raw material and final product.
- Calibrations and standardization of equipment.
- Ensuring precision and accuracy of all testing methods
- Control of all laboratory reagents

- Research and development of any new method & its validation
- Testing of any return goods
- Stability test for finish products

In-Process Quality Control

1. Appearance
2. Water content
3. Melting point
4. specific gravity
5. Odor
6. pH
7. Viscosity
8. Loss on drying
9. Solubility
10. Residue on ignition
11. Turbidity
12. Absorptivity
13. Identification
14. Assay (HPLC)
15. Sterility/Pyrogen
16. Assay (Bio)

In-process Quality Control depends on the following parameters:

For tablet:

• Thickness • Disintegration

• Friability • Appearance

• Blend Uniformity • Average weight

• Weight • Dosage uniformity

• Loss on drying (LOD) • Hardness

• Variation

Finished product specification depends on the following parameters: For Tablets,

• Dosage uniformity • Average Weight

• Loss on drying (LOD) • Hardness

- Disintegration • Friability
- Dissolution

Instrumentation of QC department:

Particle Size Analyzer:

Particle size analysis, particle size measurement, or simply particle sizing is the collective name of the technical procedures, or laboratory technique which determines the size range, and/or the average, or mean size of the particles in a powder or liquid sample.

High Performance Liquid Chromatography (HPLC): High-performance liquid chromatography (HPLC; formerly referred to as high-pressure liquid chromatography), is a technique in analytical chemistry used to separate, identify, and quantify each component in a mixture.



Gas chromatography (GC)

Gas chromatography (GC) is a common type of chromatography used in analytical chemistry for separating and analyzing compounds that can be vaporized without decomposition. Typical uses of GC include testing the purity of a particular substance or separating the different components of a mixture (the relative amounts of such components can also be determined). In some situations, GC may help in identifying a compound. In preparative chromatography, GC can be used to prepare pure compounds from a mixture.



Parts of GC:

- Carrier gas • Cullum
- Sample injection ports • Detector years

Infrared spectroscopy

Infrared spectroscopy (IR spectroscopy) is the spectroscopy that deals with the infrared region of the electromagnetic spectrum, which is light with a longer wavelength and lower frequency than visible light. It covers a range of techniques, mostly based on absorption spectroscopy. As with all spectroscopic techniques, it can be used to identify and study chemicals.



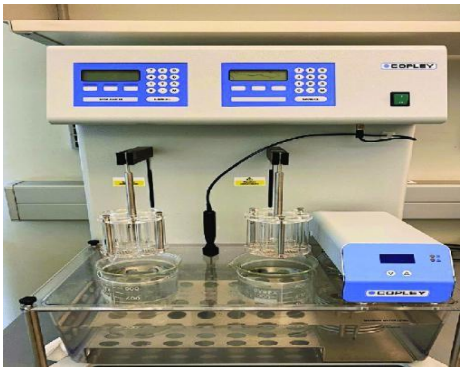
UV-VIS Spectroscopy:

Ultraviolet–visible spectroscopy or ultraviolet-visible spectrophotometry (UV-Vis or UV/Vis) refers to absorption spectroscopy or reflectance spectroscopy in the ultraviolet- visible spectral region.



Disintegration tester

Used to determine whether tablets or capsules disintegrate within the prescribed time when placed in a liquid medium under the experimental conditions.



Dissolution Tester

In the pharmaceutical industry, drug dissolution testing is routinely used to provide critical in vitro drug release information for both quality control purposes, i.e., to assess batch-to- batch consistency of solid oral dosage forms such as tablets, and drug development, i.e., to predict in vivo drug release profile. This instrument is being used in almost all the pharmaceutical companies in Bangladesh and it is important to assess the pharmacokinetics and pharmacodynamics of individual medicines. Furthermore, dissolution testing plays a significant role in formulation optimization and stability studies by evaluating the effect of manufacturing variables on drug release characteristics. It also assists regulatory authorities and pharmaceutical manufacturers in ensuring product efficacy, safety, and therapeutic equivalence among different batches and generic formulations.

Suppository testing apparatus

Test of melting range determines using this apparatus:

a) Macro Melting Range

The melting range of the fatty base is measured in capillary tubes.

b) Test of Softening Time



pH meter

A pH meter is an electronic device used for measuring the pH (acidity or alkalinity) of a liquid. A typical pH meter consists of a special measuring probe (a glass electrode) connected to an electronic meter that measures and displays the pH reading. Specialty meters and probes are available for use in special applications, harsh environments etc.



Sonicator

Sonicator is the act of applying sound energy to agitate particles in a sample, for various purposes. Ultrasonic frequencies (>20 kHz) are usually used, leading to the process also being known as ultra-sonication or ultra-sonication. In the laboratory, it is usually applied using an ultrasonic probe, colloquially known as a sonicator.



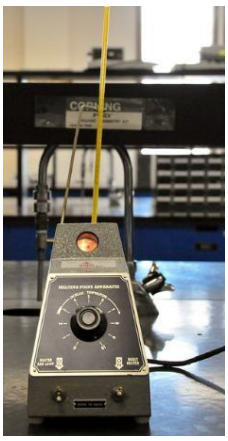
Karl Fischer Titration

Karl Fischer titration is a classic titration method in analytical chemistry that uses coulometer or volumetric titration to determine trace amounts of water in a sample.



Melting Point Apparatus

A melting point apparatus is a scientific instrument used to determine the melting point of a sample. The sample is then heated, either by a heating block or an oil bath, or as the temperature induced sample is observed to determine when the phase change from solid to liquid occurs.



Quality Assurance (QA) Department

Quality assurance is the heart of the pharmaceutical company because in this section quality of the production is assured. To maintain cGMP quality assurance department is the most important sector for any company. The system of QA appropriate for the manufacture of medicinal products should ensure that medicinal products are designed & developed in a way that takes the account of requirements of GMP &GLP (good laboratory practice). The quality measured physically, chemically or microbiologically. The quality assurance ensures the quality of the product this department inspected the quality is maintained or not. A pharmaceutical product must satisfy certain standards to claim its quality. The main characteristics of any drug, in dosage form are- safety, potency, Efficiency, stability, Acceptance, regulatory compliance. To produce quality drug product, quality must be ensured in:

- Every step in the production process
- In maintaining environment
- Personnel
- Equipment
- Operating procedure

Quality Assurance applies for both drug substances (APIs) and medicinal products, and includes current Good Manufacturing Practices (cGMPs), as well as any necessary analytical testing and stability studies. Additionally, it applies to clinical trials operations (Good Clinical Practice - GCP) and safety/toxicology studies (Good Laboratory Practice - GLP). Consulting can advise on all aspects of cGMP pertaining to medicinal products and APIs.

Quality Assurance professionals are responsible for developing, monitoring and overseeing measures that assures control, reproducibility and reliability of manufacturing and testing processes. Through their activities, Quality Assurance professionals are responsible for ensuring that the Company meets government requirements as well as providing assurance of safety and efficacy of medicines to the consumers.

Quality Assurance Department is a very organized department in Beximco Pharmaceuticals Limited, which successfully ensures the quality of the products up to the end user.

QA= Product Design + GMP + QC + Quality Goal Activities

Main functions of QA Department

Functions in Warehouse

- Visual inspection of raw and packaging materials.
- Sampling of raw and packaging materials for tests.
- Release/ rejection of raw and packaging materials on the basis of analysis

Function in Dispensing Area

- Monitoring the dispensing process
- Providing attachment of dispensing cards to materials

Functions in Development

- During manufacturing and packaging, problem analysis occurred.
- Handling of product complains and corrective measures are recommended. • Written

documents of all manufacturing procedures are developed and distributed to the relevant departments and all of these are followed accordingly.

Sample retention

Usually, QA department preserve the sample of cover batch in the archive rooms in normal temperature and process for reviewing product quality. If any complain comes from any source, they check the sample of some batch starting in the archive room. These samples are called retention samples.

Documentation

The most important task of the quality assurance department is documentation. The aim of documentation is to record import information with evidence. GMP requires that complete and accurate records of all raw /packaging materials, finished product, BMR, BPR, have to be maintained for any forcing back of any time. The following documents are maintained.

- BMR (Batch manufacturing record)
- BPR (Batch packaging record)

- Coated tablet inspection sheet
- Leak test record sheet
- Packaging order sheet
- Tablet / capsule inspection sheet
- Weight / volume inspection sheet
- Retention sample quality
- Production sheet order

Functions in SSL department:

In the manufacturing area, Prior to manufacturing test parameters:

- Room cleanliness
- Machine cleanliness
- Room temperature
- Relative humidity

After manufacturing, test parameters of product:

- Assay
- pH of the preparation
- Viscosity

During filling and sealing test parameters:

- Cleanliness
- Microbial test
- Proper weight
- Proper volume

Validation

An integral part of QA is validation. Validation is defined as a systematic study which helps to prove that the system facilities and process perform the job adequately and consistently as specified. Precisely, a validated operation is one which has been proved to have the potentials for the uniform outcome meeting the required specifications.

Validation is a systematic approach to collecting and analyzing sufficient data to give reasonable assurance and documented evidence that a process or an analytical method will, when operated within specified parameters, consistently produce results within predetermined specifications. When this approach is related to a machine equipment, rather than Validation, this is referred to as Qualification. Qualification is part of, but not limited to, a validation process, which in turn can be divided into several parts.

Some common terms used to Qualification:

- DQ – Design Qualification
- IQ – Installation Qualification
- URS – User Requirement Specific
- FAT – Factory Acceptance Tag
- PQ – Performance Qualification
- OQ – Operation Qualification

Product Validation Steps

- Product selection
- Check pre-requisition
- Monitoring and data collection from 3 consecutive batches
- Statistical data analysis
- Reporting

Types of Validation: Validation may be divided into four types:

1. Prospective validation
2. Retrospective validation
3. Concurrent validation
4. Revalidation

Cleaning Validation

Cleaning validation is the methodology used to assure that a cleaning process removes residues of the active pharmaceutical ingredients of the product manufactured in a piece of equipment, the cleaning aids utilized in the cleaning process and the microbial attributes. It can be divided for Work Product and Subsequent Product. All residues are removed to predetermined levels to ensure the quality of the next product manufactured is not compromised by waste from the previous product and the quality of future products using the equipment, to prevent cross contamination and as a GMP requirement.

Cleaning Validation Steps:

1. Residue Identification
2. Equipment characterization
3. Product& equipment grouping
4. Cleaning agent selection & SOP Development
5. Sampling site identification & method Determination
6. Limit Determination
7. Analysis selection, validation & Training
8. Protocol Development
9. Cycle Development
10. Protocol refinement, approval & report preparation
11. Monitoring

RESEARCH & DEVELOPMENT

Research and development, also known as R&D, is the process by which a company works to generate new knowledge that it might use to create new technology, products, services, or systems that it will either use or sell. Research and development (R&D) includes companies' activities to innovate and produce new products and services. It is often the first stage in the development process. The goal is to take new products and services to market and add to the company's bottom line.

- R&D represents the activities companies undertake to innovate and introduce new products and services or to improve their existing offerings
- R&D allows a company to stay ahead of its competition.

R&D is divided into two sections:

- Formulation section (relation with production)
- Analytical section (relation with QC)
    1. Raw material analysis
    2. Finished Good Analysis

Development of a new product:

Stage 1: Necessary attributes with product information from the marketing department are,

- Source
- Sample
- Q.C test (Potency, LOD, etc.)

Stage 2: Pre-formulation study of the active drug and excipients

- Chemical activity
- Function
- Boiling point
- Contraindication
- Moisture content

Stage 3: Collection of raw materials of active drugs and excipients.

Stage 4: Different trials for development of a stable, effective formulation.

Stage 5: Drug administration formalities include:

1. Submission of the recipe to the drug administration, which contains
    - Strength
    - Dosage form
    - Contraindication
    - Dosage form
    - Dissolution
    - Description
    - Precaution
    - Side effect
    - M.R.P
    - Indication

2. Sample admission (If INN Product)

3. Approval of sample from the drug administration and inclusion of D.A.R. and license no.
4. Submission of Inclusion Dossier
5. Final approval for commercial production.

Stage 6: Pilot trial and accelerated stability testing.

Stage 7: Readjustment if necessary.

Stage 8: BPR preparation if every aspect is satisfied, which contains-

- Product name
- Code
- Size
- Batch size

Stage 9:

- Transfer to commercial production
- Development of existing products
- The Product Development Department also monitors the development of existing product formulation.

Conclusion

Going through the different divisions of a pharmaceutical company in person encouraged and inspired us to not only study the topics elaborately but also made as aware of how much dedication and hard work it requires to take a pharmaceutical company to this level.

Our in-plant training opportunity in BPL covered a large number of dosage forms. Our two weeks' observation in various departments helped us to make our theoretical knowledge clear. We have observed manufacturing procedures, quality control, packaging and other related activities of pharmaceutical products and fulfilled our thirst.

We have observed various latest technology, learned the application of many valuable machines and covered the large industrial area in BPL which contains their own power stations and liquid nitrogen plant. We have also observed strict quality assurance in every step in the process of producing superior quality products, ready to be supplied to the national and international market. We all noted how all the employees at Beximco are trained and qualified to follow the GMP guidelines religiously.

Beximco Pharmaceuticals Ltd. have held a spot in the top 3 in market share in the pharmaceutical industry of Bangladesh for over 5 years. It was an honor to be able to experience the inner working of a company of this caliber.

At last, we would like to give hearty thanks to BPL and our gratitude goes to its all personnel. We would like to conclude by saying that we are grateful for the overall journey we shared with Beximco Pharmaceuticals LTD.