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A Report on In-Plant Training at Radiant Pharmaceuticals Ltd.

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RADIANT
PHARMACEUTICALS

13th May 2026

To Whom It May Concern

This is to certify that Ms. Mohsina Yeasmin (Student ID: 2221201), student of B. Pharm, Independent University, Bangladesh, has successfully completed internship from **1st April to 15th April** 2026 in Radiant Pharmaceuticals Limited at Tongi, Gazipur.

We found her punctual and sincere to her assignments during the tenure of her internship.

We wish every success in her future endeavors.

With best regards

Syed Tanvir Ayaz
AGM, Human Resources

Md. Azmal Hassan
DGM, Human Resources

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Acknowledgement

We would like to express our sincere gratitude to the management and authorities of Radiant Pharmaceuticals Limited, for granting us the valuable opportunity to undertake our in-plant training at their esteemed organization. Their support and cooperation have been instrumental in the successful completion of our training program and this report.

We are especially thankful to the respected officials, supervisors, and staff members for their continuous guidance, encouragement, and willingness to share their knowledge and practical insights. Their assistance has greatly enhanced our understanding of pharmaceutical operations and industry practices.

We would also like to acknowledge our respected faculty members of Independent University, Bangladesh, for their guidance and support throughout the preparation of this report.

Finally, we express our heartfelt appreciation to everyone who directly or indirectly contributed to making our training experience both informative and enriching.

Abstract

This report is based on the in-plant training that we did at Radiant Pharmaceuticals Limited as part of our studies at Independent University, Bangladesh. Radiant Pharmaceuticals Limited is one of the leading pharmaceutical companies in Bangladesh. It was founded with the goal of providing high-quality pharmaceutical products. Since it started, the company has been dedicated to strict adherence to quality standards, innovation in pharmaceutical manufacturing, and the ongoing development of its employees. It has a strong mission to make medicines of the highest quality and a vision to become one of the most trusted pharmaceutical companies in the country.

During our training, I was able to watch and learn about different parts of pharmaceutical manufacturing, such as production processes, quality control, quality assurance, research and development etc. To make sure that its products are safe, effective, and of high quality, the organization focuses on Good Manufacturing Practices (GMP), following the rules, and using advanced technology. The company's daily operations and workplace culture clearly show its core values of quality, innovation, teamwork, and honesty.

I learned a lot of useful things about industrial pharmaceutical processes and how a manufacturing plant works in real time through this training program. It also helped connect what you learn in school with what you do in the real world. Overall, the experience was very helpful and taught me a lot about the pharmaceutical industry and how professionals work in it.

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Abbreviations

RPL	Radiant Pharmaceutical Limited
GMP	Good Manufacturing Practice
RD	Research and Development
DGDA	Directorate General of Drug Administration
FBG	Fluid Bed Granulator
API	Active Pharmaceutical Ingredient
ICH	International Council of Harmonization
SCM	Supply Chain Management
QA	Quality Assurance
QC	Quality Control
BP	British Pharmacopoeia
USP	United States Pharmacopeia
INN	International Nonproprietary Names
RLD	Reference Listed Drug
AAS	Atomic Absorption Spectroscopy
ICPOES	Inductively Coupled Plasma Optical Emission Spectroscopy
LOD	Loss on Drying
HPLC	High-Pressure Liquid Chromatography
PPIC	Production Planning and Inventory Control
GPU	General Production Unit
SOP	Standard Operating Procedure
BMR	Batch Manufacturing Record
GRN	Good Receiving Note
QMS	Quality Management System
CAPA	Corrective and Preventive Action
SMD	Strategic Marketing Department
IPC	In Process Control
COA	Certificate of Authorization
MACO	Maximum Allowable Carryover
OSHA	Occupational Safety and Health Administration
MSDS	Material Safety Data Sheet
PPE	Personal Protective Equipment
FDA	Food and Drug Administration
RNL	Radiant Nutraceuticals Limited
PCL	Pharmacil Limited
BPR	Batch Packaging Record

Chapter 1: Introduction

Radiant Pharmaceuticals Limited (RPL) has established itself as a prominent healthcare solutions provider in Bangladesh, demonstrating rapid and consistent business growth since the commencement of its manufacturing operations in 2008. The company has earned a strong reputation as one of the most trusted names in the Bangladeshi pharmaceutical industry through its continuous investment in employee development and its strict adherence to quality assurance standards and regulatory compliance.

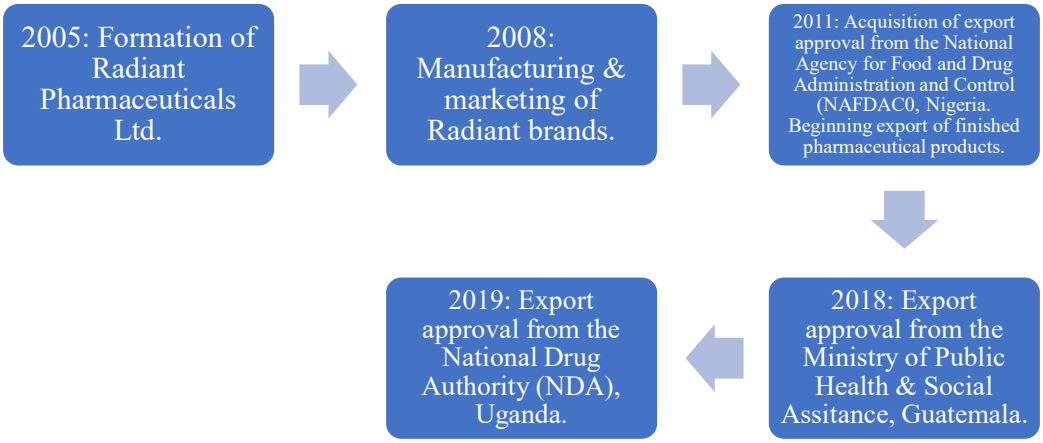


Figure 1: Journey throughout the years

Mission: Committed to the manufacture of high-quality healthcare products that meet international standards, achieved through continuous innovation and strategic diversification, with a focus on improving patient outcomes.

Vision: To become a highly trusted pharmaceutical company by consistently providing medicines that meet rigorous quality standards.

Core Values: The core values of an organization define its fundamental principles and guide its culture, decision-making, and overall way of working. They reflect the company's values and serve as the foundation for maintaining ethical standards, ensuring quality performance, and achieving long-term success. RPL has 6 core values.

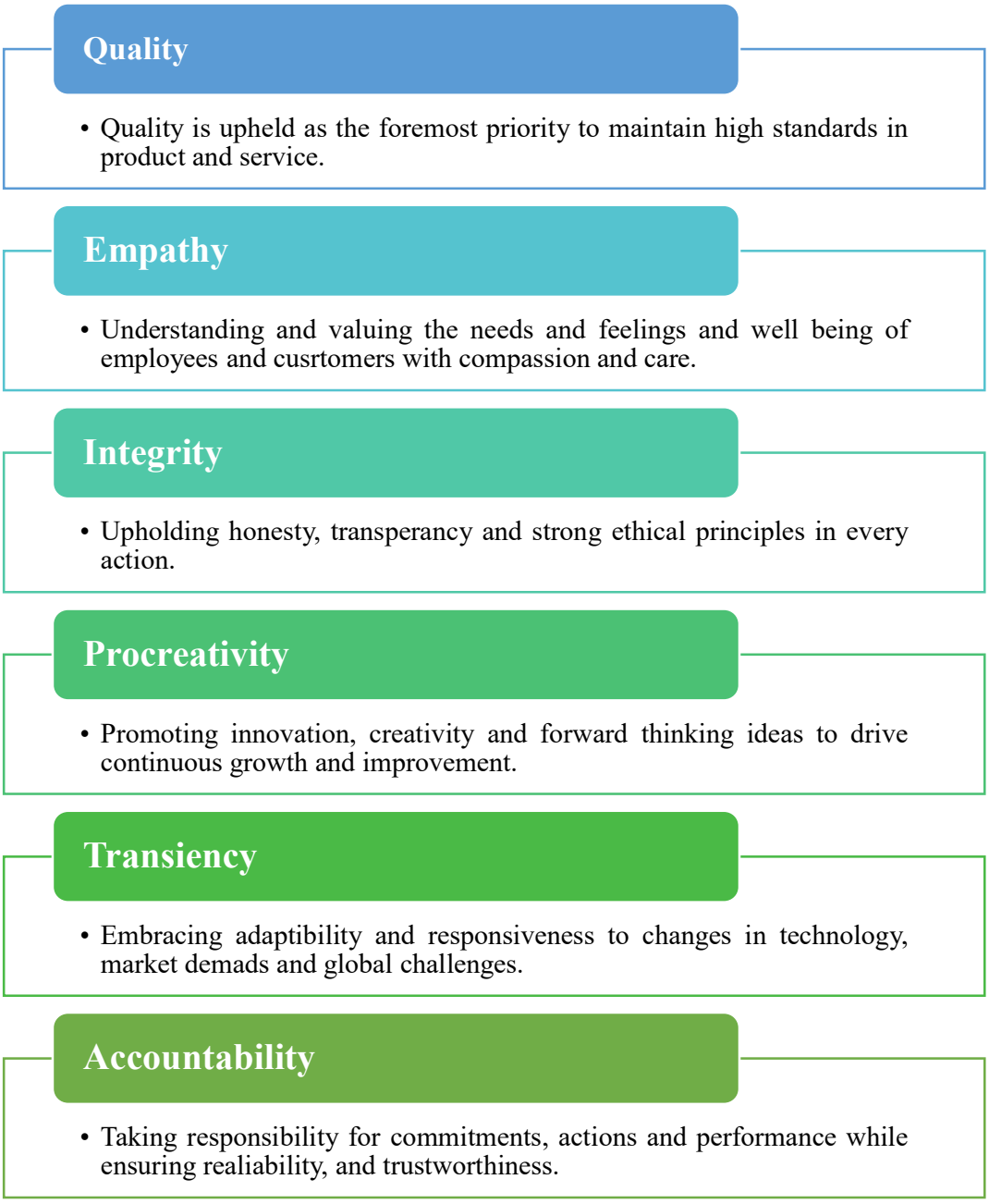


Figure 2: Core Values of RPL

Manufacturing facilities: Radiant Pharmaceuticals Limited are designed to ensure the production of high-quality, safe, and effective medicines in compliance with international standards. Equipped with modern technology and operated under strict regulatory guidelines, the facilities maintain Good Manufacturing Practices (GMP) to ensure consistency, efficiency, and product integrity throughout the production process. The facilities are divided into the following sections-

- Product Development
- Production Facilities
- Quality Control Facilities
- Engineering Facilities
- Warehouse Facilities
- Quality Management System
- Safety, Health and Environment

1.1 Leading Brand Products

This section presents some of Radiant Pharmaceuticals Limited's best-selling products. These products highlight the company's strong market performance, customer trust, and commitment to delivering high-quality healthcare solutions.

Figure 3: Brand Products of RPL

1.2: Radiant Affiliated Companies

1.2.1: Radiant Nutraceuticals:

RNL is associated with the production of herbal and natural products. The goal is to combine the benefits of nature with science and provide better healthcare.

1.2.2: Jenphar Bangladesh:

A subsidiary of RPL produces over 100 registered products, including Antibiotics, antiulcerants, antihypertensives, antihistamines, injectables, and anticancer products.

1.2.3: Pharmacil Linited:

A sister concern of RPL, focusing on innovative, niche pharmaceutical products that are modern and high-quality.

1.2.4: Radiant Care:

Produces products that are needed in our day-to-day lives while maintaining global standards through innovation and diversification.

1.2.5: Radiant Distributions:

A distribution network system that is responsible for distributing all products of all the sister concern companies locally and globally.

Figure 4: Radiant Affiliates

Chapter 2: Research and Development

2.1: Introduction

The Research and Development team in RPL has two wings having their own laboratory to formulate pharmaceutical grade generic medicines. The two wings are RD Formulation or FRD, and RD Analytical or ARD. The department as a whole is called PD or Product Development section that has their own responsibilities divided between these two wings but that work in coordination.

2.2: Basic Work Flow of PD

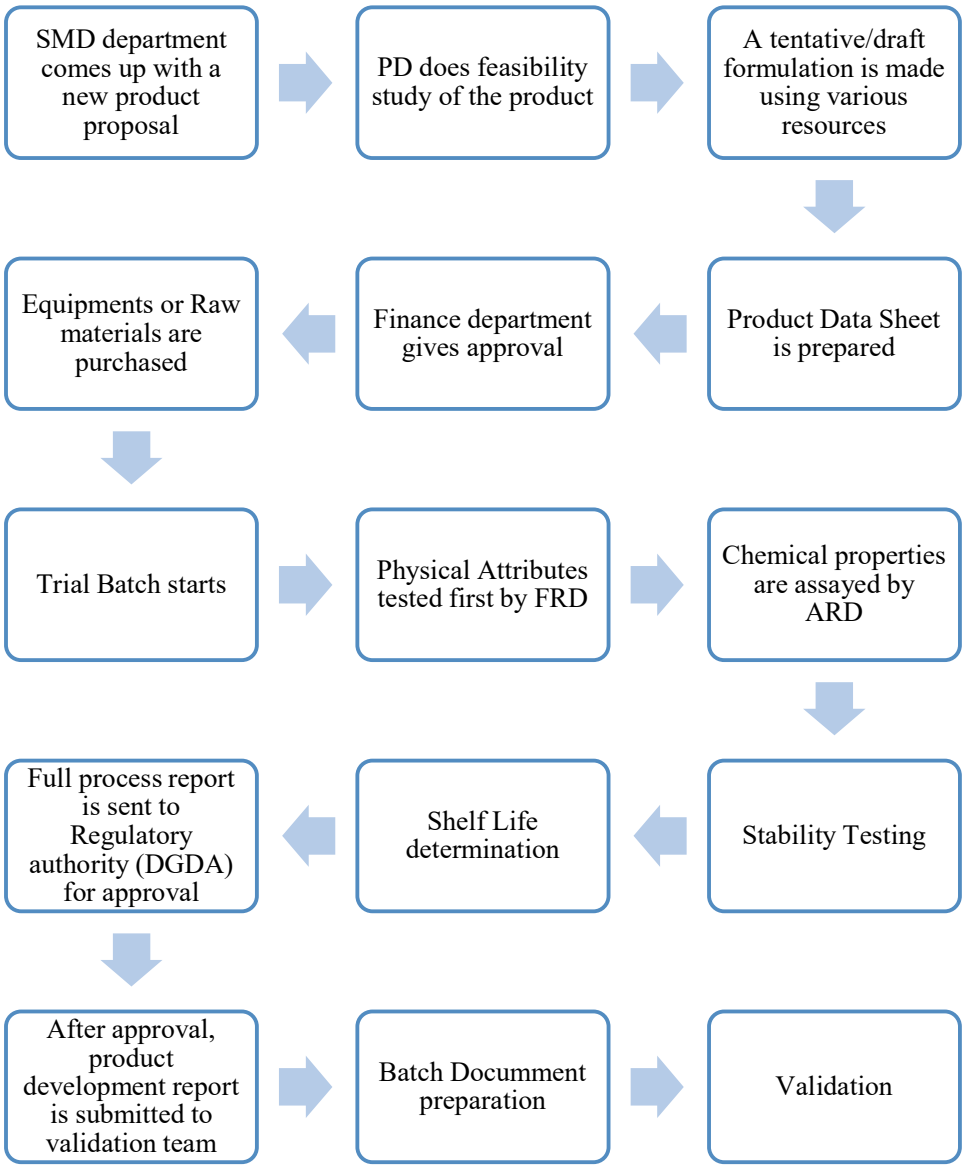


Figure 5: Workflow of PD

2.3: Research and Development Formulation (FRD):

The formulation study starts with researching using various sources available for example Google Patent, Pharmacopoeias, Regulatory Guidelines like FDA, etc. After approval and purchasing of raw materials, the trial batch starts.

RPL manufactures oral solid dosage forms which has multiple steps of manufacturing. FRD goes through each step in their own laboratory, calling it a lab batch or trial batch. In the following sections, each step is explained in detail along with the machineries used.

2.3.1: Dispensing:

Raw materials are dispensed through a passbox that has UV light to make sure no microbial contamination occurs. The weighing zone has laminar air flow to keep dust, particles away from the materials.

2.3.2: Granulation:

It is the process of converting fine particles into larger, uniform particles that has better flow properties, increases compressibility, enhances uniform mixing and prevents segregation. Granulation is two types;

- Wet Granulation
- Dry Granulation

The difference between the two types of granulations is that in wet granulation water or liquid is used while in dry granulation, no liquid is used. In RPL, there are use for both types of granulations as well as direct compression for the development and production of oral solid dosage forms.

2.3.2.1: Wet Granulation

The most used machineries for wet granulation are High-shear granulators and Fluid Bed Granulator (FBG). The core process stages include blending the dry powder mix, wet granulation with water or binder solution, adding additional components if needed, further lubrication and final compaction. Excipients used in wet granulation typically include diluents, binder, disintegrate and lubricant, while other stabilizing agents and pigments may also be included.

Fluid Bed Granulation Mechanism:

1. **Loading of materials**: The dry powder mixture is loaded into the fluid bed granulator. This process is automatic where vacuum is used to load the materials.
2. **Fluidization**: Heated air is passed upward through the powder bed, causing the particles to become suspended and behave like a fluid.
3. **Spraying of binder solution**: A granulating liquid or binder solution is sprayed onto the fluidized particles through a nozzle. The binder solution is made in a homogenizer.
4. **Granule formation**: The wetted particles collide and adhere to each other, forming granules due to continuous movement and contact.
5. **Drying**: Simultaneously, the heated air evaporates the solvent, drying the granules as they are formed.

High Shear Granulation Mechanism:

1. **Dry mixing**: The API and excipients are loaded into the granulator bowl and mixed uniformly using an impeller**.**
2. **Liquid addition**: A granulating fluid or binder solution is added to the powder bed while the impeller continues to rotate.
3. **Nucleation**: The liquid forms bridges between particles, leading to the formation of small agglomerates or nuclei.
4. **Growth and coalescence**: The impeller and chopper provide high mechanical shear, causing particles to collide and combine, resulting in the growth of granules.
5. **Densification**: Continuous agitation compacts the granules, making them denser and more uniform in size.
6. **Breakage and size control**: The chopper helps break oversized granules, maintaining a consistent particle size distribution.

2.3.2.2: Dry Granulation

Dry Granulation process is used for materials that are sensitive to moisture and heat. The process requires compaction and densification of the particles to form granule.

Mechanism:

1. **Dry mixing**: The API and excipients are blended uniformly to ensure content uniformity.
2. **Compaction**: The powder mixture is subjected to high pressure using equipment such as a roller compactor or slugging machine, forming compacted masses called slugs or ribbons.
3. **Densification**: The applied pressure reduces the void spaces between particles, increasing density and promoting interparticle bonding.
4. **Milling**: The compacted material is broken down into smaller granules using mills or crushers.
5. **Sieving**: The granules are passed through sieves to obtain a uniform particle size distribution.
6. **Lubrication and blending**: Lubricants and other excipients are added to improve flow and compression properties before final dosage formation.

2.3.3: Compression:

After granulation is done, the next step is compression. For some materials, direct compression is used which is the quickest and shortest method of tablet formation but for this the material needs to be of the right quality having enough compressibility without the needing for granulation.

2.3.4: Coating:

Coating is done for various reasons. For example, masking of taste, odor, giving aesthetic appearance, protecting the drug from moisture, enteric coating for protecting the tablet from gastric fluid etc. the two types of coating are-

- Film coating
- Sugar Coating

Mechanism:

- The coating solution is prepared by dissolving the required materials for approximately 45 minutes to ensure uniformity.
- Tablets are loaded into the film coating machine.
- Operational parameters such as pan speed, pump speed, air pressure, temperature, spray gun settings, and atomization are properly adjusted. For aqueous film coating, the gun distance is between 9 to 12 inches. For non-aqueous film coating, the gun distance is between 6 to 9 inches. Sugar coating is not used these days.
- The coating process is monitored through continuous visual inspection to ensure uniformity and detect defects.

2.3.5: Capsule Filling

There are two types of capsule filling. Pellets filling process and powder filling process. Capsules are loaded into the filling machine where they are separated into cap and body. The powder or pellets are accurately filled into the body and the cap is placed back and locked. The filled capsules are ejected and sent for further quality checks.

2.3.6: Blister packing

The tablets are put into blisters that can be two types. Alu-Alu blister packing or Alu-PVC blister packing.

2.3.7: Lab Batch:

A lab batch is created to verify the efficacy of the formulation. In this batch, the goal is to mimic the innovator drug as much as possible in order to scale up. Additionally, feasibility studies are done with lab batch as well where it is checked if the drug formulation can be done within the facilities or not. Modifications are made to the lab batch recipe as needed.

2.3.8: Pilot Batch:

Before production starts, the manufacturing procedure needs to be validated at least three times. For this purpose, pilot batch is required that is the size of $\frac{1}{10}th$ of the commercial batch. The preparation of a pilot batch helps in identifying potential challenges related to equipment, process parameters, and material behavior before

large-scale production. It also enables optimization of critical process parameters, ensuring consistency, quality, and reproducibility of the final product. Additionally, pilot batches are essential for conducting stability studies, validating manufacturing processes, and generating data required for regulatory approval.

2.3.9: Stability Study

Stability testing is essential to establish the shelf life of the product and give an expiry date. The time required for the drug content to decrease to 90% of its initial value gives the data for the shelf life. It is also important to assess how a drug maintains it's quality, efficacy and safety over time under various environmental conditions like various temperature, humidity etc.

Stability testing is done under two conditions, the methods being called a) Real Time Stability Study, b) Accelerated Stability Study.

Conditions	Temperature	Relative Humidity	Duration
Real Time Stability Study	30°C±2°C	65%±5%	36 months. Checking every 3 months during the 1st year. Checking every 6 months during the 2nd year
Accelerated Stability Study	40°C±2°C	75%±5%	6 months.

Table 1: Conditions for Stability Study

These conditions are set according to the ICH classification of climatic zones based on temperature and humidity. Bangladesh falls into Zone IV.

2.3.9: Machineries Observed in the FRD section

Name of Instrument	Company/Model	Origin	Uses
Fluid Bed Processor	Inora	Taiwan	Granulation and Drying
Super Coater	Inora	Taiwan	Film Coating
Compression machine	Eliza Press 200	India	Compress granules into tablets
Compression Machine	PTK	Korea	Compress granules into tablets
Blister Machine	Ezee Blister-Mechtek	India	Primary packaging of tablets

Table 2: Machineries in FRD

2.3.10: Parameters Checked in FRD

There are various parameters that are checked during the formulation stage of RD as following-

- Flow properties
- Compressibility
- Moisture content
- Weight variation
- Hardness
- Friability
- Disintegration time
- Appearance of the tablet
- Leak test for blister

2.4: Research and Development Analytical

ARD plays a critical role in ensuring the quality, safety, and performance of pharmaceutical products throughout the development process. Quality is ensured by various teams of source validation, method development and validation, lab management team that works alongside FRD.

2.4.1: Process of Source Validation

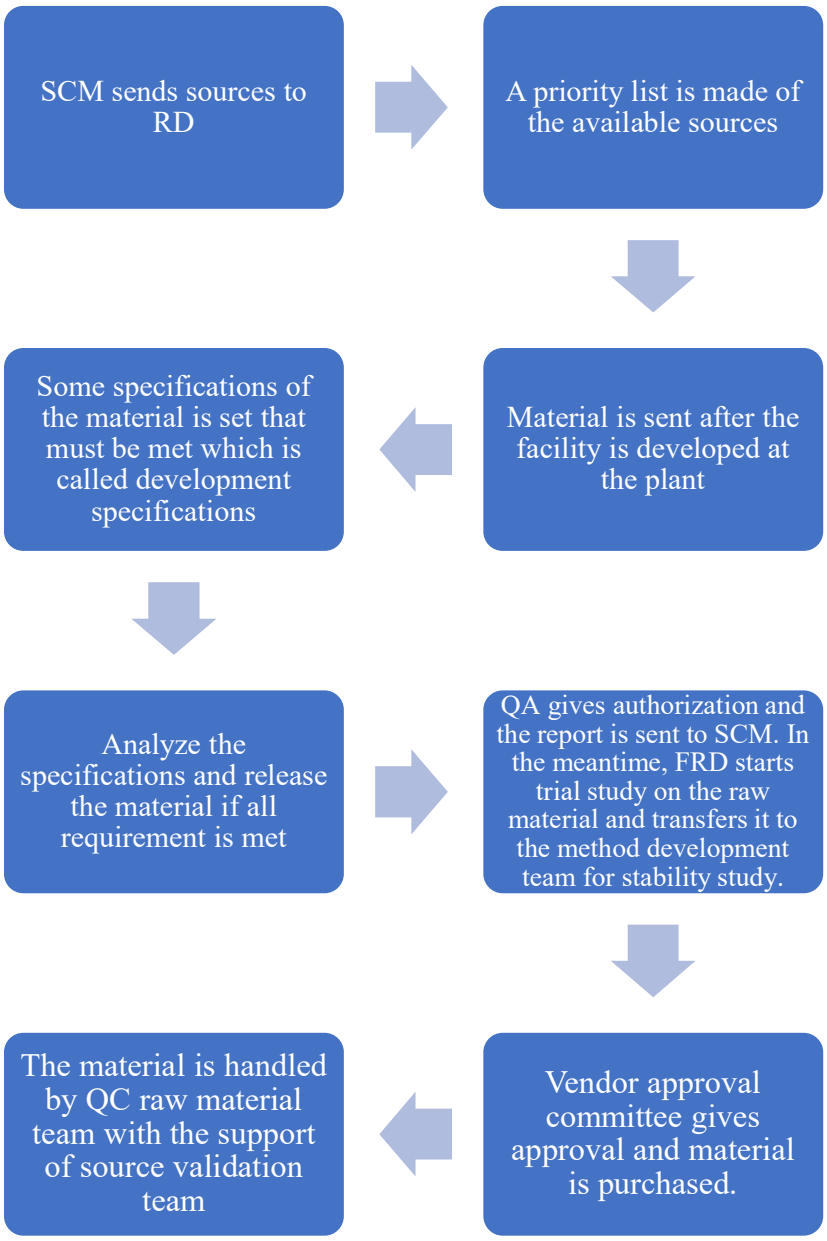


Figure 6: Source Validation Flowchart

2.4.2: Method Development Process

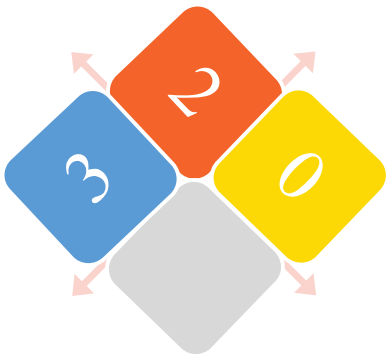
To produce pharmaceutical-grade generic drug products, the ARD team follows guidelines from the British Pharmacopoeia (BP), United States Pharmacopeia (USP), and International Nonproprietary Names (INN) to gather comprehensive information about the drug. Typically, information from the Reference Listed Drug (RLD) is studied to develop a tentative analytical method.

At this stage, appropriate analytical techniques are selected, and experimental conditions, system suitability parameters, and preliminary validation studies are established. This phase is referred to as the prequalification stage. During this stage, methods are optimized through systematic trial and error to achieve reliable and reproducible results.

Once the optimized method is developed, it is subjected to formal validation in accordance with GMP requirements.

2.4.3: Reagent Room

All reagents are kept in the reagent room according to colors and severity by numbers that indicates the level of hazards.



Health Hazard Blue Diamond

0-Normal Material

1-Slightly Hazardous

2-Hazardous

3-Extreme Danger

4-Deadly

Fire Hazard Red Diamond

0-Will not burn

1-Above 200˚F

2-Above 100˚F not exceeding 200˚F

3-Below 100˚F

4-Below 73˚F

Reactivity Yellow Diamond

0-Stable

1-Unstable if heated

2-Violent chemical change

3-Shock and heat may detonate

4-May detonate

Specific Hazard White Diamond

ACID- Acid

ALK- Alkali

COR- Corrosive

OXY- Oxidizer

☢ - Radioactive

These symbols and numbers on the reagent bottles give the idea on how to handle them, how to store, in which condition and so on. There are also symbols that indicates physical hazards, environment hazards and health hazards which are also taken into consideration.

2.4.4: Machineries Observed in The ARD department

Name	Company/Model	Use
AAS	Shimadzu	Metal, impurities detector in ppm level
ICPOES	Malver	Metal, impurities detector in ppb level
Particle Size Analyzer	Mastersizer3000	Determines average particle size of raw material
Gas Chromatography	Shimadzu	Separate, identify, and quantify volatile organic and inorganic compounds within a mixture
X-ray powder diffractor	Bruker	Polymorphism determination
Muffle furnace	Nabertherm	Burns metal
Differential Scanning Calorimeter	Shimadzu	API and excipient compatibility determinator
Vacuum oven	Vacucell	Determines LOD
Sieve shaker	Electrolab	Facilitates particle separation

Tap density tester	Electrolab	Measure tap density of bulk powder
HPLC	Shimadzu, Waters	Identification, quantification, separation
Dissolution tester	Electrolab, ERWEKA, Hanson	Measures dissolution time of tablets
Karl Fischer Machine	-	Moisture content determination
Raman Imaging Microscope	-	Compound structure determination, lid foil thickness determination

Table 3: Machineries in ARD

2.4.5: Packaging Validation

Packaging validation conducted by the RD department is essential to ensure that the selected packaging system effectively protects the pharmaceutical product throughout its shelf life. It helps verify that the packaging maintains product stability, prevents contamination, and preserves the integrity, safety, and efficacy of the drug under various storage and handling conditions. The basic workflow by RD is shown below-

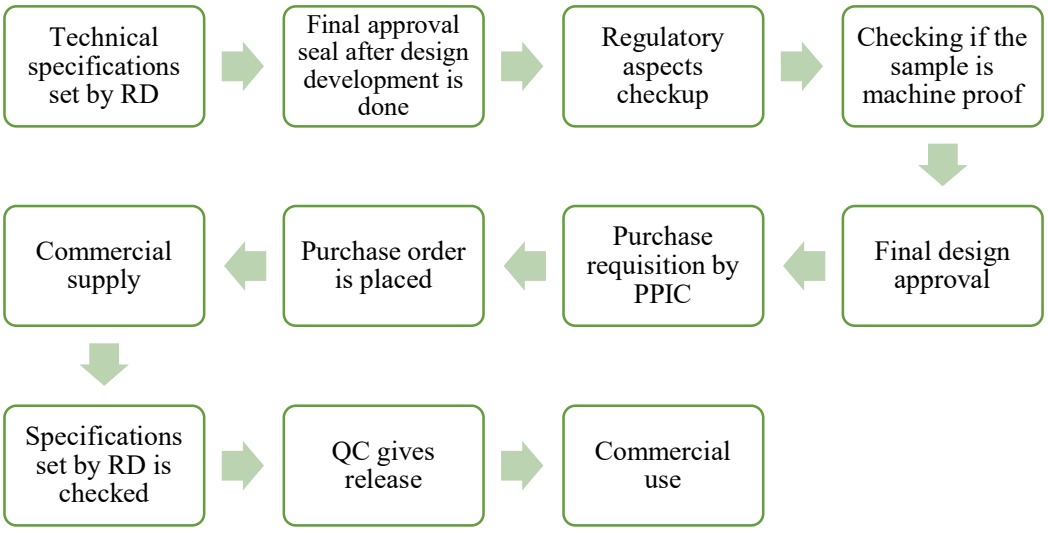


Figure 7: Packaging Validation Workflow

Chapter 3: Production

3.1: Introduction

The production facilities of Radiant Pharmaceuticals Limited is divided between GPU-1 and GPU-2 which include dispensing booths, granulation suites, tablet compression suites, coating units, encapsulation, powder filling and cap sealing areas, washing sections, storage areas for cleaned equipment, and intermediate storage units. The facilities also encompass blistering, primary packaging, and secondary packaging operations. In addition, raw material and primary packaging material warehouses, finished goods warehouses, and utility services are integrated within the overall production infrastructure.

3.2: Cleaning and Sanitization

Cleaning and sanitization in the production area is important to prevent contamination and ensure compliance with GMP. These processes ensure that equipment, surfaces, and the working environment are free from residues, microorganisms, and cross-contaminants. All cleaning and sanitization procedures are carried out according to validated protocols, with defined frequencies, methods, and approved materials. Proper documentation is maintained for each activity to ensure traceability and regulatory compliance. Regular monitoring and verification are also conducted to confirm the effectiveness of the cleaning process and to maintain a controlled production environment.

3.3: Gowning and Change Rooms

The changing room for gowning is an airlocked space. Appropriate gowning is important in the production area to ensure no contamination from clothes or from person can hamper the quality of the product. Following is the procedure of gowning-

1. Enter the scanning area by scanning an authorized card.
2. Take off outside shoes and out it on the shoe rack.
3. Swing over the bench.
4. Wear apron, pants, head cover, mask.
5. Wear the shoes provided
6. Enter the production are

3.4: Dispensing

Dispensing is one of the most vital steps in pharmaceutical manufacturing, as it marks the initial stage of the production process. The dispensing area handles only those materials that have been released or approved by the QC department. After dispensing, the materials must be used within 7 days, as specified in the SOP.

During this process, the appropriate quantity of each ingredient is accurately weighed according to the dosage specified in the BMR. Throughout the dispensing process, all activities are carefully recorded and maintained in a logbook to ensure proper documentation and traceability. Line clearance occurs and after the line clearance signature is given, the material is sent to the production floor.

There are two dispensing booths in RPL. One is for weighing and dispensing bulk amount, the other is for smaller amounts.

All materials dispensed and delivered through passbox that has UV light to kill microorganisms. For hazardous API, there is an isolator machine to ensure safe dispensing.

3.4.1: Dispensing procedure

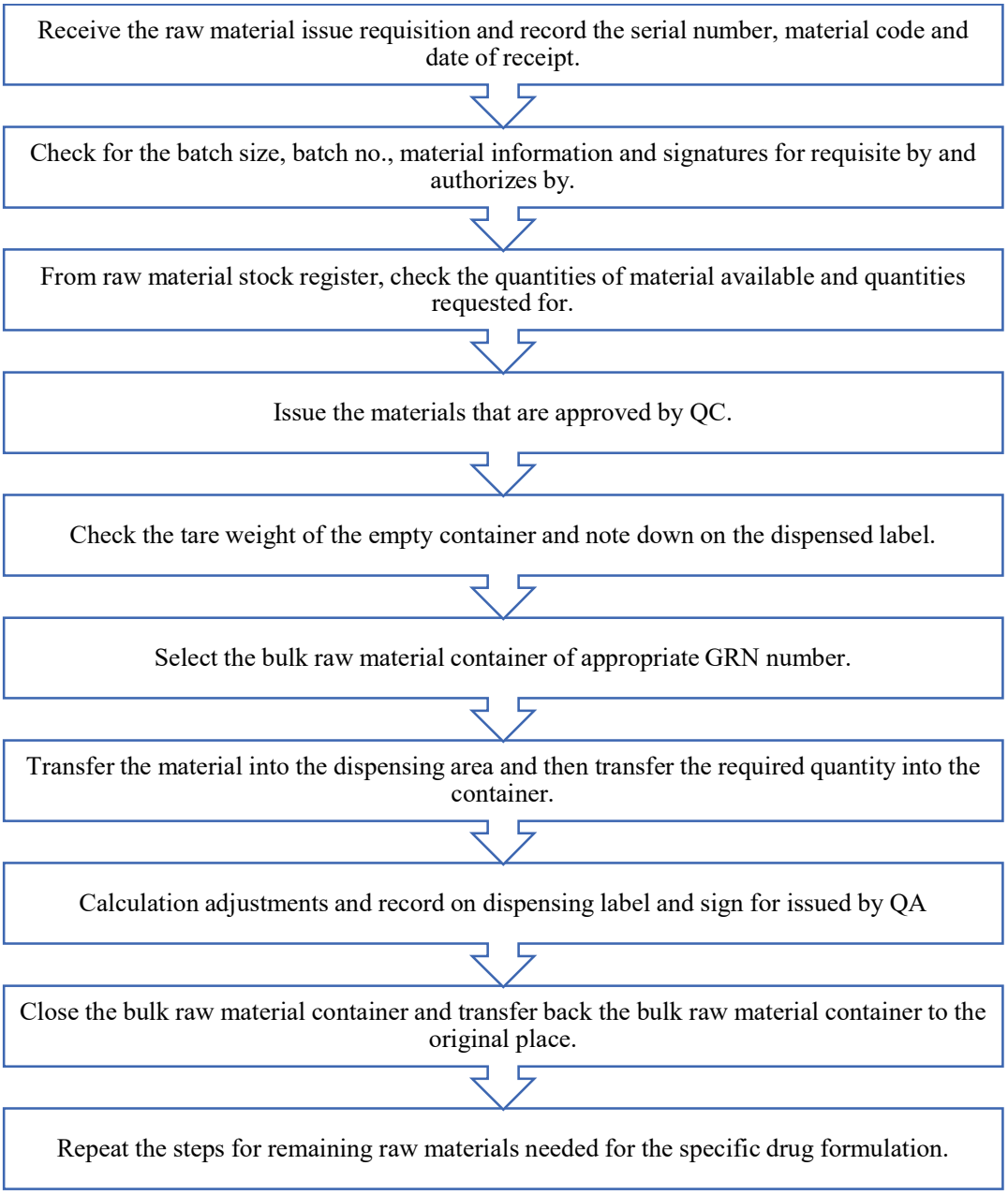


Figure 8: Dispensing procedure

3.4.2: Dispensing condition

- Temperature: Below 25°C
- Differential air pressure: 10-15 pa
- Humidity: Below 60%

3.5: Production area room conditions

Before production starts, it is important to make sure the room condition is appropriate because materials are sensitive and change in room condition may cause deterioration of materials. For production area, specific room condition is set along with alert limit and action limit that indicates when to stop the manufacturing procedure altogether.

Room condition parameters	Working Limit	Alert Limit	Action Limit
Temperature	22°C±4°C	18°C to 19°C	<16°C to >26°C
Relative Humidity	50%±10%	40%-45% 55%-60%	<40% >60%
Differential Pressure	10Pa to 25Pa	10Pa-13Pa 23Pa-25Pa	<10Pa >25Pa
Room temp. in secondary packaging area	24°C±4°C	20°C±22°C 26°C±28°C	<20°C >28°C

Table 4: Room condition in production area

3.6: Granulation

As discussed in section 2.3.2, granulation is the step to converting fine particles to large, uniform particles to increase flowability and compressibility. In this section, the basic workflow of wet granulation and dry granulation is mentioned. (For detailed information check section 2.3.2.1 and 2.3.2.2)

Wet Granulation:

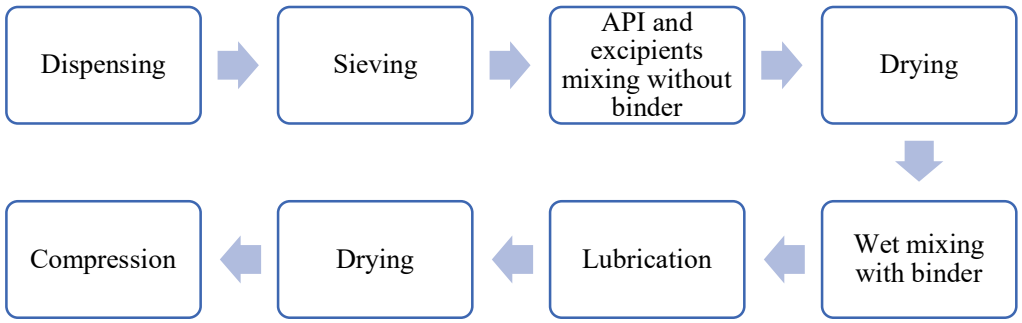


Figure 9: Wet granulation flowchart

Dry granulation:

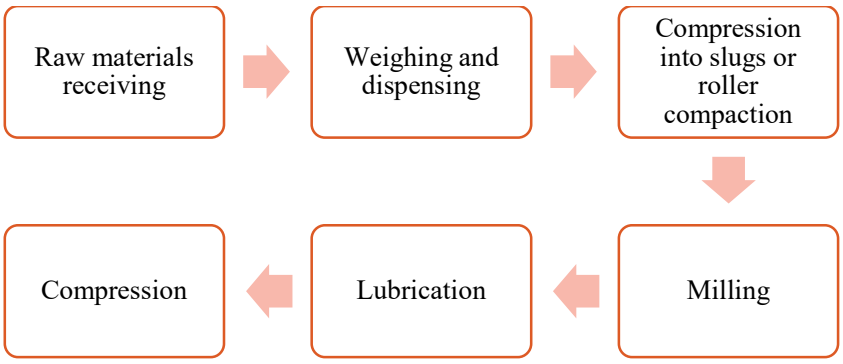


Figure 10: Dry granulation flowchart

Machineries in Granulation Room

Machine	Model	Capacity	Origin
Fluid Bed Processor	Pam Glatt	120-150kg	India
High Shear Granulator	Pam Glatt	-	India
Fluid Bed Dryer	Huttlin	-	Germany
High Shear Mixer-Granulator	Huttlin	-	Germany

Table 5: Granulation Machines

3.7: Blending

Blending involved uniform mixing of API and excipients. Lubricants and glidants are added as the last stage to blending before the granules go for compression. Enduring proper blending is important for ensuring uniformity and prevent segregation of particles. The machineries we observe at the facility for blending are as follows-

Name	Company	Capacity	Origin
Bin Blender	Canaan	200L	China
Cone blender	-	200-600L	-
Bin Blender	Servolift	2000kg	Germany

Blender mixer container	Bohle Pharma	1500-2000kg	Germany

Table 6: Blending Machines

3.8: Compression

- Granules or powder are loaded into the hopper of the compression machine.
- The material flows from the hopper into the die cavity.
- The lower punch adjusts to control the amount of powder filled (weight control).
- The upper punch presses the powder with force to form a tablet.
- The tablet is compressed between upper and lower punches.
- The upper punch moves up, and the lower punch pushes the tablet out (ejection).
- The formed tablets are collected and sent for further processing or testing.

Compression Machines

Name	Model/Company	Capacity	Origin
Fette Compression Machine	Sejong	29 punch, 43 punch	Korea
Compression machine	Legacy 6100	-	-
Compression machine	Plam Compressa	-	-
Compression machine	Dr Pharm	51 punch	Germany
Fette rotary tablet press	Fette	B type- 45 punch D type- 33 punch	

Table 7: Compression machines

3.9: Coating

Coating process involves application of a thin layer of coating material on to the surface of tablets. The process of coating is mentioned in section 2.3.4. In production, it's done in large scale while maintaining proper GMP.

Coating Machines

Name	Company	Origin
Thai coater	PMS	Thailand
Coating machine	Glatt	Switzerland

Table 8: Coating machines

3.10 Encapsulation

- Granules or pellets are transferred to the hopper of the capsule filling machine.
- Empty capsules are loaded and properly oriented in the machine.
- Capsules are separated into the cap and the body.
- The required amount of granules/pellets is filled into the capsule body.
- Excess material is removed to ensure uniform fill weight.
- Capsule cap and body are rejoined and locked.
- Filled capsules are ejected from the machine.
- Capsules may undergo polishing to remove surface powder.
- Final inspection and sampling are performed for quality control.

Encapsulation machines

Name	Company	Origin
Automatic capsule filling machine	BOSCH	Germany
Empty capsule sorter	ECSE	India
Mini capsule sorter	-	India
Unfilled capsule sorter	-	-

Table 9: Encapsulation machines

3.11: Packaging

There are three stages of packaging.

1. Primary Packaging: Direct contact with product
2. Secondary Packaging: Curtoning the primary package
3. Tertiary Packaging: For shipping

At RPL, there are blister packing, sachet filling, tube filling, pouch filling. For primary and secondary packaging, there are both automated and manual systems.

Packaging Machines

Name	Company	Origin
Blister packing machine	Buchon	Korea
TTP Blister packing machine	TTP	Vietnam
Blister machine	Romaco	Germany
Blister machine	Uhlmann	Germany
Tube filling machine	Gordic	Germany

Table 10: Primary packaging machines

3.12: In Process Control

IPC includes monitoring critical parameters at various stages of manufacturing to ensure that the product consistently meets quality standards. IPC helps detect and correct deviations during the production process, thereby maintaining product uniformity and preventing batch failures.

Manufacturing Stage	IPC
Dispensing	• Temperature and humidity within specification. • Weighing accurately as per BMR
Granulation	• Granule size • Uniformity of granules
Drying	• LOD

Compression	• Room condition • Appearance • Weight variation • Hardness • Thickness • Friability • Disintegration time
Coating	• Sticking • Absence of bridging • Color variation
Encapsulation	• Appearance of shell • Room condition • Uniformity of weight • Average weight • Disintegration time
Packaging	• Leak test

Table 11: IPC during manufacturing

3.13: BMR and BPR

During each stage of manufacturing, everything needs to be recorded in an orderly manner according to SOP of BMR and BPR which are checked by QA officer for authorization.

BMR Information		**BPR Information**	
Product name	Date of requisition	Product name	Date of starting
Batch no	Date of starting	Batch no	Date of finishing
Batch size	Date of finishing	Batch size	Line clearance
Batch quantity	Yield calculation	Batch quantity	Printing record
Manufacturing procedure		Packaging material name and quantity	Printing line clearance
Order number		Order number	Inspection
Line clearance		Date of requisition	

Chapter 4: Quality Assurance

4.1: Introduction

The primary responsibility of the Quality Assurance (QA) department is to ensure the overall quality of pharmaceutical products. It oversees that all manufacturing processes are carried out in compliance with established quality standards and regulatory requirements. The objective of QA is to ensure that the final product is safe, effective, and capable of delivering the intended therapeutic outcome for patients.

4.2: Quality Management System (QMS)

QMS is a structured system of policies, procedures, and processes established to ensure that pharmaceutical products are consistently produced and controlled according to defined quality standards. The QMS is looked after by head of Quality Assurance department and all other departmental heads work as a team to follow and maintain the QMS.

To ensure quality is maintained, there are QMS tools that are as follows-

- Risk assessment
- Change control
- CAPA
- Deviation management
- Document management
- Source Approval
- Internal audit
- GMP training
- Product complaint handling
- Product recall and
- Annual product quality reviews

With the help of these tools, QA department ensures the quality of RPL is upheld consistently.

4.3: Risk Assessment

Risk assessment within the Quality Assurance (QA) department is a systematic and structured approach used to identify, evaluate, and mitigate potential risks that may impact product quality, safety, and regulatory compliance. This process ensures that pharmaceutical operations are conducted in a controlled and risk-based manner throughout the product lifecycle.

4.3.1: Principles of Risk Assessment:

- **Proactive approach:** Identifies and prevents potential risks before they occur
- **Reactive approach:** Addresses and manages risks that have already occurred

4.3.2: Tools Used:

FMEA (Failure Mode and Effect Analysis): Used to identify possible failures in a process, equipment, or product and evaluate their effects on quality, safety, and performance. It helps prioritize risks based on their severity, occurrence, and detectability so that preventive actions can be taken before problems occur.

- **Risk Priority Number (RPN)** – Calculated from:
    - Severity (S)
    - Occurrence (O)
    - Detection (D)

$$RPN = S \times O \times D$$

HACCP (Hazard Analysis and Critical Control Point): A preventive risk management system used to identify, evaluate, and control biological, chemical, and physical hazards during manufacturing and handling processes. It focuses on controlling critical points where hazards may occur to ensure product safety and quality.

4.3.3: Components of Risk Management:

- **Risk Assessment:**
    - Identification of potential risks
    - Analysis of the nature and source of risks
    - Evaluation of risk severity and impact

- **Risk Control:**
    - Decision on risk acceptance or reduction
    - Development of action plans for risk reduction
- **Risk Review:**
    - Formation of an investigation team
    - Follow-up and monitoring of action plans to ensure effectiveness

4.4: Change Control

Change control is a formal, structured process for managing changes to materials, processes, equipment, documents, or systems that may impact product quality, safety, or regulatory compliance. It is a cross-functional process.

The process is initiated when a change is proposed, followed by a comprehensive assessment of its potential risks and impact on product quality and existing processes. Based on this evaluation, appropriate actions are defined and implemented.

The final review and approval of the change are carried out by the Quality Assurance (QA) department, ensuring compliance with regulatory requirements and that the change does not adversely affect product quality.

4.5 Deviation Control

A deviation is any departure from approved procedures, specifications, or established standards during pharmaceutical manufacturing or related activities. If there is any deviation, there is an orderly process to assess the situation as shown below-

- Deviation is reported by the concerned department
- Deviation is raised according to the prescribed annex/form
- Reasons for the deviation are documented
- An incident report is prepared
- Immediate actions are taken to control the situation
- Assessment is conducted to determine if the deviation has any direct impact on product quality or patient safety

- Detailed impact assessment is performed
- QA categorizes the deviation as minor, major, or critical
- An investigation team is formed with relevant experts
- Root cause analysis is carried out
- Appropriate CAPA are implemented
- Effectiveness of the CAPA is verified
- Deviation is formally reviewed and closed by QA

4.6: CAPA

CAPA is a quality management system used in the pharmaceutical industry to identify, investigate, correct, and prevent problems that may affect product quality, safety, or regulatory compliance. It is an essential part of GMP.

Corrective Action: Corrective action is taken to eliminate the root cause of an existing problem or non-conformance in order to prevent its recurrence.

- Correcting deviations in manufacturing
- Repairing faulty equipment
- Revising incorrect procedures

Preventive Action: Preventive action is taken to identify and eliminate potential causes of problems before they occur.

- Employee training
- Process improvement
- Risk assessment and monitoring

4.7: Batch Document

4.7.1: Batch Documentation Process

- The master document is initially prepared by the RD department.
- After approval, the master document is submitted to the QA department for control and preservation.
- Production planning requirements are determined and submitted to the PPIC department.

- Based on forecasting, batch allocation is performed monthly using the SAP system**.**
- A batch document requisition is submitted manually to QA as per production needs and planning.
- QA retrieves the master document and verifies its validity and approval status.
- The master document is then scanned and printed, and a unique batch number is assigned**.**

4.7.2: Batch Allocation Security Measures:

- The scanning process of the master document is password-protected.
- Access is restricted to authorized personnel only.
- A specific batch font/style is used to maintain document authenticity and prevent duplication.

4.7.3: Final Verification and Issuance:

- After printing, QMS tools are used to check and validate the document.
- An authorized risk assessment copy is attached to the batch document.

4.7.4: Batch Numbering System

- Batch no. starting number→ 1 for RPL, 2 for RNL, 3 for PCL
- 4 consecutive digits→ 0001, 0002, 0003 etc
- Last 2 digit of the current year→ 26 for 2026

Example of a batch no.→ 1000126

4.8 In Process Control and Batch Release

IPC performed by the QA department involves monitoring and verifying critical parameters during various stages of pharmaceutical manufacturing as mentioned in section 3.13. Apart from these, QA is also responsible for the management of SOPs of IPC instruments, manufacturing stages, primary and secondary packaging, and instrument cleaning. Batch release if given after all the IPC tests are done and batch document is completed when QC sends COA to QA for checking, head of QA checks all the documents to give approval.

4.9 Market Complaint

- Market complaints are initially collected.
- SMD forwards the complaint form to the QA department for further action.
- QA initiates sample analysis to determine whether the product is genuine or counterfeit.
- If the product is confirmed to be counterfeit, the case is escalated and reported to the relevant regulatory authority.
- An investigation team is formed, including experts from relevant departments.
- The team conducts a site visit, interviews concerned personnel, and collects all necessary data related to the complaint.
- A brainstorming session is carried out to identify the root cause of the issue.
- Based on the investigation, appropriate CAPA are implemented.
- The Head of QA reviews the case and formally closes it upon satisfactory resolution.
- SMD provides acknowledgment of the closure process.
- The concerned patient or complainant is contacted and informed regarding the resolution.
- Finally, the case is fully documented and officially closed

Chapter 5: Quality Control

In the pharmaceutical industry, Quality Control is essential for ensuring patient safety, compliance with regulatory requirements, and protection of the company's reputation.

Radiant Pharmaceuticals Limited operates a fully functional Quality Control laboratory, located in a separate building away from the production area. The laboratory is well equipped with physical, chemical, and microbiological testing facilities. A team of experienced professionals, with strong expertise in pharmaceutical analysis and a commitment to data integrity, carries out sample testing and environmental monitoring.

5.1 Quality Control of Raw Materials

1. Materials receiving System: Raw materials of every batch must require with a full certificate of analysis (COA) which is a definite binding on the part of the supplier that the materials meet the required specifications.

After receiving the raw materials, a GRN (Goods Receive Note) recorded with details such as material's name, supplier's name, total quantity, number of containers, manufacturer's batch number(s), physical condition of the containers etc. The raw materials should remain in quarantine until sampled, tested and released or rejected by the laboratory

2. Sampling: It is important that the QC personnel independently inspect the raw materials during sampling. Sampling is done by using sampling thieves. It takes materials from three positions from top, middle and bottom. If there are large numbers of containers sampling is collected from containers for excipients by using Vn+1 equation, where n is the no. of the containers. For API, sample is collected from every container.

3. Raw material release: The raw materials should be released in a batch fashion and with proper status labeling. Approved raw materials are marked green and available to warehouse staffs

If the raw materials don't comply with specifications, they are rejected and marked red label Control of Packaging materials.

5.2 Finish products testing

For validation batch, the sampling and testing is done by RD and for Commercial batch, sampling is done by QA department and sent to QC for chemical testing. These tests are done to ensure the content uniformity of the product, to detect any impurity and other assays are done according to the pharmacopoeia of that drug.

5.3 Method Validation

Both quantitative and qualitative analyses are performed to validate analytical methods used in QC. Quantitative analysis is carried out to determine the potency of the product, while qualitative analysis is used to evaluate its physical and chemical characteristics. The method is further assessed to ensure that it meets the required validation parameters, including accuracy, precision, and robustness, thereby confirming its reliability and suitability for routine use.

5.4 Handling of Waste Disposal

Waste management in the QC department of the pharmaceutical industry is crucial to ensure compliance with environmental regulations and GMP. The goal is to safely dispose of waste generated during the testing, analysis, and quality control of pharmaceutical products.

1. Segregation of Waste: Hazardous vs. Non-hazardous Waste: Waste is categorized into hazardous (e.g., solvents, acids) and non-hazardous materials (e.g., packaging). The segregation ensures proper disposal according to regulatory requirements.

2. Biohazardous Waste: Any waste that has been in contact with biological samples, such as blood or microbial cultures, is segregated and treated differently (e.g., autoclaving before disposal).

3. Labeling and Storage:

• Proper Labeling: Containers with waste materials are properly labeled to indicate the type of waste, hazards involved, and date of storage.

• Temporary Storage Areas: QC labs often have designated areas for temporary waste storage before being transferred to the final disposal facility. These areas comply with safety regulations to prevent contamination and accidental exposure.

4. Chemical Waste Disposal:

• Neutralization and Recycling: Acids, bases, and other chemicals are sometimes neutralized 6or treated before disposal. Solvents are often recycled if feasible.

• Authorized Disposal: Hazardous chemical waste is handled by certified waste disposal companies that specialize in safe and compliant disposal methods.

5.Waste Minimization Strategies

• Efficient Testing Protocols: QC departments aim to minimize the generation of waste by optimizing their testing protocols, such as using smaller sample sizes or employing alternative methods that generate less waste.

• Reuse and Recovery: Where possible, materials like solvents are recovered, purified, and reused within the lab.

6. Regulatory Compliance

• Environmental Regulations: QC departments adhere to local and international regulations, such as the Environmental Protection Agency (EPA), and Good Laboratory Practices (GLP), to ensure proper waste management.

• Documentation and Reporting: Detailed records are maintained to track waste generation, disposal methods, and compliance with regulatory requirements. These records are often subject to audits by internal and external agencies

5.5 Cleaning Validation

1. Rinse Test Parameters

- Rinse testing is performed to verify the cleanliness of equipment after the cleaning process. The acceptance criteria for rinse samples are as follows:
- pH: The acceptable range is 5 to 7.
- Conductivity: Not more than (NMT) 1.30 µS/cm.
- Total Organic Carbon (TOC): NMT 500 ppb.
- If all parameters fall within the specified limits, it indicates that there is no significant residue remaining on the equipment.

2. Swab Sampling Procedure

- Swab sampling is conducted to detect residues on equipment surfaces, especially in hard-to-clean areas.
- A lint-free cotton swab is used for sampling.
- The swab is pre-moistened with a suitable diluent before use.
- A defined surface area of 100 cm^2 is swabbed. Swabbing should be performed in multiple directions (horizontal and vertical strokes) to ensure proper coverage.
- Sampling locations should include the most difficult-to-clean areas, such as corners, edges, and joints. This method ensures effective recovery of potential residues from equipment surfaces.

3. Microbiological Sampling

- Microbiological evaluation is also performed using the swab method.
- Results are expressed as colony-forming units (CFU) per 25 cm^2.
- The acceptance criterion is Not More Than (NMT) the specified microbial limit as per quality standards.

4. Risk Assessment Criteria

Toxicity	Solubility	Potency
High toxicity = 3	Very soluble = 1	High= 3
Moderate toxicity = 2	Moderately soluble = 2	Medium= 2
Low toxicity= 1	Poorly soluble = 3	Low= 1

Table 12: Risk assessment for cleaning validation

The overall risk score is calculated by multiplying the three factors:

Risk Score = Toxicity × Solubility × Potency

The maximum possible score is 27.

Products with the highest score are classified as highest risk and are given priority for cleaning validation group-

5. Acceptance Limits

a. MACO (Maximum Allowable Carryover): MACO is calculated using the following formula:

MACO=Dose previous × Batch Size next Safety Factor MACO=Safety Factor Dose previous×Batch Size next

Common criteria include: 1/1000th dose criterion and 10 ppm criterion

b. MSR (Maximum Surface Residue)

MSR defines the maximum allowable residue per unit surface area and is derived from MACO calculations

5.5.1: Process of cleaning

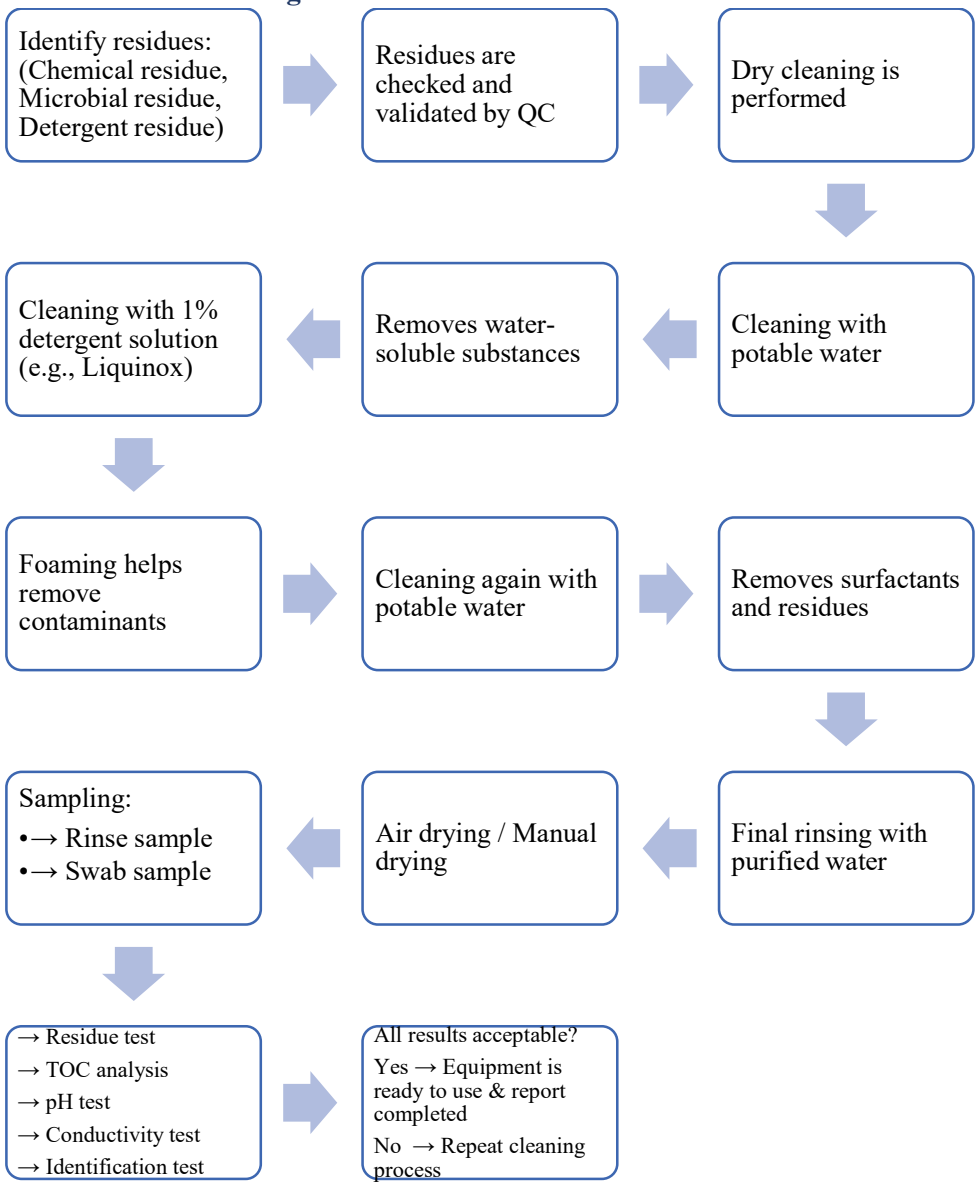


Figure 11: Cleaning validation flowchart

5.6 Stability Product

5.6.1: QC Stability Study Process

- RD prepares the stability protocol following the Standard Testing Procedure (STP).
- An authorized copy of the protocol is sent to QA.
- Stability studies are initiated as per STP, including long-term, accelerated, and intermediate conditions.
- Samples are stored under defined conditions (30°C / 60% RH / 75% RH).
- Testing is performed at scheduled intervals such as 3 months, 6 months, 9 months, 12 months, continuing up to the expiry date.

5.6.2: Sample Handling and Testing

- QA collects stability samples and transfers them to QC.
- QC receives samples and places them in stability chambers after verification.
- Test Request Sheet (TRS) is prepared.
- LIMS entry is completed with protocol and sample details.
- Analysis is initiated within the defined timeline.
- Analytical Worksheet (AWS) is issued.
- Testing is performed strictly according to STP (within 30 days).
- Raw data is recorded immediately and attached to AWS.
- Calculations are performed using Excel.
- Final reports are prepared in Excel format.
- Results are entered into LIMS.
- Summary reports are prepared.
- An authorized copy is sent to RD, while QC retains the original copy.

5.7 Packaging material testing

After receiving materials:

Certificate of Analysis (COA) is sent to QC Sampling is conducted as per Standard Operating Procedures (SOP)

Testing includes:

* Physical tests (e.g., thickness, durability)

* Leak testing

* Limited chemical and microbiological tests Examples:

- Type-1 tests for vials and ampoules
- 3-layer checks for bottom lids Advanced testing tools such as
- Raman imaging machine may also be used for analysis.

The packaging development process involves multiple stages, including design, supplier selection, testing, and quality assurance. Continuous improvement and strict quality control ensure that packaging materials meet required standards, protect the product effectively, and comply with regulatory requirements.

5.8 Microbiology

The Microbiology Department in the QC of pharmaceuticals plays a pivotal role in ensuring the safety, efficacy, and quality of pharmaceutical products. This department is responsible for testing and monitoring the pharmaceutical products and raw materials for microbial contamination, ensuring compliance with regulatory standards and guidelines. Microbiology Lab Work:

- Sterility Test
- Bacterial Endotoxin Test/LAL Test
- Microbial Assay
- Microbial Limit Test
- Bioburden Test
- Environmental monitoring for viable and non-viable count

5.9 Machineries Observed in QC and Microbiology Department

Equipment	Company	Origin	Use
HPLC	Shimadzu	Japan	Analytical Test: Identification Qualification Separation
HPLC	Agilent	Germany	Analytical Test: Identification Qualification Separation
Atomic absorption spectrophotometer	Shimadzu	Japan	Trace metal determination and metal identification
FTIR	Shimadzu	Japan	Material identification and functional group determination
TOC Analyzer	Shimadzu	Japan	To measure total organic Carbon impurified
Water Conductivity Tester	Sartorius	Germany	To test conductivity
Sieving machine	Fritsch	Germany	To do sieve analysis
PH meter	Mettler Toledo	Switzerland	To determine pH
UV-Visible Spectrophotometer	Shimadzu	Japan	A wide range analytical test

Semi-automatic Dissolution Taster	ERWEKA	Germany	Dissolution testing
Centrifuge machine	Hermle	Germany	Separation Technique
Waterbath	GEL	Germany	Controlled Temperature reaction
Vaccum Oven	Memmert	Germany	Drying and to Check LOD
Weighing Balance	Mettler Toledo	Switzerland	Analytical weighing
Karl Fischer titrator	Mettler Toledo	Switzerland	Moisture content determination
Gas Chromatography	Shimadzu	Japan	Potency determination of volatile substance
Particle Size Analyzer	Aimil	USA	To measure the particle no. in solid and liquid
Dry Heat Sterilizer	Used for dry sterilization	Memmert	Germany
Autoclave (Hiclav eHV-85)	Used for preparation	Harayama	Japan

Table 13: Machines in QC

Chapter 6: Engineering

The Engineering Department is responsible for ensuring the smooth operation, maintenance, and environmental control of the manufacturing facility. It is broadly divided into three major segments:

- Civil Construction
- Engineering Operations
- Health Sector Support

6.1: HVAC and Environmental Control Systems

The facility maintains controlled environmental conditions through a well-designed HVAC system to ensure product quality and compliance with GMP requirements. Cooling systems utilize chillers for air conditioning. Heating systems are supported by steam boilers. Temperature is initially maintained within 18°C – 20°C during cooling phases and stabilized at 22°C – 25°C in controlled areas. Relative humidity is maintained below 50%, while hygroscopic-sensitive areas are maintained below 25%. Equipment such as dehumidifiers and dryers are used for moisture control. HEPA filters are installed to ensure purified air circulation within production areas.

6.2: Utility Management

The Utility Team is responsible for the continuous supply and maintenance of essential services required for production and facility operations:

- Purified water systems, including potable water supply and water softening systems to control hardness within specified limits
- Gas supply management
- Electricity distribution and backup systems
- Compressed air systems

6.3: Maintenance and Equipment Management

A dedicated maintenance team ensures the proper functioning and efficiency of all machinery and equipment. Both preventive and corrective maintenance activities are carried out regularly to minimize downtime and ensure operational reliability.

6.4: Validation and Qualification

All machines and equipment within the facility undergo systematic validation and qualification processes to ensure compliance with regulatory standards and to confirm their suitability for intended use.

6.5: Water Treatment Plant

Raw water is processed in several steps at Radiant Pharmaceuticals to satisfy requirements for diverse applications. Process water must adhere to USP requirements for purified water. In addition, soft water is utilized in the cooling tower of generators and as boiler feed water. Potable water is utilized for washing, sanitary, and other purposes.

Chemicals like poly electrolyte and poly aluminum chloride are employed in wastewater treatment plants. It is made up of a clear water tank, buffer tank, aeration tank, accumulation tank, and lamella tank.

Chapter 7: PPIC and Commercial

Product planning and inventory control is referred to as PPIC. The core function of PPIC is to balance supply and demand to optimize efficiency and works in close contact with Production.

7.1: Functions of PPIC

- Maps, updates, and monitors production capacity to ensure uninterrupted product supply and timely delivery of finished goods.
- Plans, schedules, and monitors day-to-day production activities at the Tongi Plant and toll manufacturing sites to ensure on-time manufacturing and dispatch.
- Coordinates with the Production In-charge and Commercial Manager to perform rough cut capacity planning and capacity leveling for optimal resource utilization.
- Continuously monitors production schedules and performance on a daily basis and adjusts plans as necessary to ensure efficient utilization of machinery and to meet sales and marketing demand.
- Material Planning and Supply Coordination
- Determines material requirements based on demand forecasts and issues purchase requisitions accordingly.
- Coordinates with vendors and internal departments such as Production, QA, Distribution, and Marketing to ensure smooth operational flow.
- Collaborates with Production, Purchase, and Supply Chain departments to develop day-wise production plans.
- Works closely with the Purchase Team to ensure timely procurement of materials to meet month-to-month demand, and communicates schedule changes to vendors while accommodating necessary rescheduling requests from internal stakeholders.

7.2: Commercial

A pharmaceutical company's commercial department is essential to its expansion, profitability, and market share. The Commercial Department is crucial to the pharmaceutical industry's tax management, especially when it comes to Value-Added Tax (VAT) and other sales-related taxes. The Commercial Department is in charge of making sure that the right VAT rate and amount are included on invoices. This entails including information on each invoice, such as the tax identification number, VAT amount, and appropriate product classification. To file taxes, the department creates sales reports that contain details on both taxable and exempt sales. The VAT collected and owing to tax authorities is tracked by these reports.

Chapter 8: Warehouse

The warehouse is a controlled storage area where bulk raw materials (APIs and excipients), primary and secondary packaging materials, and finished products are stored under appropriate, optimized environmental conditions. It is designed to ensure the integrity, safety, and quality of materials throughout storage and handling. The warehouse includes loading and unloading zones, quarantine areas, a warehouse office, and secured locked sections designated for rejected or complaint-related materials.

8.1Areas of the Warehouse

- **Sampling Area**: After approval from QA, materials are sent to QC for sampling. Sampling is conducted in a dedicated sampling booth, where samples are collected from each container. A QC executive must be present during the entire process. The sampling area is physically separated from other sections of the warehouse to prevent contamination of materials during sampling activities.
- **Rejected Area**: Materials that fail to meet QC specifications are marked with a red rejection tag by QA on each container or box. These rejected materials are stored in the rejected area until a final disposition decision is made. Formal communication regarding the rejection is issued to the concerned department for further action.
- **Special Area**: The special storage area is designated for materials that are sensitive to light and heat, such as capsule shells, colors, flavors, vitamins, and certain toxic or hazardous substances. These materials are stored under controlled conditions to maintain their stability and quality.
- **Narcotic area**: This area should be separated from other areas. Following the DGDA approval and guidelines, a specific amount of narcotic materials can be stored. Without permission, entry is restricted in this area.

8.2: Receiving system

i. The supplier provides the purchase order (PO) or lateral contract (LC) with the materials, which should be checked while receiving the materials. It contains material specificity Quantity, quality, time frame, rate, etc.

ii. After receiving the materials Good Receiving Notes (GRN) are prepared and every batch has a specific GRN number

iii. The labeling of materials should be carefully checked to make sure that they belong to the same batch. Only materials from the same batch receive the same Good Receiving Notes (GRN) number. The GRN is the identification number for that raw material.

iv. The packaging of the materials should be inspected visually for damage v. The materials are then carefully labeled ‘Quarantine’ with the GRN number. vi. The first people allowed to open the material labeled "Quarantine Quality Control (QC) officials. For active pharmaceutical ingredients, QC takes samples from every container.

vii. After the materials have conformed to the specification, they are released by QC authorities and are labeled 'released' meaning they are ready to be used in manufacturing.

viii. Rejected materials should be separated from the released materials and labeled rejected. Rejected materials are placed in the disposal area, and raw materials that are rejected by the vendor are contacted immediately.

8.3: Storage condition

The physical or chemical characteristics of both raw materials and completed goods determine how they are preserved. While certain completed goods and raw materials are stored at ambient temperature in the RPL warehouse, temperature-sensitive products are kept at a specific temperature to preserve their quality and purity. Four conditions are identified based on temperature:

➢ Chest freezer (-15°C to -25°C), eg- Purified egg lecithin, Ice gel product (Fatisol)

➢ Cold storage (2°C to 8°C), eg- Insulin and Vaccine.

➢ Controlled temperature storage (15°C to 25°C), eg- Major API, capsule shell, printed foil, tab coating materials, etc.

➢ Ambient condition (25°C), eg- Packaging materials, and some finished products. Finished products such as solid dosage forms are kept under lock and key such as Pethidine containing product Because of the risk of misuse, it is kept under strict lock and key and access is restricted to authorized personnel only. To prevent the mix-up of printed containers and labeling materials, each printed packaging material is stored in alphabetical order along with the specific GRN number and code number for identification and to avoid contamination.

8.4 Handling of Hazardous Products

Handling hazardous products in a warehouse requires strict safety measures to protect employees and ensure regulatory compliance. Key steps include:

1. Regulatory Compliance: Follow safety regulations (OSHA, EPA), and keep updated material Safety Data Sheets (MSDS) for all hazardous products.

2. Proper Storage: Store hazardous materials in designated areas with proper ventilation, temperature control, and segregation of incompatible substances.

3. Labeling and Signage: Clearly label hazardous products with appropriate hazard symbols and handling instructions.

4. PPE: Provide personal protective equipment (PPE) like gloves, goggles, and respirators to staff handling hazardous materials.

5. Safe Handling: Use mechanical aids to minimize direct contact, and apply secondary containment to prevent spills.

6. Emergency Response: Ensure spill kits, safety showers, eyewash stations, and fire suppression systems are available, and train staff on emergency procedures.

7. Training: Provide regular training on hazardous materials handling, safety protocols, and emergency responses.

8. Inspection and Audits: Conduct routine safety inspections and compliance audits to ensure proper storage and handling procedures.

Chapter 9: Health Environment and Safety

Health, Environment, and Safety (HES) are critical aspects of operations in any pharmaceutical factory, including Radiant Pharmaceuticals. These elements ensure employee well-being, environmental protection, and standards. Below are the key components of HES management in a pharmaceutical setting:

9.1: Health: Ensuring Worker Well-being

• Occupational Health Programs: Regular health check-ups, vaccination drives, and health awareness programs for employees.

• Personal Protective Equipment (PPE): Providing and ensuring the use of appropriate PPE such as gloves, masks, goggles, and lab coats to minimize exposure to harmful substances.

• Training and Awareness: Conducting training sessions on the safe handling of chemicals, machinery, and biological agents.

9.2: Environment: Sustainable Practices

• Waste Management: Ensuring the safe disposal of pharmaceutical waste, including expired drugs, chemicals, and packaging materials, to prevent environmental contamination.

• Air and Water Emissions Control: Using advanced filtration and treatment systems to minimize emissions and effluents from production processes.

• Energy Efficiency: Implementing energy-saving technologies and renewable energy sources to reduce the factory's carbon footprint.

• Sustainability Initiatives: Encouraging green practices, such as recycling, reducing resource usage, and implementing green building standards.

9.3: Safety: Preventing Accidents and Hazards

• Hazard Identification and Risk Assessment (HIRA): Regularly assessing potential hazards in the workplace and implementing measures to mitigate risks.

• Emergency Preparedness: Establishing and practicing emergency response plans for fire, chemical spills, and other incidents.

• Fire Safety: Installing fire alarms, extinguishers, and sprinkler systems, and conducting regular fire drills.

• Chemical Safety: Proper storage, labeling, and handling of chemicals, along with Material Safety Data Sheets (MSDS) for all substances used.

• Machine Safety: Regular maintenance and inspection of equipment, along with the use of safety interlocks and guards.

9.4: Compliance with Regulatory Standards

Adhering to local and international standards such as:

Good Manufacturing Practices (GMP): Ensuring product quality and safety. Environmental Protection Agency (EPA): Guidelines for pollution control. o Occupational Safety and Health Administration (OSHA): Equivalent regulations in the region.

9.5: Employee Involvement and Culture

• Safety Committees: Engaging employees in identifying risks and suggesting improvements.

• Reporting Systems: Encouraging transparent reporting of near-misses, incidents, and unsafe conditions.

• Continuous Improvement: Regularly reviewing and updating HES policies and practices.

Chapter 10: Human Resource

The Human Resource (HR) Department in a pharmaceutical industry plant plays a crucial role in managing the workforce, ensuring compliance with industry regulations, and fostering a productive work environment.

- The HR department is responsible for hiring employees with the necessary technical skills, including roles such as production operators, quality control specialists, research scientists, engineers, and maintenance staff.
- HR ensures that new hires understand and are familiar with industry regulations such as Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).
- HR may collaborate with educational institutions to recruit fresh talent, such as pharmacists, chemists, and engineers.
- HR ensures that all employees are trained in industry-specific regulatory requirements (e.g., FDA, EMA guidelines) and that this training is kept up-to-date.
- HR ensures that the plant complies with all local and international labor laws, including those related to working hours, wages, and employee rights.
- HR plays a role in ensuring that employees are prepared for audits and inspections, which are common in the pharmaceutical industry.
- HR conducts employee engagement surveys, facilitates team-building activities, and promotes a positive organizational culture that enhances morale and job satisfaction. o HR uses HR Information Systems to manage employee data, track attendance, monitor performance, and ensure regulatory compliance.
- HR ensures that employees understand and follow the company's code of conduct, particularly in areas like ethical behavior, anti-bribery, and interactions with healthcare professionals.

Important HR Considerations for Pharmaceutical Companies:

Talent Acquisition & Retention: HR concentrates on locating specialized specialists for research, development, and marketing because of the intense competition.

Regulatory Compliance: HR is responsible for ensuring that employees follow international and local standards.

Training and Development: Training on new technologies and compliance standards is essential for ongoing skill development.

Employee Welfare: Handling stressful situations, preventing burnout, and offering competitive pay and chances for professional advancement.

In Plant Training: As part of their academic program, Human Resources oversees a training program for university students. HR organizes the training schedule, sets up the trainees' attire and meals, assesses their cGPA, evaluates their overall performance during the in-plant training program, and finally issues certificates.

Attendance: Prepare daily absence reports, monthly attendance summaries, job cards, and oversee and track staff attendance, among other things.

Performance Appraisal: Monitor the performance appraisal of employees on an annual basis.

Over Time: Employees are assigned to three separate shifts. If an employee continues working beyond the scheduled shift hours, HR monitors and records the overtime accordingly and ensures appropriate compensation is provided.

Chapter 11: General Services

The General Services function is organized into two primary wings:

- Support wing
- Administration (Admin) Wing

11.1: Main Working Areas

The department oversees a wide range of essential support and operational activities, including:

1. Transportation services
2. Security management
3. Canteen operations
4. Cleaning and housekeeping
5. General administrative work
6. Stationery management
7. Mail and dispatch services
8. Medical services coordination
9. Procurement and purchasing
10. Regulatory and compliance affairs
11. Laundry and tailoring services
12. Physical fitness programs
13. Annual health check-ups
14. Half-yearly eye examinations
15. Event management

Chapter 12: ICT

The Information and Communication Technology (ICT) function supports both plant operations and corporate/head office (CHO) activities. It plays a central role in enabling business processes across departments.

Core Operations Supported	Cross-Functional Support
Human Resources (HR)	Production (PRD)
General Services (GS)	Warehouse (WH)
Engineering (Engg.)	Quality Control (QC)
Finance & Accounts (F&A)	Research & Development (RD)
Supply Chain Management (SCM)	Cross-Functional Support

Table 14: Departments to which ICT support is given

User Support Services

- Email account management
- Software installation and maintenance
- IT training for employees

Networking and Infrastructure

- File server management
- Telecommunication support
- Network design and maintenance
- Data backup systems

Hardware Support

- Desktop and laptop maintenance
- Access control systems
- IT asset inventory management
- Device security implementation

Enterprise Systems (SAP)

- Front-end user support
- User account management

Enterprise Management Systems (EMS)

- User administration
- System development and enhancements

Network Architecture

The organizational network is secured and managed through a centralized firewall system. Multiple locations (e.g., RPL, PCL, RNL, and CHQ) are interconnected through this firewall to ensure secure communication and data exchange.

File Server Structure

Data is organized systematically on file servers using a folder-based structure:

- Common folders accessible to all users
- Personal user directories
- Department-specific shared folders

Endpoint Security

To ensure data protection and system integrity:

- Firewalls and antivirus solutions are deployed
- Unauthorized portable devices are restricted
- Internet usage is monitored and controlled

Digital Data Archiving

A digital data archiving system is currently under implementation. This project aims to ensure secure storage, easy retrieval, and long-term preservation of critical business data.

User Management Process

User access is controlled through a structured workflow:

- Submission of request form
- Creation or modification of user ID
- Approval and confirmation of access rights

Laboratory Systems and Data Management

- Machine access is controlled and monitored
- Data backups are performed either manually or through scheduled automation
- Backup data is stored securely within the system
- All activities are recorded and maintained in logbooks for traceability

Chapter 13: Conclusion

Visiting the many divisions of a pharmaceutical firm in person not only inspired us to study the topics in depth but also made it clear how much dedication and effort it takes to get a pharmaceutical company this far. Radiant Pharmaceuticals Limited gave us the chance to participate in an in-plant training program covering a variety of dosage forms. During the two weeks we spent observing in several departments, our theoretical comprehension was clarified. Observing the manufacturing procedures, quality control, packaging, and other related activities of pharmaceutical items has quenched our desire. In addition to learning how to use numerous valuable machineries and observing a variety of cutting-edge technologies, we also visited RPL's primary industrial section, which includes its power plants and liquid nitrogen plant. We all saw that Radiant Pharmaceuticals Limited's staff members are all qualified and trained to adhere strictly to G.M.P. norms. Finally, we would like to express our sincere gratitude to Radiant Pharmaceuticals Limited and all of its employees. Finally, we would want to express our gratitude for the entire experience we had with Radiant Pharmaceuticals Ltd.