

Eris

POWER OF EMPATHY
TRUTH OF SCIENCE



Welcome to the youngest organization



Youth is about certain traits and spirit

Eris is young not just by age but in traits and spirit

As an organization we have demonstrated Speed, Agility, Adaptiveness and high level of Energy



Business Overview

Eris



Founded in the year 2007
by Mr. Amit Bakshi



Eris has scaled rapidly since inception: **Among the Top-20 pharmaceutical companies in India in less than 20 years since inception.**



Dominant presence and amongst the fastest growing companies in chronic therapeutic segments: Cardiovascular & Anti-diabetic



12 marketing divisions with a sales team of over 3000, focusing on multiple super specialty areas



Eris entered the primary markets with the biggest IPO in the Indian Pharmaceutical Industry over INR 17,400 Mn (USD 259.7 Mn) in 2017

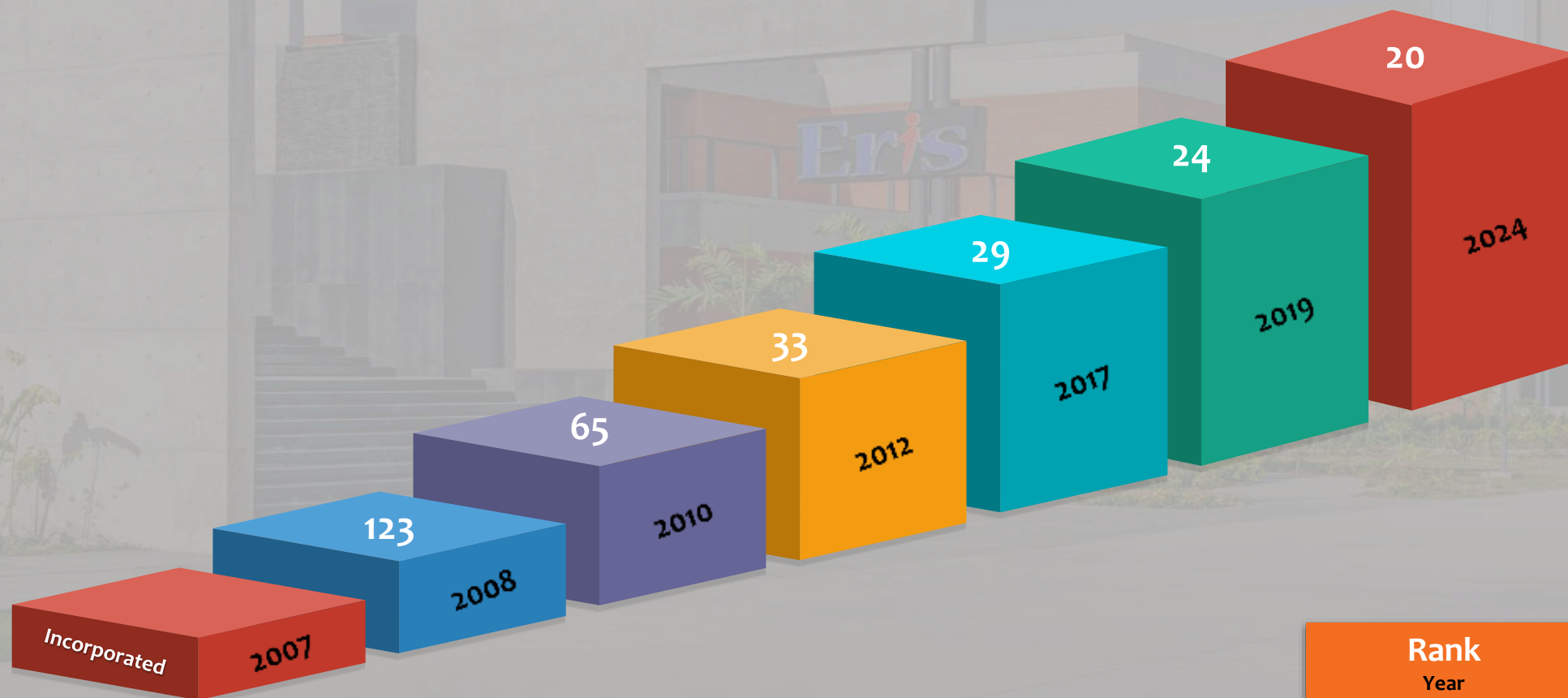


Current Market Capitalization of Eris Life Sciences is ~ INR 177 Billion*



09 Manufacturing Units having capabilities across a wide range of dosage forms and specialties

Eris Progression Since Inception



Rank
Year

Eris Acquisitions and Strategic Partnerships



UTH, Kinedex & Strides

Eris acquires UTH, Kinedex
Eris also acquires majority of Strides brands

2017

2019

Zomelis (Abbott Brand)

Eris acquired Zomelis Mother Brand of Vildagliptin market from Abbott

MJ Biopharm

Eris forms Joint Venture with MJ Biopharm to enter Insulin Segment

2021

2022

Oaknet Healthcare

Eris acquires Mumbai based dermatology formulations company Oaknet Healthcare

Glenmark & DRL

Eris acquired 9 Dermatology brand from Glenmark in Jan'23.
Eris also acquired 9 Dermatology brand from DRL in Mar'23, Acquisition of Nephro & Derma Units from Biocon

2023

2024

Acquisition of Swiss Parenterals

Acquisition of Biocon Biologics India branded formulation business: Metabolics, Oncology & Critical Care division

2024

STATE OF THE ART MANUFACTURING FACILITIES ACROSS INDIA



ELL Guwahati

- Drug
- Tablets
 - Capsules
 - Sachet
 - Softgel
- Food
- Supplement
 - Nutraceutical



ETL Ahmedabad

- Sterile Preparation***
- ***Ampoules***
- OSD***
- ***Tablets***
 - ***Capsules***
- External Preparation***
- ***Ointment***
 - ***Lotion***
- Oral Liquids***
- ***Solution***
 - ***Suspension***



Swiss Parenterals

- Unit-I
- Gen. Liquid ampoules
 - Gen. Liquid vials
 - Gen. Dry powder vials
 - Prefilled syringes
 - Lyophilized vials
 - Ophthalmic drops
 - Ophthalmic ointments
 - Inhalation anesthetics

- Unit-II
- Cephalosporins
 - Penicillins
 - Carbapenems/Monobactams



Eris Bionxt

- Insulins
- GLP-1
- MABs
- rDNA products



Levim Lifetech

- Biosimilar DS
- Biologic products



Virchow Biotech (LL)

- LL site for Insulin

STATE OF THE ART MANUFACTURING FACILITIES NEAR AHMEDABAD



ORAL SOLID DOSAGE & EXTERNAL PREPARATION BLOCK

Tablet / Capsule / Liquid / Ointments / Lotions

STERILE MANUFACTURING BLOCK

Injection Ampoules Line

ROOFTOP SOLAR PLANT

ADMIN / QA

QC LAB

R&D / ADL / F&D

40-member R&D team

based out of a 11,000 square feet
R&D Centre with designated sections for

- **Formulation Development** ▪
- **Analytical Development** ▪
- **Tech. Transfer** ▪
- **Stability & Research Quality Assurance** ▪



Our Technologies/ Dosage Forms

- **Sterile Injections** – Solutions, Long-acting injections (Microsphere/ Liposomal), Suspensions, Emulsions, Dry-Powder, Lipid Complex, Lyophilized Injections, Pen Devices (With Cartridges)
- **Topical Semisolids** – Gels, Ointment, Creams
- **Oral Solid Dosage** – Tablets and capsules
- **Oral Liquids** – Solution, Suspension, Syrup
- **Ophthalmic** – Drops, Solutions, Suspensions, Gels and Ointments
- **NDDS**

Formulation Capabilities and Strengths

Eris



Tablets - 247 M per Month



Capsules – 29 M Per Month



Liquid Oral 0.8 M Per Month



Ointment & Lotions - 12 M Per Month



Sterile injectables & ampules – 1.2 M Per Month



Currently having 300+ Skilled Manpower



FEATURES OF MANUFACTURING FACILITY



cGMP standards have been used as the basic skeleton of the manufacturing facility.

Equipped to produce high-quality products efficiently, safely, and in compliance with Regulatory standards

Advanced Equipment and Automation with **SCADA and e-system.**

Integrated Software Systems for production and Quality Control.

Unidirectional flow of Man & Material Movement has been followed.

All controlled areas are maintained at temperature of **NMT 25°C** and **RH of NMT 55%**.

Warehouses of "Raw material, Primary packing materials & Finished products" are maintained at NMT 25 °C.

Controlled areas have been separated from uncontrolled areas by placing bubble airlocks and dynamic pass boxes in between. These airlocks and pass boxes are provided with interlock provisions.

Air quality is maintained with a well-established HVAC system. State of art Oral Solid Dosage Form Manufacturing Facility

Robust Packaging Solutions.

Environmental Control through **BMS/EMS**

Close loop material transfer systems with minimum human intervene to eliminate errors.

Independent Quality Unit to ensure implementation of TQM principles.

WHO-GMP
Certification ✓

GHANA GMP
Inspection
Completed ✓



Yemen GMP
Inspection
Completed ✓

ANVISA Facility
Inspection
Triggered

EU-GMP
inspection in
pipeline

WHO-GMP Certificate



 **Food & Drugs Control Administration**
BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN : 382010 

Certificate No. : **24044920**

On the basis of the inspection carried out on 13-14/03/2024 & 08/04/2024 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1 Name & Address of site : **ERIS THERAPEUTICS LIMITED,**
SURVEY NO. 589, 600, VILLAGE - KALYANGADH, OPP ATUL AUTO,
BAVLA - BAGODARA HIGHWAY,
BAVLA, DIST. - AHMEDABAD - 382 240,
GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/25/2619** **G/28/1692**

3 Table : 1

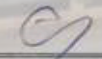
Dosage Form (s)	Category (ies)	Activity (ies)
Tablet, capsule, Oral Liquid, External Preparation, Injectible (SVP Ampoule)	General	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.


This certificate remains valid until **21/04/2027** It becomes invalid if the activities and /or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority
Food & Drugs Control Administration, Block No. 8, 1ST floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State, India. - Pin : 382010

Name & function of responsible Person :  **(Dr. H. G. KOSHTIA)**
Commissioner

Email : comfdca@gujarat.gov.in
Phone : 91-79-23253417, Fax : 91-79-232-5341, 0
Date : 22/04/2024







Confederation of Indian Industry

Indian Green Building Council (IGBC)

hereby precertifies

Eris Therapeutics Limited

S.No. 589/600 , Opp. Atul Auto, Bavla - Bagodara Highway , Village : Kalyangarh , Taluka : Bavla, Dist. : Ahmedabad, Gujarat 382240

(IGBC Registration No: GFB 24 0042)

*The project has demonstrated intent to design and build
high performance building in accordance with*

IGBC Green Factory Building Rating System

Precertified Platinum

November 2024

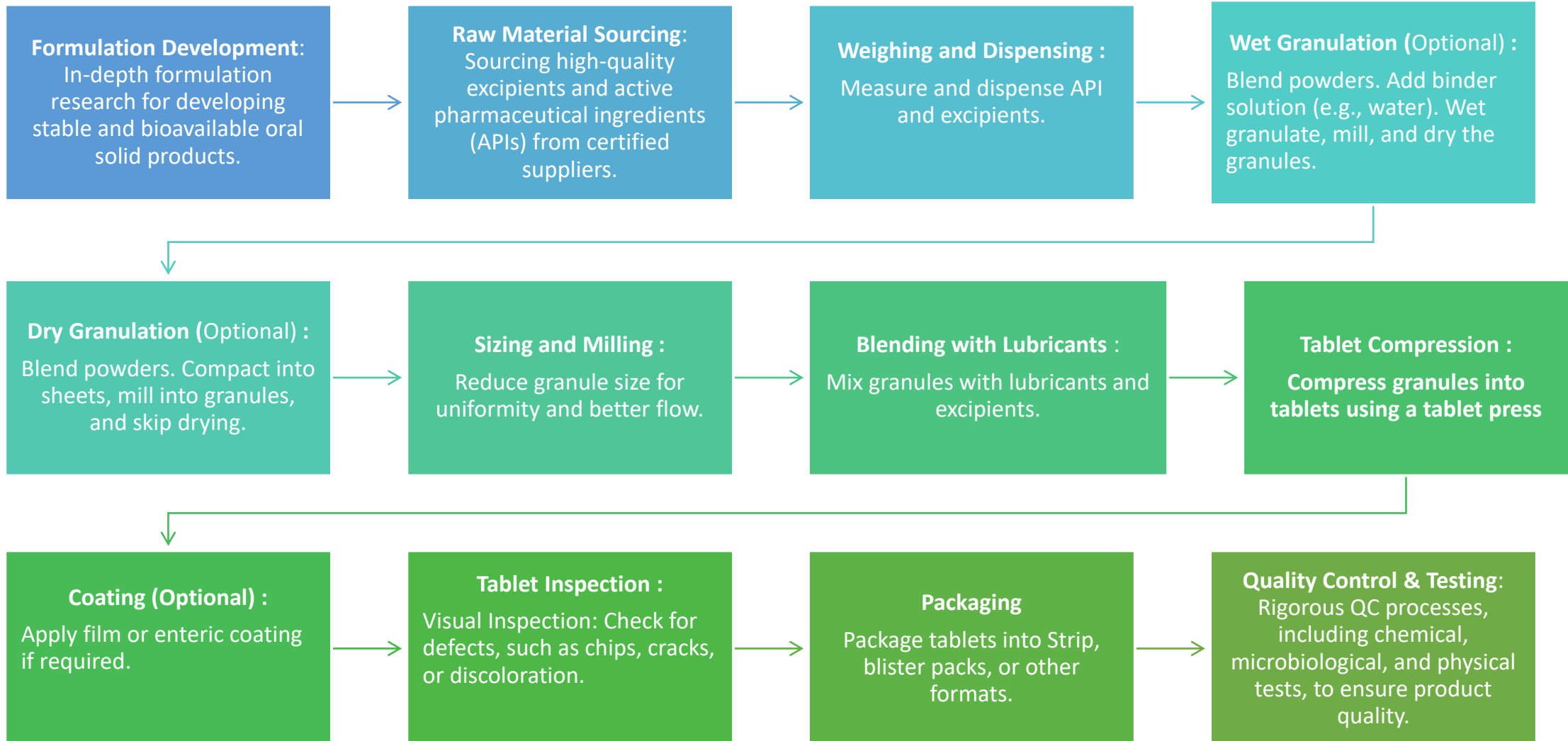
(Precertification is valid for 3 years, renewed based on six monthly progress updates till certification)

Pradeep Bhargava
Chair, IGBC Green Factory Building

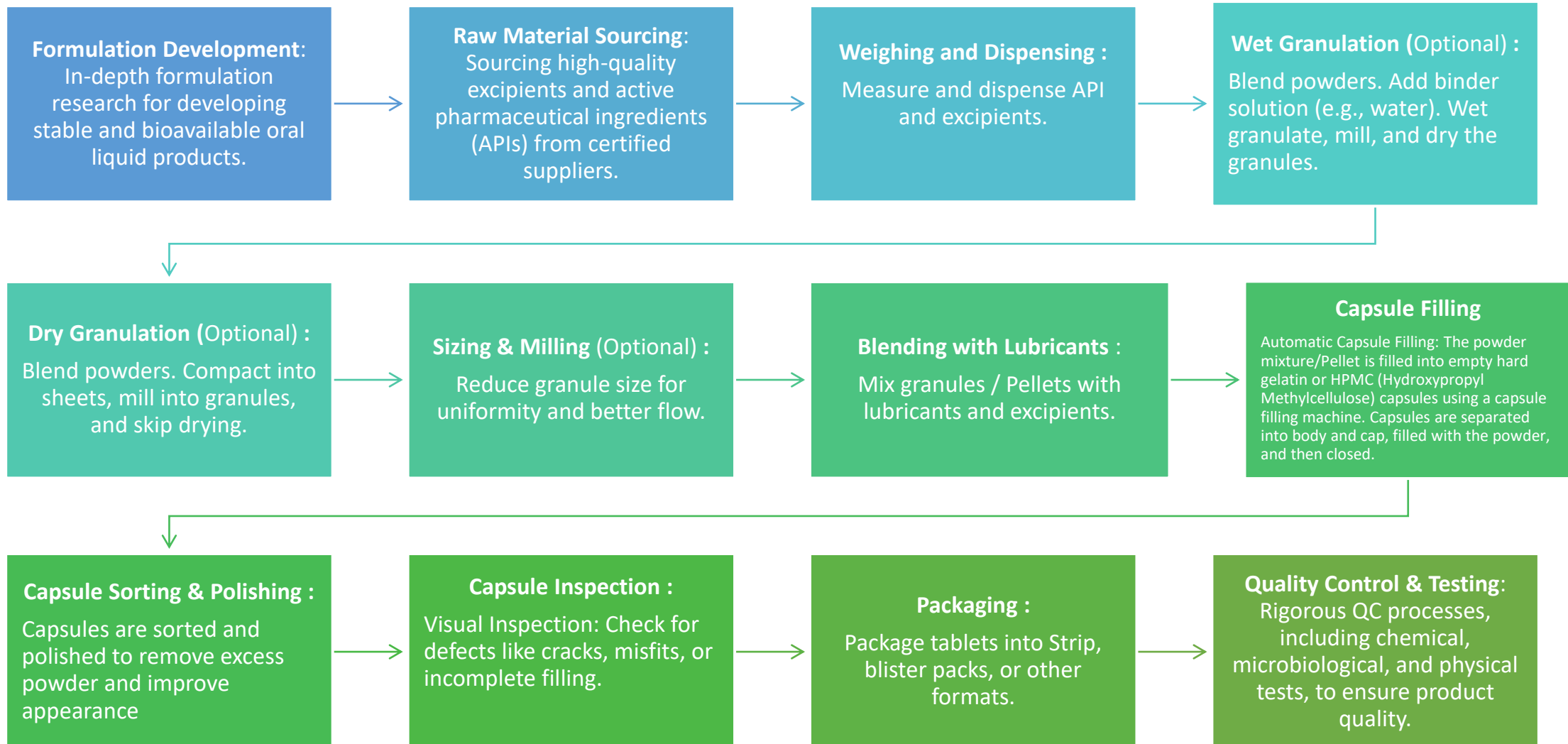
B Thiagarajan
Chairman, IGBC

K S Venkatagiri
Executive Director, CII-Godrej GBC

Manufacturing Process for Tablets



Manufacturing Process for Capsules



Production Equipment:

- Cutting-edge machines and systems are designed to enhance efficiency, precision, and quality control in tablet and capsule manufacturing, enabling faster production cycles, better compliance with regulatory standards, and consistent product quality.
- Close loop Power transfer System and Integrated Equipment chain with SCADA.

Technologies for Quality & Safety:

- Real-Time Monitoring Systems: Continuous monitoring of production conditions (temperature, humidity, pressure) through BMS/EMS.
- SCADA and Validated PLCs handle labeling, sealing, and packaging, reducing human error.
- Digital platforms like SAP, eBMR, e-Logbooks, and ATL TMS are revolutionizing manufacturing operations and quality control by integrating skill development and Quality by Design (QbD) principles.

- Warehouse Area



Warehouse Build up Area : 661 m²

Key Features :

- Temperature and humidity control for sensitive Materials
- Accurate inventory management and real-time tracking
- Compliance with Good Distribution Practices (GDP) and regulations
- Robust security with access control and surveillance
- Cleanliness and hygiene following GMP standards
- Proper labeling and segregation of Materials
- Use of automated systems (SAP, eLOG, BMS/EMS)
- Ongoing staff training on safety and handling
- Efficient warehouse layout for easy product access
- Risk management systems to ensure product quality and safety.

- Dispensing Area



Dispensing Booth features:

- Controlled environment (temperature, humidity, air quality)
- Airflow systems with HEPA filters or laminar flow
- Ergonomic design for operator comfort
- Compliance with safety and regulatory standards (GMP, OSHA)
- Efficient material handling for raw materials or Solvents
- Transparent PVC sleeves for clear visibility
- Prevents cross-contamination between ingredients
- Easy-to-clean, smooth, non-porous surfaces
- Lockable access for security and product integrity

- Production Corridor



Production Area features :

- Bubble Airlock:** Prevents cross-contamination between zones.
- Controlled Environment:** Maintains temperature, humidity, and airflow for product integrity.
- Area Classification:** Zones classified by cleanliness (Grade D) per GMP. Zoning for high, medium, and low-risk activities.
- Positive Pressure:** Ensures no contamination from adjacent areas.
- Airflow Systems:** HEPA filters or laminar flow for sterile conditions.
- Safety and Compliance:** Adheres to GMP, FDA, and regulatory standards.
- Continuous Monitoring:** Tracks air quality, pressure, and humidity.
- Cleanability:** Easy-to-clean materials and surfaces for contamination control.

• Granulation Line



Granulation Line Equipments	Make / Model	Capacity
	Bectochem	500 kg / 250 kg
	GMP	/ 60 kg

Key Features	
	<ul style="list-style-type: none">• Closed Loop Material Transfer: Ensures precise, controlled material movement.• Vacuum Transfer System: Efficient, contamination-free powder/granule transfer.• Material Handling Device: Automates dosing, transfer, and mixing for accuracy.• Inline Co-Mill: Achieves uniform particle size during granulation.• SCADA System: Centralized control, real-time monitoring, and data tracking.• IP (Clean-in-Place) System for cleaning of equipment, pipes, and tanks without disassembly

- OGB with VTS



	Make / Model	Capacity
OGB with VTS	Bectochem	5000 Ltr.
	GMP	
Key Features	<ul style="list-style-type: none">• Uniform Mixing: Ensures consistent blending of powders/granules.• Vacuum Transfer System: Efficient, contamination-free material handling.• Gentle Handling: Minimizes damage to fragile ingredients.• High Capacity: Suitable for large batch sizes.• Easy Cleaning: Simplifies hygiene maintenance and reduces downtime.• SCADA Control: Enhances operational efficiency with precise monitoring.	

• Compression Machine



Compression Machine	Make / Model	Capacity
	Cadmach	0.3 millions Tablets/Hr. To 0.53 millions Tablets/Hr
	Cadpress V-45 STN - D tooling Cadpress V-55 STN - B tooling CADPRO A -31 STN - D tooling CADPRO A -39 STN - B tooling	
Key Features	<ul style="list-style-type: none">• Automatic Weight Control: Ensures precise tablet weight.• MHD: Automates material transfer for efficiency.• Efficient Compression: Delivers uniform, high-quality tablets.• Real-Time Monitoring: Continuous quality control.• Reduced Downtime: Minimizes interruptions in production.• SCADA Control System	

• Coating Machine



Coating Machine	Make / Model	Capacity
	Solace 48"/37" Interchangeable & 66" GMP	48": 80-150Kg 37": 40-70Kg 66": 450- 550 kg

Key Features

- **SCADA Integration:** Real-time monitoring and control.
- **CIP:** Automated cleaning for minimal downtime.
- **Interchangeable Pan:** Flexibility for different batch sizes.
- **Efficient Coating:** Uniform, high-quality results.
- **Reduced Downtime:** Quick pan changeover and cleaning.

- Capsule Filling Machine



Capsule Filling Machine	Make / Model	Capacity
	ACG-PAM	90000 capsules/hr
	AF-90T	
Key Features	<ul style="list-style-type: none">• SCADA Integration: Real-time monitoring and control for precise operation.• High-Speed Filling: Efficiently fills a high volume of capsules.• Automated Control: Reduces human error and ensures consistent quality.• Data Logging: Tracks production data for compliance and traceability.• User-Friendly Interface: Simplifies operation and monitoring.	

- Strip packing machine



Strip packing machine	Make / Model	Capacity
	Pharmatech	Upto 60
	Pharmatech-310	cycles/min (02)

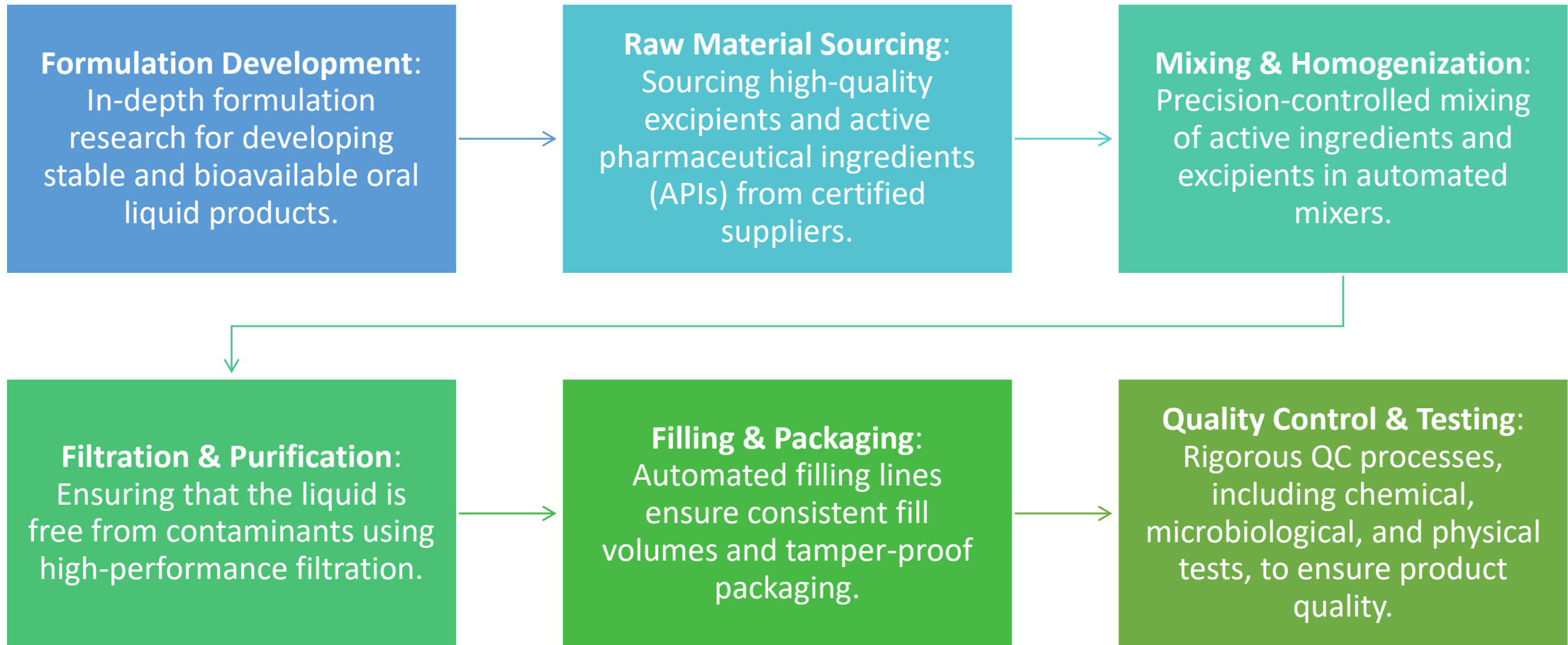
Key Features	<ul style="list-style-type: none">• NFD Detector: Detects missing or misfed strips.• High-Speed Packing: Efficient, fast strip packing.• Quality Control: Reduces errors and ensures consistency.• GMP model.
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• Blister Packing Machine



	Make / Model	Capacity
Blister Packing Machine	Elmach Packages	50 cycles/min (03)
	EPI-3015 PDA	
Key Features	<ul style="list-style-type: none">• Automated blister formation for efficient packing• Precise ampoule placement in cavities• Secure sealing for airtight packaging• High-speed operation for large-scale production• Blister Inspection System• Pin hole detector• Integrated inspection for quality control• User-friendly interface for easy operation• Durable and GMP-compliant design	

Manufacturing Process for Oral Liquids



Production Equipment:

- Automated High Shear Homogenizers & Mixers: Ensure uniform size reduction (Nano Particles) and distribution of active ingredients and excipients in liquid formulations.
- Automatic Filling Machines: High-speed machines for filling liquid in bottles with minimal human intervention.
- High-Efficiency Filters: Advanced filtration technologies like cross-flow filtration for the removal of particulate contaminants.

Technologies for Quality & Safety:

- Real-Time Monitoring Systems: Continuous monitoring of production conditions (temperature, humidity, pressure) through BMS/EMS.
- SCADA and Validated PLCs handle labeling, sealing, and packaging, reducing human error.
- Digital platforms like SAP, eBMR, e-Logbooks, and ATL TMS are revolutionizing manufacturing operations and quality control by integrating skill development and Quality by Design (QbD) principles.

- Warehouse Area



Warehouse Build up Area : 661 m²

Key Features :

- Temperature and humidity control for sensitive Materials
- Accurate inventory management and real-time tracking
- Compliance with Good Distribution Practices (GDP) and regulations
- Robust security with access control and surveillance
- Cleanliness and hygiene following GMP standards
- Proper labeling and segregation of Materials
- Use of automated systems (SAP, eLOG, BMS/EMS)
- Ongoing staff training on safety and handling
- Efficient warehouse layout for easy product access
- Risk management systems to ensure product quality and safety.

- Dispensing Area



Dispensing Booth features:

- Controlled environment (temperature, humidity, air quality)
- Airflow systems with HEPA filters or laminar flow
- Ergonomic design for operator comfort
- Compliance with safety and regulatory standards (GMP, OSHA)
- Efficient material handling for raw materials or Solvents
- Transparent PVC sleeves for clear visibility
- Prevents cross-contamination between ingredients
- Easy-to-clean, smooth, non-porous surfaces
- Lockable access for security and product integrity

- Production Corridor



Production Area features :

- Bubble Airlock:** Prevents cross-contamination between zones.
- Controlled Environment:** Maintains temperature, humidity, and airflow for product integrity.
- Area Classification:** Zones classified by cleanliness (Grade D) per GMP. Zoning for high, medium, and low-risk activities.
- Positive Pressure:** Ensures no contamination from adjacent areas.
- Airflow Systems:** HEPA filters or laminar flow for sterile conditions.
- Safety and Compliance:** Adheres to GMP, FDA, and regulatory standards.
- Continuous Monitoring:** Tracks air quality, pressure, and humidity.
- Cleanability:** Easy-to-clean materials and surfaces for contamination control.

- Sugar Melting Vessel



Sugar Melting Vessel	Make / Model	Capacity
	Propack	2000 Ltr.
	SYP-3KL	

Key Features

- SCADA System
- SS 316 L
- Heating & Mixing Capabilities
- CIP System
- Close loop System

- Premix Vessel



	Make / Model	Capacity
Premix Vessel	Propack	500 Ltr.
	SYP-3KL	

Key Features

- SCADA System
- 316 L MOC
- Heating & Mixing Capabilities
- CIP System
- Close loop System

- Manufacturing Vessel



Manufacturing Vessel	Make / Model	Capacity
	Propack	3000 Ltr. (02)
	SYP-3KL	

Key Features

- SCADA System
- 316 L MOC
- Heating & Mixing Capabilities
- Inline Homogenizer (IKA)
- CIP System

- Holding Vessel



	Make / Model	Capacity
Holding Vessel	Propack	3000 Ltr. (02)
	SYP-3KL	

Key Features

- SCADA System
- 316 L MOC
- Heating & Mixing Capabilities
- CIP System

- Bottle Washing Machine



Bottle Washing Machine	Make / Model	Capacity
	Maharshi Udyog	Upto 100 Bottle/Min
	96 Station	
Key Features	<ul style="list-style-type: none">• Multiple Cleaning Stages• Pre-loaded wash cycles• High-Pressure Spray System	

- Automatic Servo Piston filling machine



Automatic Servo Piston filling machine	Make / Model	Capacity
	Maharshi Udyog	Upto 100 Bottle/Min
	8-Head	
Key Features	<ul style="list-style-type: none">• Servo Motor Control• Precise Volume Control• No Bottle-No Fill Mechanism	

- Automatic ROPP Capping Machine



Automatic ROPP Capping Machine	Make / Model	Capacity
	Maharshi Udyog	Upto 100 Bottle/Min
	8-Head	
Key Features	<ul style="list-style-type: none">• Precise Capping Mechanism• Adjustable Capping Torque• No Bottle-No Cap Mechanism	

- Automatic Sticker Labelling Machine



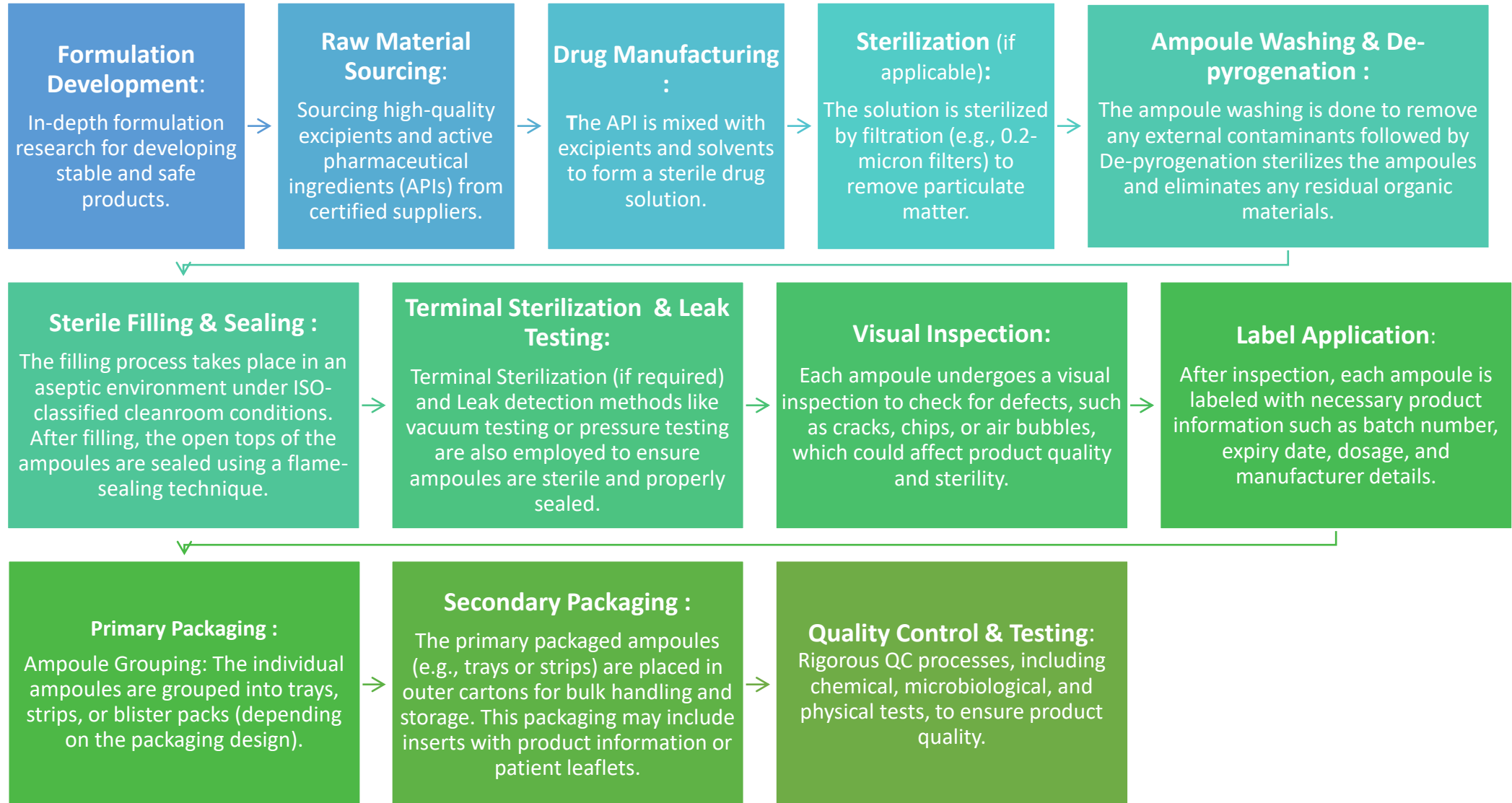
Automatic Sticker Labelling Machine	Make / Model	Capacity
	Maharshi Udyog	Upto 100 Bottle/Min
	VSC/VLC/100	
Key Features	<ul style="list-style-type: none">• Precise Label Application• High Precision Sensors• Label Detection and Rejection	

- Auto-Cartonator



Auto-Cartonator	Make / Model	Capacity
	Maharshi Udyog	Upto 100 Bottle/Min
	CMC-120	
Key Features	<ul style="list-style-type: none">• Automatic Carton Erecting• Product Feeding System• Product and Carton Detection Systems	

Manufacturing Process for Sterile Preparation



Production Equipment:

- Automated Ampoule Washing and De-pyrogenation Machines : Ensuring removal of particulate matter, dust, and other contaminants from the ampoules also ensuring the sterility of ampoules before filling.
- Automatic Filling Machines: High-speed machines for filling sterile preparations in Ampoules with minimal human intervention.
- High-Efficiency Filters: Advanced filtration technologies like cross-flow filtration for the removal of particulate contaminants.

Technologies for Quality & Safety:

- Real-Time Monitoring Systems: Continuous monitoring of production conditions (temperature, humidity, pressure) through BMS/EMS.
- SCADA and Validated PLCs handle labeling, sealing, and packaging, reducing human error.
- Digital platforms like SAP, eBMR, e-Logbooks, and ATL TMS are revolutionizing manufacturing operations and quality control by integrating skill development and Quality by Design (QbD) principles.

- Warehouse Area



Warehouse Build up Area : 661 m²

Key Features :

- Temperature and humidity control for sensitive Materials
- Accurate inventory management and real-time tracking
- Compliance with Good Distribution Practices (GDP) and regulations
- Robust security with access control and surveillance
- Cleanliness and hygiene following GMP standards
- Proper labeling and segregation of Materials
- Use of automated systems (SAP, eLOG, BMS/EMS)
- Ongoing staff training on safety and handling
- Efficient warehouse layout for easy product access
- Risk management systems to ensure product quality and safety.

- Dispensing Area



Dispensing Booth features:

Controlled environment (temperature, humidity, air quality)

Airflow systems with HEPA filters or laminar flow

Ergonomic design for operator comfort

Compliance with safety and regulatory standards (GMP, OSHA)

Efficient material handling for raw materials or Solvents

Transparent PVC sleeves for clear visibility

Prevents cross-contamination between ingredients

Easy-to-clean, smooth, non-porous surfaces

Lockable access for security and product integrity

- Production Corridor



Production Area features :

- Bubble Airlock:** Prevents cross-contamination between zones.
- Controlled Environment:** Maintains temperature, humidity, and airflow for product integrity.
- Area Classification:** Zones classified by cleanliness (Grade A, B, C & D) per GMP. Zoning for high, medium, and low-risk activities.
- Positive Pressure:** Ensures no contamination from adjacent areas.
- Airflow Systems:** HEPA filters or laminar flow for sterile conditions.
- Safety and Compliance:** Adheres to GMP, FDA, and regulatory standards.
- Continuous Monitoring:** Tracks air quality, pressure, and humidity.
- Cleanability:** Easy-to-clean materials and surfaces for contamination control.

- Manufacturing Vessel



Manufacturing Vessel	Make / Model	Capacity
	Propack	100 Ltr. / 50 Ltr.
	501-2205-01-22- Sterile Plants	
Key Features	<ul style="list-style-type: none">• Seamless construction for easy cleaning• Sterile access points with air filters• Clean-in-Place (CIP) for automated cleaning• Pressure/temperature control for process stability• HEPA filtration for sterile air• Validated sterilization methods• Non-reactive materials to prevent contamination• Integrity monitoring for seals• Automated controls for precision and compliance• Aseptic technique compatibility during processing	

- Holding Vessel



	Make / Model	Capacity
Holding Vessel	Propack	100 Ltr. / 50 Ltr.
	510-2205-01-22- Sterile Plant	
Key Features	<ul style="list-style-type: none">• Temperature and pressure control to maintain optimal storage conditions• Material compatibility to prevent contamination or reactions• Sealed design to prevent leaks and maintain sterility• Level monitoring for accurate inventory tracking• Clean-in-Place (CIP) for automated cleaning• Sterilize-in-Place (SIP) for sterilizing without disassembly• Filtration system to ensure sterile air or liquid• Safety features like pressure relief valves• Insulation to maintain temperature and prevent contamination	

- Ampoule Washing Machine



Ampoule Washing Machine	Make / Model	Capacity
	Petals	300 Amp. per Minute
	PEPL-URAWM-300	
Key Features	<ul style="list-style-type: none">• Automated washing for efficient cleaning of ampoules• High-pressure water jets to remove contaminants• Sterilization capability (e.g., with hot air or steam) to ensure sterility• Air drying system to dry ampoules post-wash• Adjustable settings for different ampoule sizes• Integrated filtration for clean washing water• Automatic loading/unloading for high throughput and efficiency	

- Ampoule Depyrogenation Tunnel



Ampoule Depyrogenation Tunnel	Make / Model	Capacity
	Petals	NA
	PEPL-ST-450	
Key Features	<ul style="list-style-type: none">• High-temperature heat treatment to remove pyrogens• Continuous conveyor system for efficient processing• Precise temperature control for effective depyrogenation• Sterile environment to prevent contamination• Multi-zone heating for controlled temperature increase• Cooling section for safe temperature reduction• Insulated structure for energy efficiency• Automatic loading/unloading for high throughput• Air filtration to maintain clean air• Real-time monitoring for process control	

• Filling And Sealing Machine



Filling And Sealing Machine	Make / Model	Capacity
	Petals	300 Amp. per Minute
	PEPL-FSM-8HD	

Key Features

- Automated filling for precise dosing
- Hermetic sealing to prevent leakage
- High-speed operation for efficiency
- Sterile environment to avoid contamination
- Adjustable filling volume for various ampoules
- Integrated inspection system for quality control
- Easy-to-operate controls for process monitoring

- Terminal Steam Sterilizer



Terminal Steam Sterilizer	Make / Model	Capacity
	Machine Fabrik	810 Ltr.
	NA	

Key Features	<ul style="list-style-type: none">• Steam sterilization for effective sterilization• Vacuum leak test for container integrity• Precise temperature/pressure control for consistency• Multi-cycle programs for different loads• Automatic vacuum for enhanced steam penetration• Sterile environment to prevent contamination• Built-in monitoring for cycle tracking• Safety valves for overpressure protection
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• Ampoule Inspection Booth



Ampoule Inspection Booth	Make / Model	Capacity
	Daarvi	04 Station / 02 Station
	NA	
Key Features	<ul style="list-style-type: none">• Visual inspection for cracks, chips, and other defects• Bright, adjustable lighting for clear visibility• Ergonomic design for operator comfort• Magnification tools for detailed inspection• Waste collection system for discarded defective ampoules• Compliance with GMP for quality control standards	

• Automatic Sticker Labelling Machine



Automatic Sticker Labelling Machine	Make / Model	Capacity
	Maharshi Udyog	300 Amp. per Minute
	VSC - HS - A - 300	
Key Features	<ul style="list-style-type: none">• Automatic label application for high-speed operation• Precise positioning for accurate label placement• High-quality print for clear, readable labels• Roll-fed label system for continuous operation• Sensor-controlled alignment for consistent labeling• Easy-to-use controls for quick adjustments• Label detection to avoid mislabeling or errors	

- Blister Packing Machine



	Make / Model	Capacity
Blister Packing Machine	Elmach Packages	30 cycles/minute
	EPI-3015AV	
Key Features	<ul style="list-style-type: none">• Automated blister formation for efficient packing• Precise ampoule placement in cavities• Secure sealing for airtight packaging• High-speed operation for large-scale production• Adjustable settings for different blister sizes• Integrated inspection for quality control• User-friendly interface for easy operation• Durable and GMP-compliant design	

Manufacturing Process for External Preparation



Production Equipment:

- Automated High Shear Homogenizers & Mixers: Ensure uniform size reduction (Nano Particles) and distribution of active ingredients and excipients in formulations.
- Automatic Filling and Packing Machines: High-speed machines for filling and packaging of Ointment, Cream and Lotions with minimal human intervention.

Technologies for Quality & Safety:

- Real-Time Monitoring Systems: Continuous monitoring of production conditions (temperature, humidity, pressure) through BMS/EMS.
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- Airflow systems with HEPA filters or laminar flow
- Ergonomic design for operator comfort
- Compliance with safety and regulatory standards (GMP, OSHA)
- Efficient material handling for raw materials or Solvents
- Transparent PVC sleeves for clear visibility
- Prevents cross-contamination between ingredients
- Easy-to-clean, smooth, non-porous surfaces
- Lockable access for security and product integrity

- Production Corridor



Production Area features :

- Bubble Airlock:** Prevents cross-contamination between zones.
- Controlled Environment:** Maintains temperature, humidity, and airflow for product integrity.
- Area Classification:** Zones classified by cleanliness (Grade D) per GMP. Zoning for high, medium, and low-risk activities.
- Positive Pressure:** Ensures no contamination from adjacent areas.
- Airflow Systems:** HEPA filters or laminar flow for sterile conditions.
- Safety and Compliance:** Adheres to GMP, FDA, and regulatory standards.
- Continuous Monitoring:** Tracks air quality, pressure, and humidity.
- Cleanability:** Easy-to-clean materials and surfaces for contamination control.

- Manufacturing Vessel



	Make / Model	Capacity
Manufacturing Vessel	Propack	1600 Ltr. (02) +
	575/2205/05-23/O.M.P-1200KG	550 Ltr. (01) + 100 Ltr. (01)
Key Features	<ul style="list-style-type: none">• SCADA System• SS 316 L• Heating & Mixing Capabilities• CIP System• Close loop System	

- Melting Vessel (Wax)



Melting Vessel (Wax)	Make / Model	Capacity
	Propack	1100 Ltr. (02) + 350 Ltr. (01)
	575/2205/05- 23/O.M.P-1200KG	
Key Features	<ul style="list-style-type: none">• SCADA System• SS 316 L• Heating & Mixing Capabilities• CIP System• Close loop System	

- Automatic Tube Filling Machine



Tube Filling Machine	Make / Model	Capacity
	Pacmac Mac240/84-80C	240 TPM (02) + 150 TPM (01)
Key Features	<ul style="list-style-type: none">• High-Speed Filling• Precision Filling• Automatic Tube Handling• Adjustable Fill Volume• Sealing and Crimping• Capping and Closing• Touchscreen Control Panel• No Tube-No Fill Mechanism• SCADA System	

- Auto-Cartonator



Auto-Cartonator	Make / Model	Capacity
	Pacmac	240 TPM (02) +
	Pac240/Pac150	150 TPM (01)

Key Features

- Automatic Carton Erection
- High-Speed Operation
- Adjustable Carton Size
- Automatic Carton Filling
- Accurate Carton Sealing
- Flexible Product Handling
- Integrated Conveyor System
- Minimal Human Intervention
- Error Detection
- SCADA System

- Bundling Machine & Shrink Tunnel



Bundling Machine & Shrink Tunnel	Make / Model	Capacity
	Pacmac XV-35-1 / ST-35H20	240 TPM (02) + 150 TPM (01)

Key Features

- Automatic Bundle Formation
- Customizable Bundle Sizes
- Efficient Packaging
- Adjustable Parameters
- Flexible Product Handling
- Error Detection

- Efficient Shrink Wrapping
- Variable Temperature Control
- Even Heat Distribution
- Automatic Conveyor System

- Lotion Filling Machine



Lotion Filling Machine	Make / Model	Capacity
	Maharshi	50 BPM
	FPC-60	

Key Features

- Precision Filling
- Adjustable Fill Volume
- Semi-Automatic Operation
- High-Speed Filling
- Viscosity Handling
- Piston Filling Mechanisms with 04 Head
- GMP Model

- Automatic Sticker Labelling Machine & Turn Table



**Automatic
Sticker
Labelling
Machine &
Turn Table**

Make / Model

Capacity

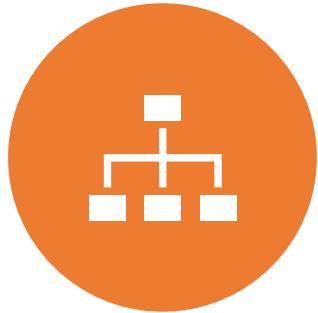
Maharshi

VSC-VLC-D5-R-120

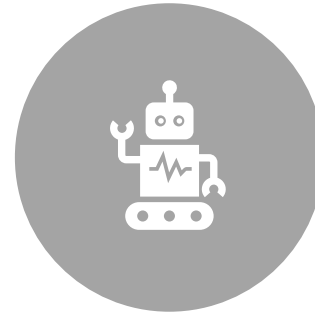
50 BPM / 30"

Key Features

- High-Speed Labeling
- Precision Label Placement
- Automatic Label Feed
- Adjustable Labeling Settings
- Versatility
- Sensing Technology
- Customizable Labeling Heads
- No-Label Detection
- Flexible Labeling Types



Separate and independent Quality Assurance department with well qualified & experienced personnel are engaged to design, maintain and improve the Quality Management Systems (QMS)



QMS includes Documentation control, Validation activities, Change control / Deviation control systems, Market complaint handling, Product Recall system, Vendor Qualifications, Annual Product Quality Review, Risk analysis, CAPA and SOPs for all the Activities and Operations.



Quality systems are based on Drugs & Cosmetics Act/Rules, PICs, Technical Report Series of WHO, 21 CFR Part 210 & 211, ICH Guidelines and MHRA Orange guide.



Qualified personal from QA releases the final finished products to the market.

VALIDATIONS



Company has framed a well organised Validation Master Plan which acts as a guide for carrying out all sorts of validation and qualification activities.

Trained and skilled personnel are involved in validation and qualification studies.

Following systems have been validated / qualified :

HVAC system

Water system

Software

Analytical Methods

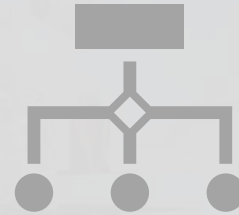
Compressed Air

Manufacturing
Processes

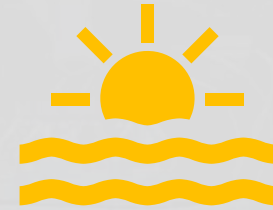
Instruments,
Equipments,
Vendors and QC
analysts.



The Quality Control laboratory ensures product safety and effectiveness through rigorous analysis, following strict specifications and global guidelines.



QC is an independent unit with the necessary instrumentation and skilled personnel to analyze Raw Materials, Packaging Materials, In-process samples, and Finished Products, ensuring online documentation.



QC is equipped with sophisticated instruments, including GC, HPLC, UV-Spectrophotometer, FTIR, Dissolution apparatus with auto-sampling, AAS, Auto-titrator, and other advanced devices.

Quality Control - Photo Gallery



- HPLCs



HPLC	Make / Model	Quantity
	Agilent	10
	1260 INFINITY II / III	

Key Features

- High performance and resolution for accurate analysis
- Stable, reproducible flow with advanced pumping system
- Low dead volume for enhanced sensitivity
- Diode Array Detector (DAD) for UV detection
- Automatic sample injection for high-throughput analysis
- Agilent OpenLab CDS software for data analysis
- Fast, precise analysis for time-sensitive applications
- AIC Central Server: Centralized data management
- 21 CFR Part 11 Compliance: Ensures data integrity and regulatory compliance

- Atomic Absorption Spectroscopy



	Make / Model	Quantity
AAS	Agilent	01
	240FS	

Key Features

- Detects metal elements at trace concentrations
- High sensitivity with graphite furnace atomization
- Suitable for a wide range of metals (e.g., lead, mercury, copper)
- Flexible calibration methods (standard, internal standard)
- Low detection limits for precise analysis
- User-friendly operation and rapid results
- Analyzes liquids, solids, and solutions
- 21 CFR Part 11 Compliance: Ensures data integrity and regulatory compliance

• Dissolution Apparatus



Dissolution Apparatus	Make / Model	Quantity
	Electrolab	5 + 3
	TrustE-8	(With DC sample Collector)

Key Features

- Automated sample collection at set intervals
- Precise control of temperature, agitation, and medium
- High throughput with simultaneous sample testing
- User-friendly interface for easy operation
- Consistent, reproducible results
- Complies with USP and regulatory standards
- Data integration for analysis and reporting
- Minimizes human error for accurate results
- 21 CFR Part 11 Compliance: Ensures data integrity and regulatory compliance

- Gas Chromatography



	Make / Model	Quantity
GC	Agilent	01
	8860	

Key Features

- Analyzes volatile compounds in gases and liquids
- High sensitivity for trace detection
- Versatile detectors (FID, MS, TCD)
- Fast separation and analysis
- Reliable and reproducible results
- Compatible with various columns
- Supports automated, high-throughput analysis
- Accurate compound quantification
- 21 CFR Part 11 Compliance: Ensures data integrity and regulatory compliance

• Stability Chambers



Walk In Stability Chamber	Make / Model	Quantity
	Thermolab	1 (14000 Ltr)
	SG14K0M602/SG8K00M621	+ 2 (8000 Ltr)
Key Features	<ul style="list-style-type: none">• Precise temperature and humidity control• Large capacity for sample testing• Adjustable environmental settings• Uniform conditions throughout the chamber• Compliance with ICH, FDA, and industry standards• Real-time monitoring with data logging• Customizable racks for flexible sample arrangement• Stable, reliable performance• 21 CFR Part 11 Compliance: Ensures data integrity and regulatory compliance	

HVAC SYSTEMS



Air to all the operational areas is supplied through AHUs. Facility is provided with dedicated AHUs for manufacturing facilities and QC.



AHUs are equipped with a pre-filter of 10 microns followed by fine filter of 03 micron and finally through terminal 0.3 μ HEPA filter of 99.997% efficiency.



Processing areas have been designed for a minimum of 60 air changes per hour for sterile and 20 air changes for non-sterile facilities.

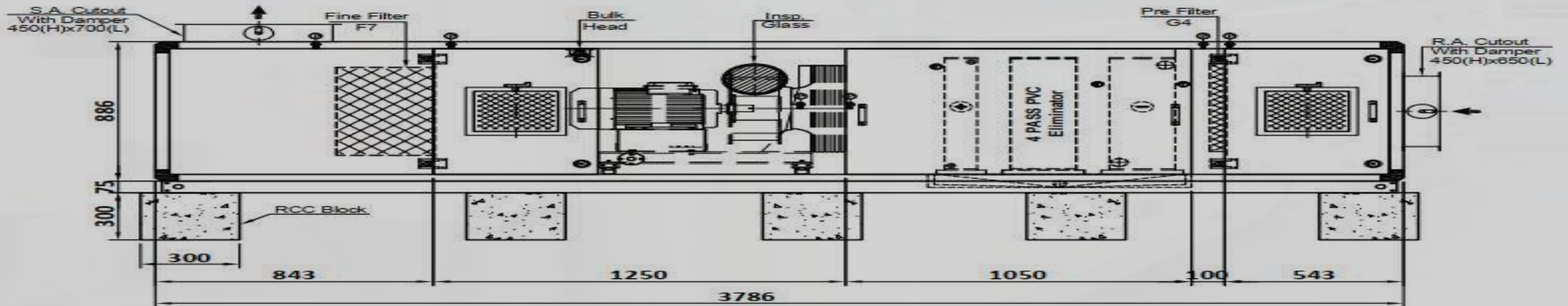
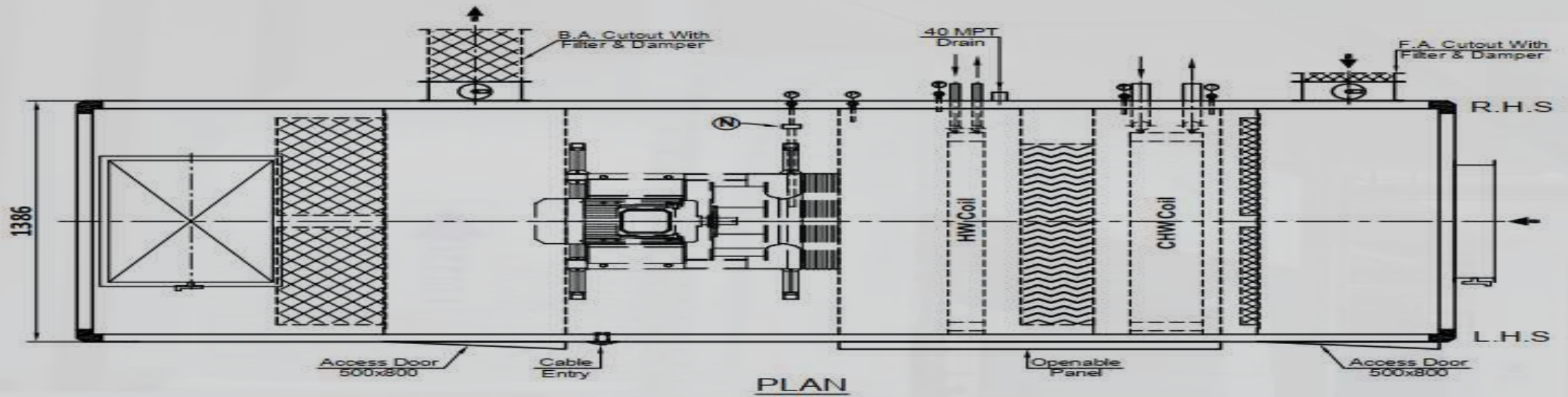


Each operational area has been supplied with a separate AHU with defined ACPH & differential pressure to prevent cross contamination.



Corridor is supplied with separate AHUs. The process areas are maintained at Negative pressure with respect to the Corridor.

AHU Drawing



HVAC System - Photo Gallery





Bore well is the source of raw water. The water is pre-treated and passed through double pass Reverse Osmosis Units (CSRO & HSRO) followed by Electro deionization (by EDI system). Thereby producing purified water meeting IP standard.



The water distribution is done through a closed loop (SS316L) from the Jacketed storage tank (SS316L, capacity-5000 Ltrs.).

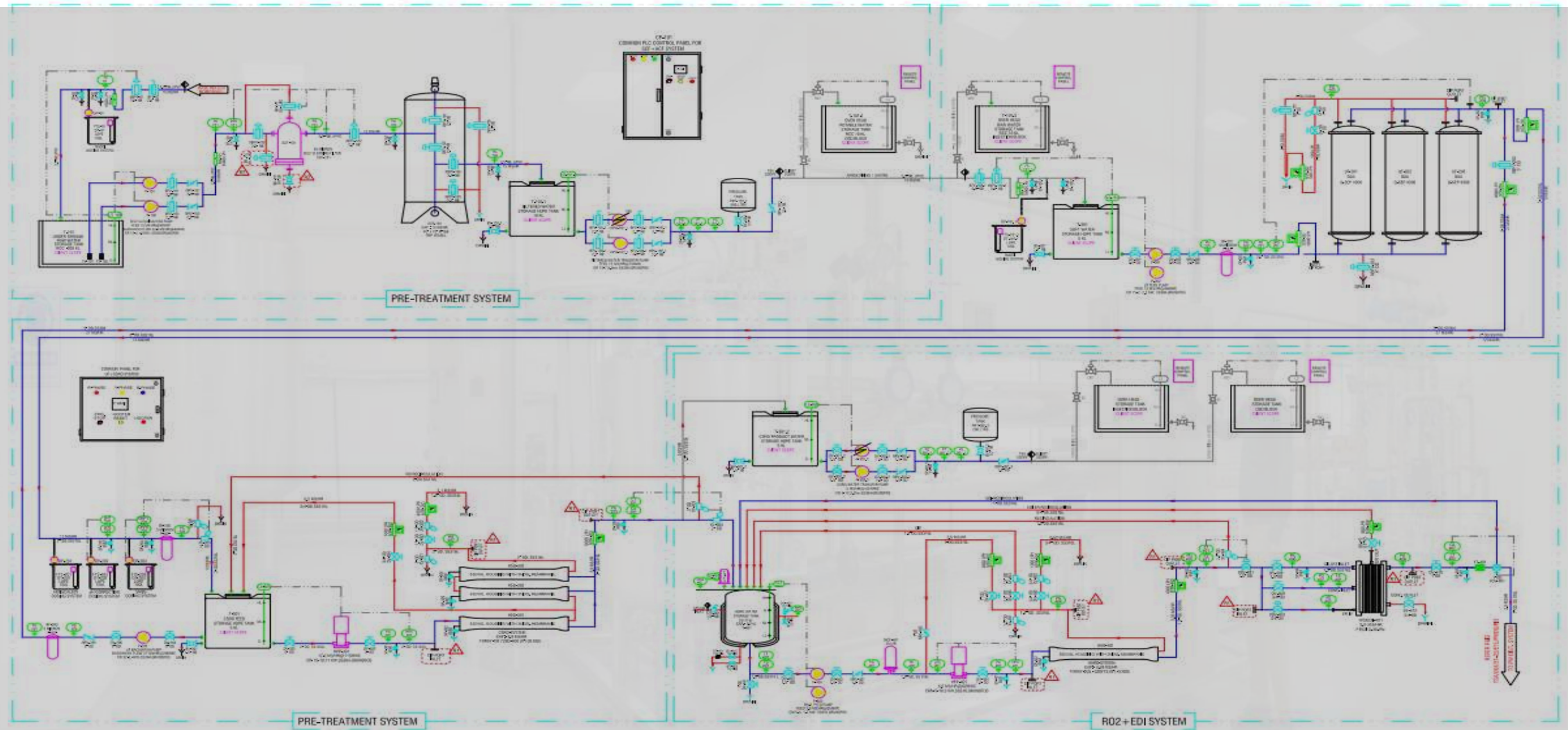


Water system validation is at the verge of end with a complete one-year data (Phase-1, 2 & 3) of microbiological as well as chemical analysis.



Closed distribution loop sanitization is done with hot water at 85°C and 121°C for WFI as per the sanitization procedure.

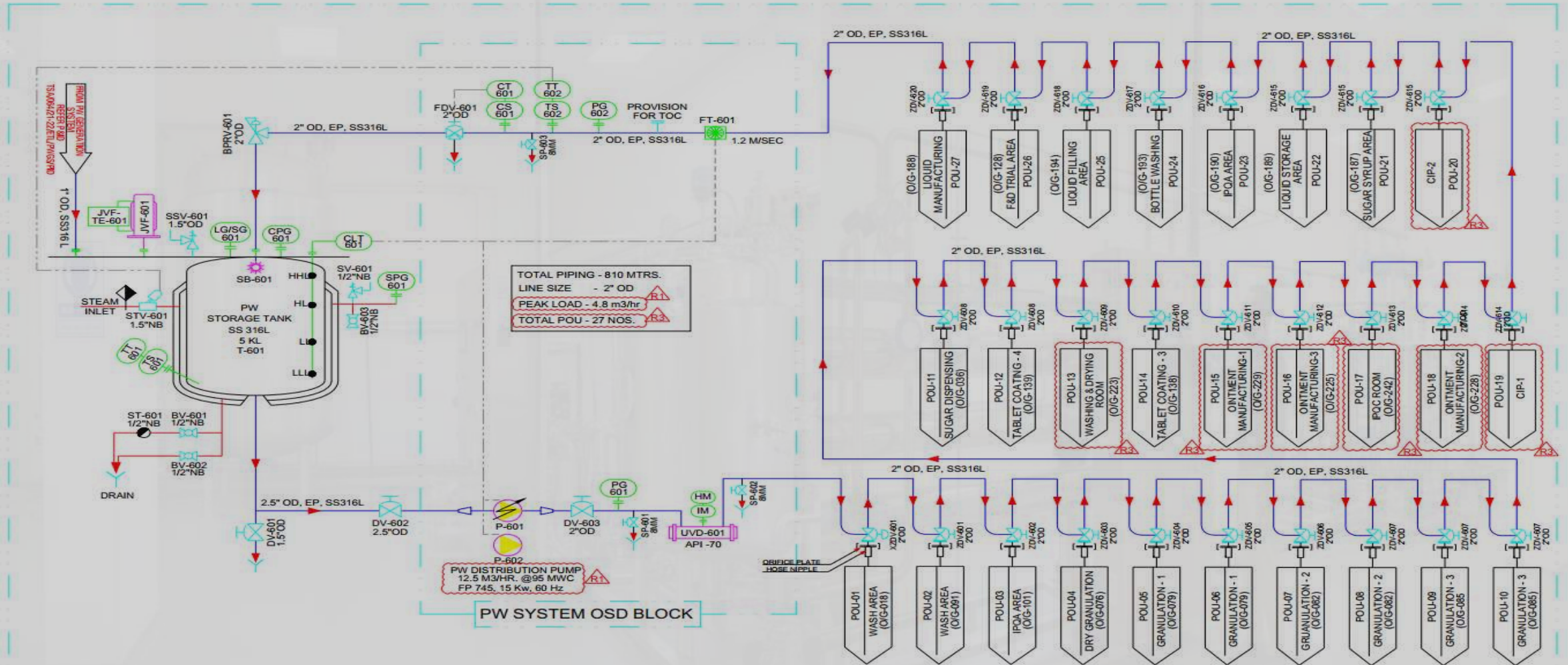
WATER SYSTEM



Purified Water Generation Plant



DISTRIBUTION LOOP



Solar Power Plant-A Step towards Green Energy



Solar Power Plant	Area / Capacity	Percentage of Total Consumption
	100,000 Sq. Feet 1.1 MW (megawatt)	40 %

Key Features

- **Renewable Energy:** Inexhaustible, clean energy source.
- **Sustainability:** No greenhouse gas emissions during operation.
- **Energy Independence:** Reduces reliance on fossil fuels and imports.
- **Low Environmental Impact:** Minimal impact on air quality and water usage.

TRAINING

Eris



Training needs are identified in the beginning of the year based on the activities performed by the personnel and evaluation by the dept. in charge.



Induction Training : The induction training is given to all the newly appointed candidates & recorded.



Classroom Training: Classroom training is given through Training Manuals or discussions on the subject.



On Job Training: To make the training more effective – workers are given on job training at the place of activity.



External training are also organized as and when required.



Training and development are streamlined and enhanced through ATL TMS (Automated Training and Learning Management System) software, empowering organizations to deliver, track, and manage employee learning efficiently.

Key highlights :

- Scalable and effective training solution
- Consistent training delivery
- Flexible learning (anytime, anywhere)
- Improved tracking and compliance
- Enhanced learner engagement
- Time-saving automation
- Data-driven performance insights.

THANK YOU!