

ASOLUTION PHARMACEUTICALS PVT. LTD.

January 2024

Corporate Deck 2024

ROOP GANJU
VP - BUSINESS DEVELOPMENT
EMAIL: ROOP@ASOLUTION.IN





About the Company

- ▶ Regulatory focused cGMP custom development & manufacturing services from gram to commercial scale for specialty molecules, intermediates and APIs.

Our Services



**Synthetic
Development**



**Clinical
Supply**



**Commerical
Manufacturing**

Our Milestones

Timeline





Site Details

- Site address : ASolution Pharmaceuticals Pvt. Ltd., K-3/8, Anand Nagar MIDC, Ambernath (E) – 421506, Thane, Mumbai, INDIA
- Site in Ambernath (E), Well connected by road, rail, sea & air
 - Railway Station : approx. 5 km away
 - Airport : CSIA approx. 60 km away
 - Sea Port : Nhava Sheva approx. 70 km away
 - Head office at Nariman Point, Mumbai : 80 km away
- D-U-N-S Number : 67-548-4557
- FEI : 3013999816
- Total no. of employees : 108
- Shifts Worked : General + 3



Environment, Health & Safety

- Safety Instructions to Visitors.
- All buildings are equipped with
 - Fire smoke detector alarm
 - Water sprinklers
 - Fire hydrant system
 - Fire extinguishers
 - Lightning arrestors
 - Fire exit route.
- ETP with Primary, Secondary, & Tertiary treatment Plant with RO.
- Fire Hydrant Systems are in place

Quality Policy

ASolution Pharmaceuticals Pvt. Ltd. is dedicated to delivering a comprehensive range of products, spanning from small-scale to commercial production, while adhering to worldwide standards for quality, regulatory compliance, and safety.

The leadership team at ASolution assumes responsibility for establishing a robust quality management system. We are committed to structuring the organization, providing effective leadership, continually enhancing the quality system, defining policies, setting objectives and plans, and regularly reviewing the systems to identify opportunities for improvement.

At ASolution, our Quality System is anchored in seven fundamental principles:

(1) Emphasis on Quality, (2) Robust Product Development, (3) Quality Risk Management, (4) Corrective and Preventive Actions (CAPA), (5) Change Control, (6) The Responsibilities of Quality Unit, and (7) The Six-System Model for Regulatory Compliance.

We seek to foster strong partnerships with our suppliers by upholding transparency regarding our expectations and deliverables, and by providing support to ensure the sustainability of a dependable long-term supply chain. Our management team is dedicated to instilling a culture of ownership, trust, and transparency among our employees. This is achieved through continuous knowledge sharing, fostering personal growth, and maintaining a safe and secure working environment.

ASolution's management is committed to building customer delight by maintaining full transparency about our capabilities, project timelines, costs, and quality. Our goal is not only to meet customer expectations but to consistently surpass them.

Above all, ASolution Pharmaceuticals places the utmost importance on safety – safety for the environment, for the health and well-being of our personnel, and, ultimately, for the patients we serve. Our management team is steadfast in creating an organizational environment where this core value is integrated into the decision-making processes of every individual.



Site Plan

Approximate built up area of 70,000 sq.ft. spread over 5 blocks.

Block 1 - 16600 sq. ft. for API manufacturing

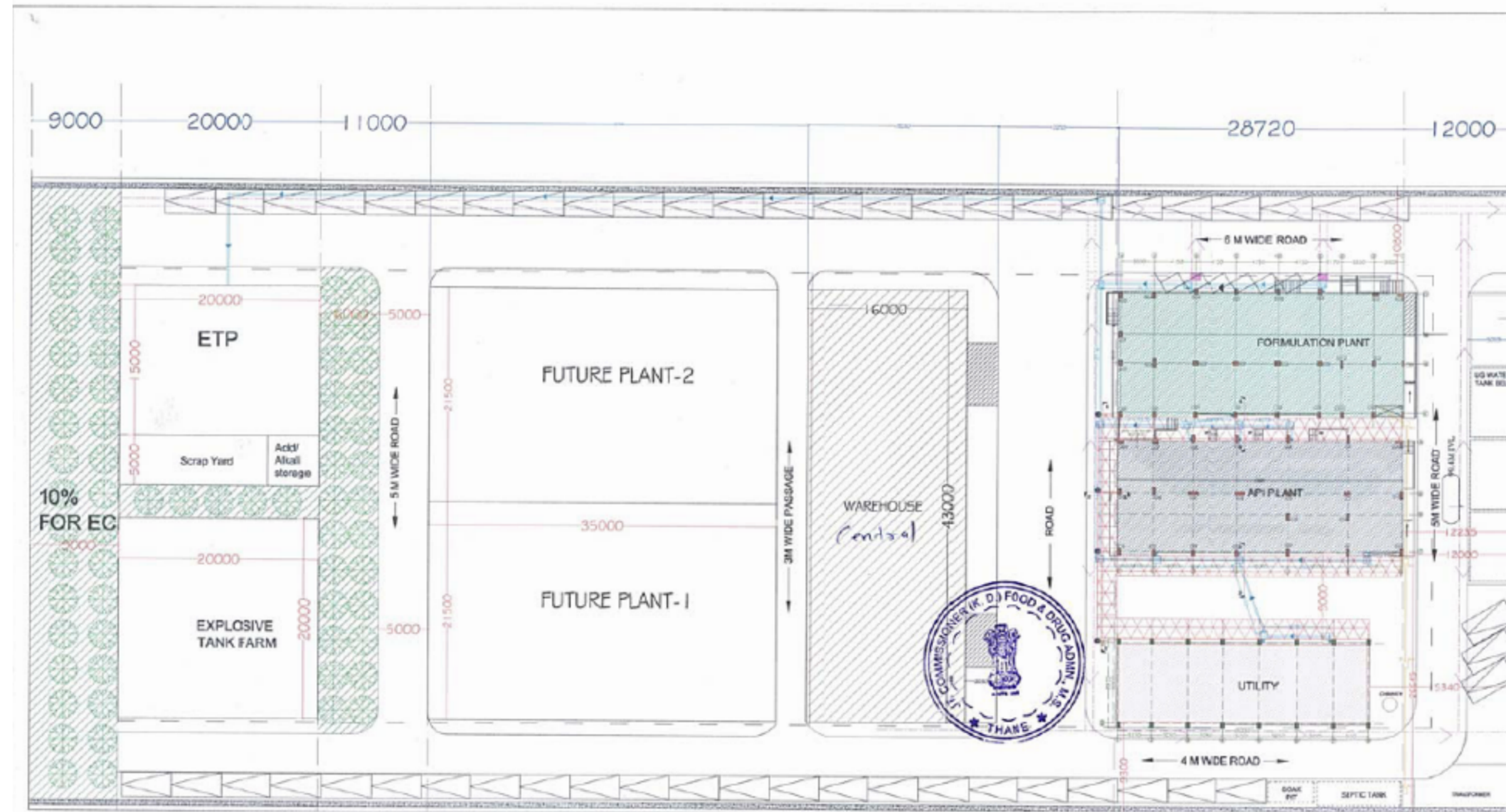
Block 2 - 18000 sq. ft. for Analytical & Administration

Block 3 - 22000 sq. ft. for Warehouse

Block 4 - 4000 sq. ft. for Utility

Block 5 - 10000 sq. ft. for Storage

Total Area - 2.2 Acres



ASOLUTION PHARMACEUTICALS PVT LTD SITE PLAN

Plot plan
1/1

15/04/2024
1/1
Joint Commissioner (Koskan Division,
Food and Drug Administration
(H. S.), Thane

Site Breakup

Approximate built up area of 70,000 sq.ft. spread over 5 blocks.

Block 1 - 16600 sq. ft. for API manufacturing

Block 2 - 18000 sq. ft. for Analytical & Administration

Block 3 - 22000 sq. ft. for Warehouse

Block 4 - 4000 sq. ft. for Utility

Block 5 - 10000 sq. ft. for Storage

Total Area - 2.2 Acres

	Block 1	Block 2	Block 3	Block 4	Block 5
Level	API Manufacturing	QC ; Analytical; Administration	Warehouse	Utility	Storage
Area in Sq. Ft.	16600	18000	22200	4000	10000
Level 4	Process Development Lab	Admin & Training Water purification on Terrace	NA	NA	NA
Level 3	Process Scale up under renovation	Quality Control	NA	NA	NA
Level 2	Manufacturing Mini-pilot plant	FRD (Not in use)	NA	NA	NA
Level 1	Product Isolation	Future Expansion	Stability, Microbiology lab, QA (Mezzanine)	Cooling Tower, Engineering Stores, Pantry	NA
Ground	API Powder Processing Area	Reception & Future Expansion	FP, RM, PM Stores, Sampling, Dispensing	Chilling Plant, Compressor, Boiler, Ejector	Solvent Storage, Acid & Alkali, ETP

Site Inspection History

Name of Authority	Audit Date	Number of Days	Purpose of Audit	Validity	Remarks
PESO	28/12/2017	1	Petroleum & Explosive safety organization license	31/12/2027	Approved
MPCB	07/10/2018	1	Pollution Certification Maharashtra Pollution Control Board	31/10/2024	Approved
Local FDA	31/05/2019	1	License for Manufacturing Products	06/08/2024	Approved
MSME & ISHD	26/12/2019	1	License for Industry1. Ministry of Micro Small & Medium Industries2. Industrial Safety & Health Department	31/12/2027	Approved
CDSCO	15-16/02/2021	2	For Written Confirmation approval	18/06/2023	Applied For Renewal
CDSCO	11-12/10/2021	2	For Renewal of WHO GMP Certification	07/02/2025	Approved
Local FDA	21/02/2023	1	For Regular inspection	12/09/2024	Approved
Ministry of Food & Drug Substances (MFDS)	11-13/ 07/2023	3	Manufacturing Site Inspection for GMP compliance	Valid for three (03) years	Under Approval
United States Food and Drug Administration	06-10/11/2023	5	PAI for Nitrofurantoin Macrocrystals & Monohydrate	NA	Zero 483s. Awaiting EIR

Major Manufacturing Equipment

- Stainless Steel Reactors: 6
- Glass Lined Reactors: 5
- Hastelloy reactors: 2
- Hydrogenators: 2
- Sparkler Filter: 4
- Centrifuge: 6
- Agitated Nuetsche Filter: 1

- Fluid Bed Dryer: 3
- Vacuum Tray Dryer: 1
- Rotocone Vacuum Dryer: 1
- Fritzmill: 1
- Multimill: 2
- Homogenizer: 1
- Sifter: 2

Major Analytical Instruments

- HPLCs : 12
- GCs : 03
- LCMS : 01
- KF Titrator : 01
- UV : 01

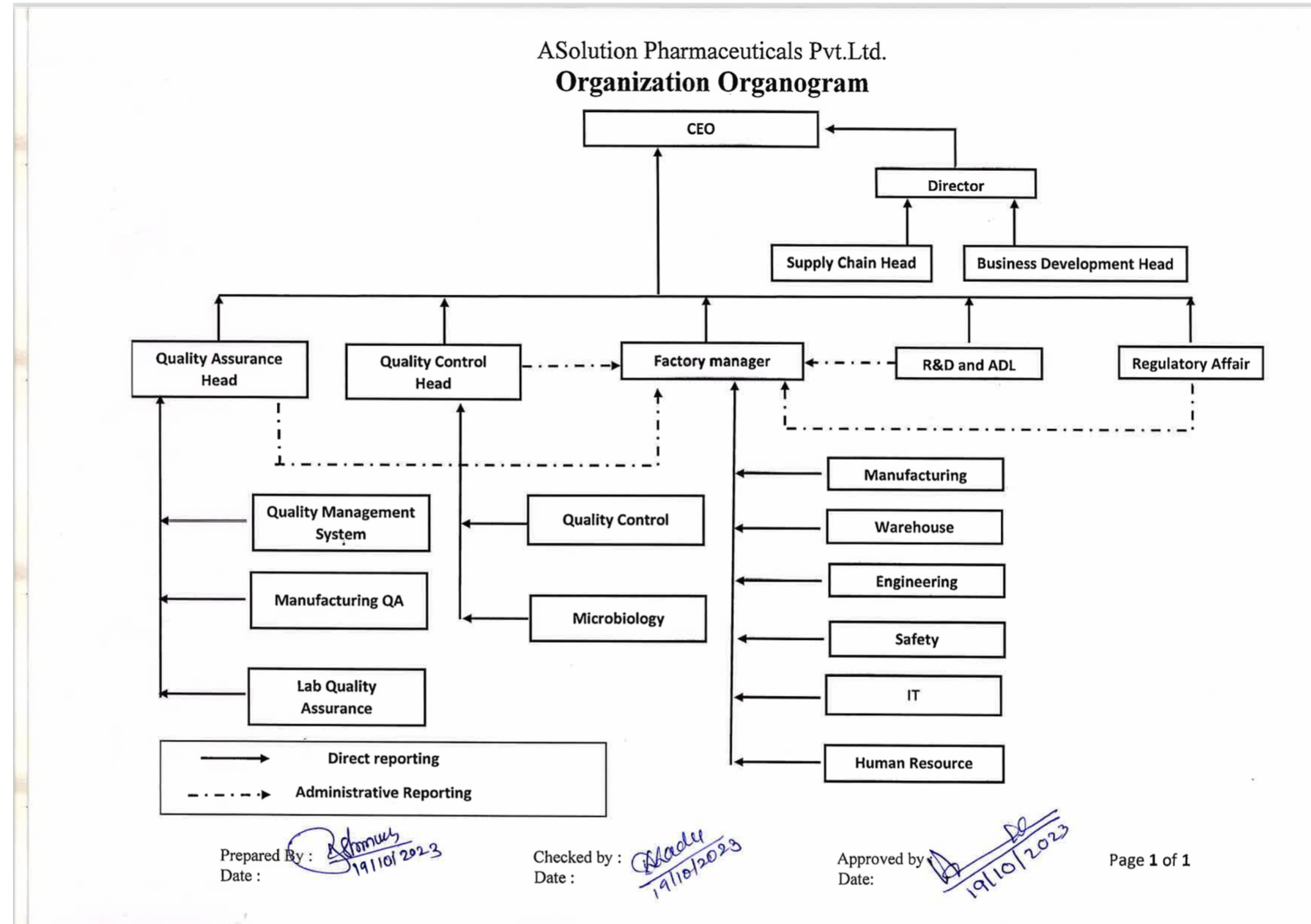
- FT- IR : 01
- Sieve Shaker : 01
- Melting Point Apparatus : 02
- HPLC with CAD : 01
- Alpine Air Jet : 01

Organogram

Quality Unit is independent & reports directly to CEO.

Quality System overarches and drives the

- Production System
- Facilities & Equipment System
- Lab Control System
- Material System
- Packaging & Labelling System



Employees



1 Factory Manager

32 Production

12 R&D & ADL

26 Quality Control

12 Quality Assurance

9 Engineering

3 HR & Administration

6 Warehouse

4 Regulatory Assurance

1 Information Technology

1 Supply Chain

1 Business Development

Key Persons



Dr. Nandkumar Chodankar

Chief Executive Officer



Dr. Laxmi Chodankar

Director



Sandeep Kurkure

Factory Manager



Dr. Ashutosh Dikshit

General Manager - Quality Assurance



Santosh Jagtap

General Manager - Quality Control

Key Products



1 Dexibuprofen

2 Isovanillin

3 Nitrofurantoin Macrocrystals

4 Nitrofurantoin Monohydrate

5 Prilocaine

6 Propofol

7 Sugammadex Sodium

8 Sulfametrole

9 Tolfenamic Acid

10 Trimethylsulfoxonium Chloride

For a complete list of our products kindly connect with us.

Global Customers

We supply our Specialty Molecules, Intermediates and APIs to our customers that are Innovators, Brands, & Generics from all over the globe whose turnover ranges from 1 Million USD to over multiple Billion USD, where the end users cover the following geographic locations

1. North America
2. South America
3. Europe
4. CIS Markets
5. Australia
6. ROW Markets

**Our Client List is
confidential to maintain
the secrecy of our
customers business
strategies.**

**To know more about our
Clients please connect
with us.**



Solving Pharma Challenges



e: roop@asolution.in