ASOLUTION

Solving Pharma Challenges

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Founded in 2010, ASolution is a new facility led by a vastly experienced team focused on providing novel, cost efficient, and regulatory focused CGMP development and manufacturing services for supply of APIs, finished formulations and specialty molecules from early development to commercial manufacturing.

Our commitment to our customers is to solve pharmaceutical challenges, no matter how big or small, with a focus on integrity, responsiveness, and an always on time approach ensuring our value system is infused into every delivery.

We are well connected by road, rail, air and sea and are located about 55 kms from Mumbai Airport and and 70 kms Nhava Sheva Sea Port

About Us

Core Team

Dr. Nandkumar Chodankar
CEO

Dr. Laxmi Chodankar
Promoter Director

Dr. Rajesh Dave
VP – Research & Development

Mr. Sandeep Kurkure
Factory Manager

Value System

We strive to

- Inculcate a culture of ownership, trust and transparency in our people
- Create mutually beneficial and delightful relationships with our suppliers – our backbone
- Build customer delight leading to long term customer loyalty

IN SPEC – ON TIME – EVERY TIME

Quality Management System

- Based on ICH Q7 Guidelines, 21 CFR Part 210 & 211 requirements and Eudralex GMP guidelines
- Documentation structured on ISO 9001 QMS standard

QA involved in all activities

- Selection & approval of vendors of RMs, PMs, Equipment/ Instrument/ System qualification, TT, Validations, Training, Documentations, Manufacturing, Testing, Storage & Distribution activities

- QA has the major responsibility of assuring that the entire operations within the organization meets the regulatory requirements as well as ASolution's internal policies, product manufacturing policy and where applicable the customer's specific requirements detailed in Quality / Technical agreement.

- QA is INDEPENDENT and reports only to CEO

QRM (ICH Q9)

- QRM processes used with the aim of detecting and assessing risk relating to the safety, effectiveness and quality of the medicinal products over their complete lifecycle

- QRM process is applied to the supply chain processes in order to guarantee the appropriate and continuous provision of approved medicinal products from ASolution

Site Layout – 70,000 Sq. Ft.

Floor	Block 1 – DP Development	Block 2 – DS Development & Manufacturing	Block 3 – Utility	Block 4 – Warehouse & DP Manufacturing	Block 5 - Storage
Area Sq. Ft.	18,000	16,600	4,000	22,200	10,000
4th	Administration & Training	Process Development Lab	NA	NA	NA
3rd	Analytical Lab	Analytical & Kg Lab	NA	Drug Product Manufacturing Phase 2	NA
2nd	Drug Product Development & Clinical Supply	Mini Pilot Plant & Manufacturing	NA	Drug Product Manufacturing	NA
1st	Under Development	Product Isolation	Cooling Tower, Engineering Stores, Pantry	Stability, Microlab, Packaging	NA
Gr	Reception & Under Development	API Powder Processing	Chilling Plant, Compressor, Boiler, Ejector	RM Stores, Sampling, Dispensing + QA & Document Store	Solvent Storage, Scrap Yard, Acid & Alkali, ETP

Services

Synthetic Chemistry

CUSTOM SYNTHESIS SERVICES

- Medicinal Chemistry
- Multistep Synthesis
- Early Stage SMs & KSMs
- Intermediates
- Polymorphs
- Crystal size shape and distribution
- Impurities
- Metabolites
- Degragants
- Optical-isomers
- Polymorphs
- Particle size distribution
- Reference Standards
- Working Standards

CHEMISTRY STRENGTHS

- Alkylation
- Amidation
- Buchwald Reaction
- Chiral Separation
- Chiral Synthesis/ Resolution
- Condensation
- Coupling Reaction
- Dehydrogenation
- Reduction
- Sandmeyer Reaction
- Wittig Reaction
- Grignard
- Heck Coupling
- Suzuki Coupling
- Hydrogenation
- Oxidation
- Heterocyclic Ring Formation
- Oxidation
- Esterification
- Formylation
- Fidel Craft Acylation & Alkylation

Analytical Development

CORE CAPABILITIES

- Analytical Method Development & Validation
- Method Transfer
- Process Development, Optimization & Validation
- Stability-indicating methods
- Gas and liquid chromatography, including HPLC, UPLC, GC/MS and LC/MS/MS
- UV-Vis and IR spectroscopy
- Wet chemistry

ANALYTICAL EQUIPMENT

- Spectrophotometers – UV/ Visible & FTIR
- HPLCs – PDA, UV & IR
- UPLCs
- HUPLC with Carona Charged Detector
- GCs with auto samplers
- LCMS
- KF Titrators
- Polarimeter
- Dissolution Testing System
- Analytical Balances
- Walk in & Reach in Chambers for Stability Testing

STABILITY STORAGE

CHAMBER	CAPACITY
25°C/60% RH	8000
40°C /75% RH	1000
30°C /65% RH	1000
30°C /75% RH	1000
2-8°C	1000
PHOTOSTABILITY	227

Formulation Development

CORE DEVELOPMENT SERVICES

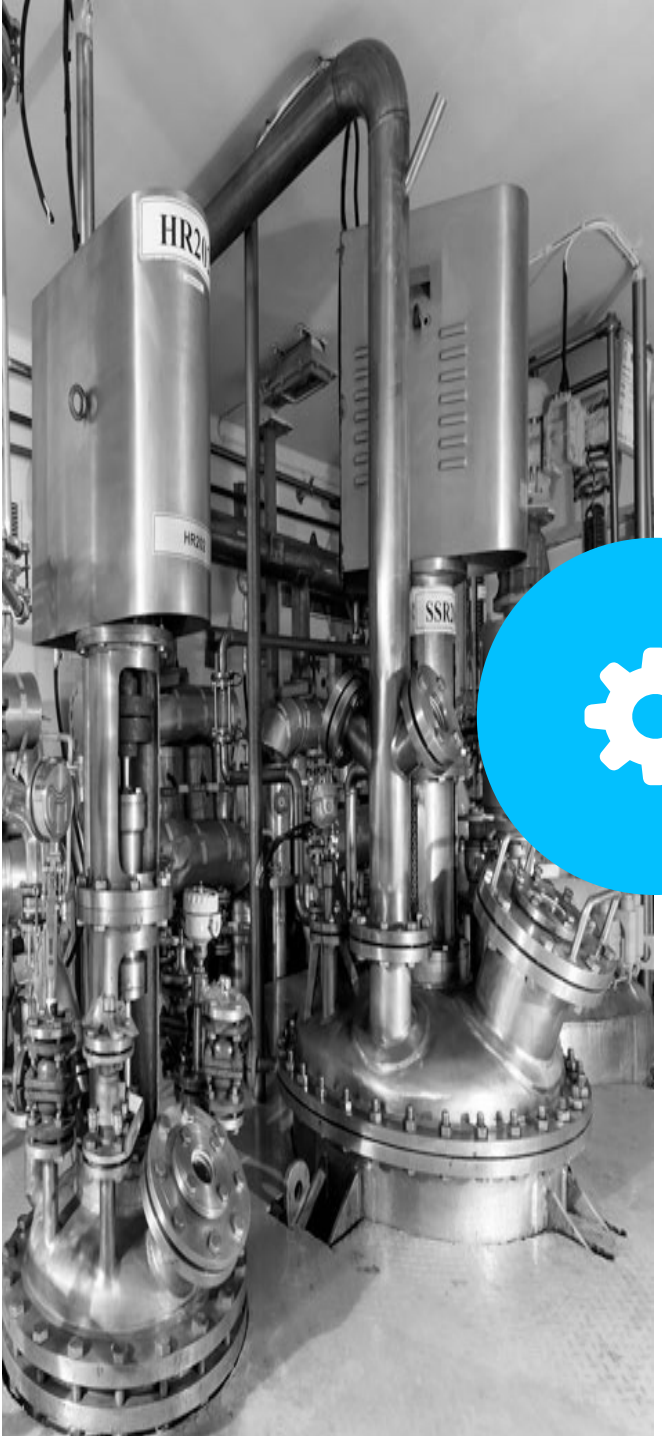
- Sourcing of Raw & Packaging Materials
- Pre-formulation Studies
- API & Excipient Compatibility Studies
- Structural Stability Studies
- Development for Pre-clinical and Clinical Studies
- Development for Dossier Application
- Scale up & Pilot Batch Manufacturing
- Tech Transfer to External Site
- Compilation of Regulatory Documents

DRUG DELIVERY SYSTEMS

- Oral IR & SR
- Topical
- Suspensions
- Ophthalmic
- Suppositories
- Pessaries
- Transdermal Sprays
- Metered Dose Inhalers
- Injectable

EQUIPMENT

- Autocoaters
- Blister Packing Machines
- Capsule Filling Machines
- Compressions Machines
- FBD & FBP
- Rapid Mixer Granulators
- Spheronizers



Clinical Supply

CORE DEVELOPMENT SERVICES

At ASolution, our capabilities offer you full API development and CGMP scale up services for clinical supply material. Our cGMP development facility supports quantities for Phase I studies and our cGMP mini pilot plant and cGMP pilot plant ensure quantities for Phase II and Phase III trials. So no matter what stage you are at ASolution is there for your needs.

Regulatory requirements, Documentation, Quality Systems are ingrained right from the pre clinical stage and all our process are tailor made to suit your needs.

EQUIPMENT FOR API

- Reactors – Glass Lined, Stainless Steel, Hastelloy
- Stainless Steel Hydrogenator
- Receivers – Stainless Steel, Glass Lined
- Filters – Halar Coated
- Dryers – RCVD, FBD,

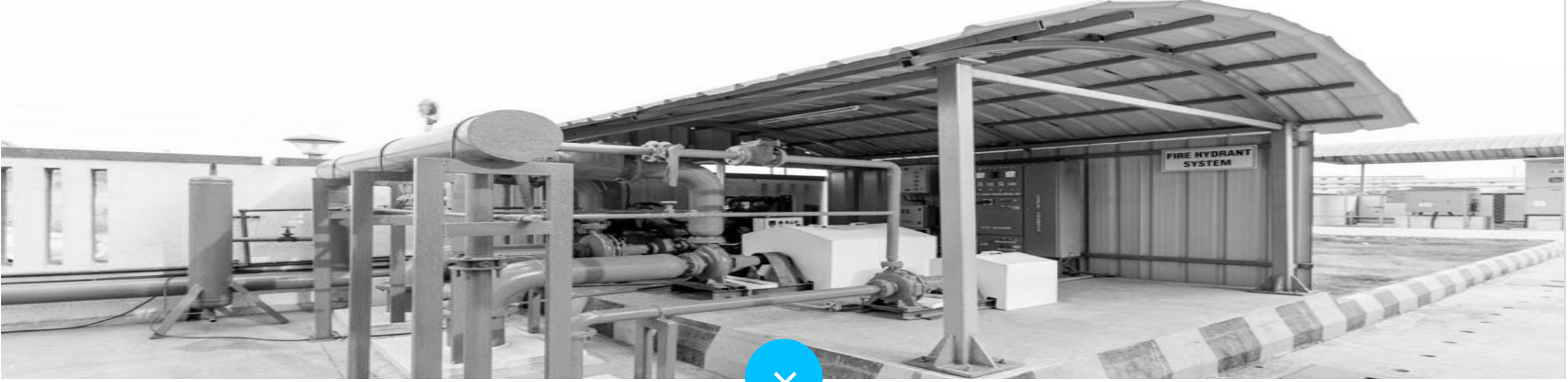
API Manufacturing

CORE DEVELOPMENT SERVICES

- Strict cGMP compliance standards (ICH guidelines)
- Domestic FDA inspected & approved
- WHO Approval en-route
- Multi Purpose Plant
- 15,000 Sqft. Facility
- Low Temperature, High Temperature, High Pressure Reactions (-10C to 160C, 15kg)
- Batch Sizes – 20L to 1600L (15000L Combined Vol.)

EQUIPMENT

- Reactors – Glass Lined, Stainless Steel & Hastelloy
- Hydrogenators
- Filters – Halar Coated, Stainless Steel, Agitated Nutsche, Sparklers
- Dryers – Fluid Bed, Rotovac & Vacuum Tray
- Powder Processing – Multi Mill, Jet Mill, Sifter & Homogenizer
- CGMP Kg Scale Mini Pilot Plant
- Hydrogenators
- Halar Coated Centrifuge



EHS

- En-route for ISO 14000 & ISO 18000
- All buildings equipped with Fire smoke detector alarm, Water sprinklers, Fire hydrant system, Fire extinguishers and Lightening arrestors.
- OSH Room & Safety apparel for staff
- Gas evaluation reactor vents connected to Scrubbers
- Pressure reactors with safety valves and rupture disc
- ETP with Primary, Secondary, & Tertiary treatment Plant
- Disaster Management plan, HAZOP study of processes, Risk Assessment (QRA) developed
- Mock drills, Fire fighting Team, evacuation Team, Safety Committee are in place

Credentials

- Systems are based on ICH Q7, Q8, Q9, Q11 & ISPE Guidelines
- ASolution is WHO GMP inspected and approved.
- Approved for the Manufacture of APIs by the Domestic Authorities. (# MH/ 101056)
- All Licenses have been obtained (Approved by Factory Inspector, Pollution control Board, Environmental Clearance Board, Fire department, etc.)
- The facility has been visited by number of customers and have approved for the design, cleanliness & the implemented GMP systems
- International third party GMP Certification Audit is planned in 2018.
- Implementation of ISO 9000, 14000, 18000

QMS

Thank you

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