Ami Lifesciences
Driven by Chemistry. Powered by people.

A Pure Play Specialty API Company

81	60	26	14	15	4	2
APIs	DMFs	USDMFs	CEPs	KMFDS	CADIFA	PMDA

Certification

WHO cGMP Certificate

ISOQAR REGISTERED UKAS MANAGEMENT SYSTEMS 0026

Cofepris Comisión Federal para la Protección contra Riesgos Sanitarios

edqm

KFDA

DSIR Department of Scientific and Industrial Research

Agenzia Italiana del Farmaco AIFA

JK KOSHER

HALAL INDIA حلال INDIA

URS UNITED REGISTRAR OF SYSTEMS

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Leadership

Meet Our CMD

Home » Leadership » Meet Our CMD

Greetings from Ami Lifesciences !

Germany rose from the ashes of World War II to become a wealthy and powerful modern nation not because it had access to abundant resources, but because it had a highly advanced fine chemistry sector.

The fine chemistry sector is a source of immense added value and a sector we need to foster and nurture in the 21st century if we are to elevate our nation's status to that of an advanced one.

Manufacturing of active pharmaceutical ingredients, in particular, is a fine chemistry industry requiring endless research and constant advancements in technology and simultaneously promises a huge potential for future growth and value.

Here at Ami Lifesciences, each and every one of us is dedicated to researching and developing innovative technologies that will enable us to deliver products of the highest quality possible in the quickest timeframe possible in order to survive and thrive in today's open and globalized market environment.

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Two of our first tasks following the founding of the company were to establish a Central Research Center and to institute a system for selective adoption of advanced technologies from abroad. We have since then been making concerted and enterprise-wide efforts to develop new technologies and products of great economic value.

Efficient manufacturing of active pharmaceutical ingredients through the use of biotechnology, the very future of fine chemistry, is also a key pursuit of Ami Lifesciences.

Ami Lifesciences contributes to national health promotion, through providing with active pharmaceutical ingredients as well as finished products.

As a leader in the manufacturing of pharmaceutical ingredients and a pioneer in fine chemistry, Ami Lifesciences pledges to continue to grow as a corporation of the people and the world and to remain committed to improving the health and the welfare of humankind and to protecting the environment.

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Manufacturing Production

Production Capabilities

Coupled with the synthesis of process intermediates and GMP raw materials, we also offer cGMP manufacturing of your API in small scale and in production scale. Ami Lifesciences handles small-scale API production critical for discovery and development, GMP scale and manufacturing at our facility. We handle your cGMP manufacturing needs seamlessly from grams to metric tons - and through all phases of clinical trials - without the need for technology transfer to another company. Whether you require the preparation of API for toxicological studies, Phase I-III clinical trials or commercial supplies, we leverage the expertise and technology to make your project a success.

Ami Lifesciences has the infrastructure to perform scale-up. Our kilo-scale laboratories are equipped for the preparation of cGMP starting materials and other process intermediates on a scale from hundreds of grams to tens of kilograms.

Our capabilities include:

- 10 production blocks with 11 clean room area covering 1500 metric tons of production capacity.
- 136 reactors and total reactor volume of around 650 KL.
- 100 litres to 16MT glass lined and SS reactors with fully integrated manufacturing plant
- Capability of handling high pressure and complex organic reactions
- Facility have been inspected by EDQM, Cofepris (Mexico).
- The site is under USFDA approval.
- Site is also WHO GMP approved and ISO 9001:2000 certified.
- The flow of materials and personnel through the facility is designed to prevent mix-ups or contamination.

Regardless of scale or complexity, we have the expertise, capacity, and capabilities to rapidly meet custom synthesis needs. From milligram quantities of a metabolite to several kilograms of a scaffold, we tailor our services to suit the needs, applying a chemical or bio catalysis approaches depending on the complexity of your molecule. For the quickest turnaround, including the synthesis of reference standards, impurity markers and scaffolds, we offer a rapid scale-up facility. Our world-class facilities are equipped with the latest in process and analytical instrumentation and offer cost-competitive solutions for project.

QC Lab Instrument Details:

For Quality Control, we have various equipment as follows:

- Chromatography: HPLC, UPLC, GC, GC Headspace
- Spectroscopy: FT-IR, UV-Vis, ICP-MS, Microwave digestion
- Particle Size Distribution: Malvern Mastersizer, Microscopy, Bulk Density and Tap Density Tester
- Wet chemistry and Pharmacopeial analysis: Cooling Cabinet, Karl Fischer Titrator, Auto Titrator, pH Meter, Turbidity Meter, Halogen Moisture, Melting Point Analyser, Colony Counter, Autoclave, Incubator, Fogger Machine, Anaerobic Culture Jar, Bio-safety Cabinet, Conductivity Analyser, Air Sampler
- Other Systems:
  Mass Detector, Polarimeter, Muffle Furnace, Milli-Q Water Purification, Vacuum Oven, LOD Oven, Glassware Oven, Conductivity and TDS Meter, Ultrasonic Bath, Stability Chambers, Air Sampler

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Quality and Regulatory Expertise

We deliver quality in every aspect of our work, across all of our facilities, systems, and teams. Whether we're in the early stages of development or the final manufacturing process, we ensure that everything we do is to an exceptionally high standard. Our dedicated team are passionate about ensuring quality in all parts of the process, delivering a high-quality product every time.

Our products are specifically manufactured to meet strict cGMP standards, and our facilities are audited by agencies worldwide - all helping to ensure a high level of regulatory excellence. What's more, we have a team of regulatory affairs experts on board that are actively involved in maintaining good manufacturing requirements.

We have received regulatory accreditations as follows:

- European Directorate for the Quality of Medicines and Healthcare
- Pharmaceuticals and Medical Devices Agency (PMDA, Japan)
- National Medical Products Administration (Formely China FDA)
- Ministry of Food and Drug Safety, Korea (Formely Korea FDA)
- Federal Commision for the Protection against Sanitary Risk (COFEPRIS, Mexico)
- WHO cGMP
- ISO 9001-2015

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Research and New Technology Development Centre

Reaction Capabilities

Ami Lifesciences has vast experience with reactions from the following classes including scale-up of those reactions to commercial quantities:

- Acetal Formation
- Acylation
- Addition Reaction
- Aldol Condensation
- Alkylation
- Arylation
- Beckmann Rearrangement
- Biginelli Reaction
- Clark-Eschweiler Reductive alkylation
- Condensation
- Curtius Rearrangement
- Cyclization
- Darzens Glycidic Ester Condensation
- De-Alkylation Cleavage
- Decarboxylation
- Dehydration
- Esterification / Trans-esterification
- Formylation
- Friedel - Craft Reaction
- Halogenation (Br2, Cl2, I2, ICl, SOCl2, PCl5, PCl3, KF etc.)
- Knoevenagel Condensation
- Leuckart Wallach Reaction
- Oxidation (KmNO4, CrO3, HNO3, O2, H2O2)
- Perkin Reaction
- Pinner Synthesis
- Reduction (H2/Pd, Ni, Pt, NaBH4, Zn, Vitride, Sodium)
- Sandmeyer Reaction
- Sarett Oxidation
- Schiff Base Reaction

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Research and New Technology Development Centre

Analytical Development Lab Services:

Our analytical departments support the entire product life cycle of active pharmaceutical ingredients with scientific expertise and an extensive technical portfolio. Our core competencies are:

- Development of analytical methods
- Optimization of existing analytical methods to optimize robustness or efficiency
- Validation, verification, and transfers of analytical methods
- Development-accompanying analyses
- Release analyses of key starting materials, active pharmaceutical ingredients, and intermediates
- Production-accompanying in-process controls
- Cleaning validations
- Creation of Purity Profiles / Impurity Tracking; Determination of genotoxic impurities
- Risk considerations and control strategies for elemental impurities for APIs according to ICH Q3D
- Qualification of reference standards
- Development of specifications
- Carrying out stability studies:
- Stability studies of active pharmaceutical ingredients according to ICH guidelines in certified and controlled climate chambers
- Stress tests/forced degradation studies including photostability studies

Sophisticated testing laboratory instruments:

- Chromatography: HPLC, UPLC, GC, GC Headspace
- Spectroscopy: FT-IR, UV-Vis, XRD, LC-MS, GC-MS, ICP-MS, Microwave digestion
- Particle Size Distribution: Malvern Mastersizer, Microscopy, Bulk Density and Tap Density Tester
- Wet chemistry and Pharmacopeial analysis: Cooling Cabinet, Karl Fischer Titrator, Auto Titrator, pH Meter, Turbidity Meter, Halogen Moisture, Melting Point Analyser, Colony Counter, Autoclave, Incubator, Fogger Machine, Anaerobic Culture Jar, Bio-safety Cabinet
- Other Systems: Mass Detector, Polarimeter, Muffle Furnace, Milli-Q Water Purification, Vacuum Oven, LOD Oven, Glassware Oven, Conductivity and TDS Meter, Ultrasonic Bath, Stability Chambers, Air SamplerM

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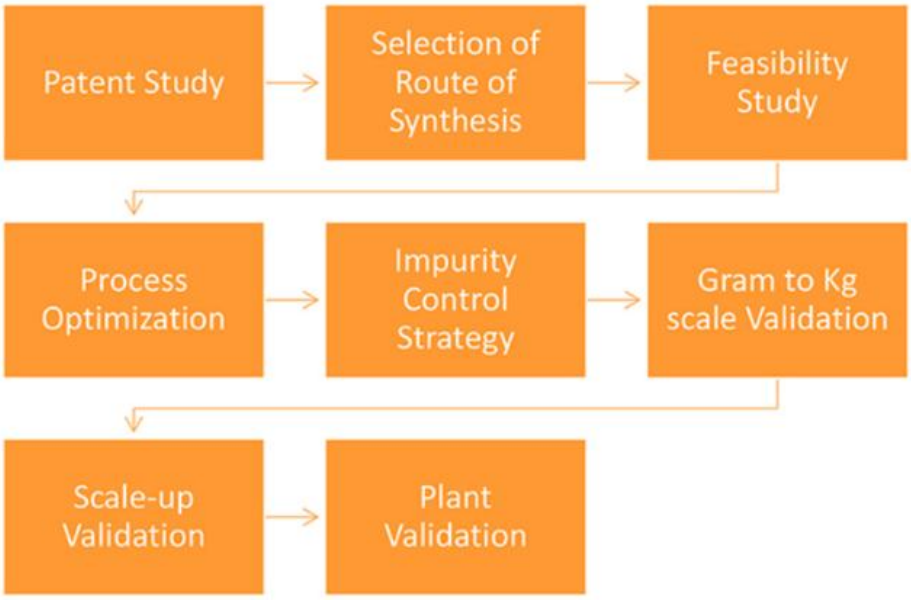
CMO/CDMO for Exclusive Synthesis

As a contract development and manufacturing organization (CDMO) partner with locations in India and International, we offer services for API development and Commercial Manufacturing to the Innovators and Formulators:

R&D

- Our expert team can develop and validate complex APIs.
- We have new R & D center having 60 fume hoods for development of complex APIs.
- We have excellent supporting analytical laboratory having sophisticated equipment like HPLC, GC, LC-MS, GC-MS, XRD etc.
- We can scale up from grams to kgs to tons.



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ESG Sustainable Initiatives

5.0%

GHG Emission Reduction

Environment

Total CO2 reduction compared to baseline year April 2022 - March 2023.

2.7%

Renewable Electrical Energy Used

Environment

Green Energy used against Total Electrical Energy Consumption for the year April 2023 - March 2024.

23.2%

Water Recycle

Environment

Recycle water used for production against total water consumption for the year April 2023 - March 2024.

40%

Sustainable Sourcing

Recycling & Reuse Solvents to prevent resource depletion against total consumption for the year April 2023 - March 2024.

0%

Accident & Incident

Social Governance

Loss Time Injury, 0 Fatal Accident for the year April 2023 - March 2024.

ISO 27001
SA8000

Certified

Social Accountability

Ethical Governance Site certified with ISO 27001 & SA8000 for the year April 2023 - March 2024.

100%

Value Chain

Governance

Supplier evaluated for environment social & governance before issuing work order for the year April 2023 - March 2024.

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