



Ami Lifesciences

Driven by Chemistry. Powered by people.

Our Purpose

We improve people's lives by redefining how medicines and health products are delivered.

Ami Lifesciences was founded with the goal of changing the way in which quality medicines are delivered to people in need. We operate on the principle by extending our focus and services to maximize our impact on the global pharmaceutical industry

We have spent last two decades in building up our scientific and technological capabilities, research, and manufacturing competencies. Along the way we have earned a reputation for being innovative, inventive and resourceful. We have built long term business association pharmaceutical companies of the world.



To this end we have spent the past two decades in building up our scientific and technological capabilities, research, and manufacturing competencies.

Along the way we have earned a reputation for being innovative, inventive and resourceful. We have also built longstanding and deep P2P relationships with leading pharmaceutical companies of the world.

We are **Ami Lifesciences**.

We believe health is a healthy business.

Manufacturing Facility

A First look at our manufacturing facilities.

Ami Lifesciences API plant is located at Karakhadi, Vadodara, a city around 450 kms away from the financial capital of India – Mumbai. It is easily accessible by Air, Road, and Rail. The manufacturing unit has a total land area of 26,000 sq. meters and manufacturing capacity of 200 M3. The Facility is fully licensed as per the Indian factory Act and it is Compliant with and approved by EU-GMP, WHO GMP, ISOQAR, KFDA, PMDA, TFDA, COFEPRIS, IRAN MOH, etc.

The Plant has clean Rooms for API and has infrastructure and equipment's for a large spectrum of reactions. The plant also has a separate Microbiological Laboratory Microbiological Laboratory for carrying out Bacterial, Fungal and Pathogen tests.



Our Laboratory is made up of properly Coved Epoxy Flooring, with HVAC systems and Dynamic Pass Box for the movement of samples and media. The walls are painted with the Antifungal paints and are periodically fumigated to ensure the sterile environment.

Our R&D Labs engage more than 45 experienced chemists and scientists and is well equipped with Modern Fume Hood Systems, Auto Claves, High Vacuum Distillation Assembly, Large flasks and Glass reactor assembly from 250 ml to 10 liters volume and Vacuum Tray Dryers.

The different kinds of reactions we can handle

- > Acetal Formation
- > Addition Reaction
- > Condensation
- > Esterification / Trans-esterification
- > Halogenation (Br₂, Cl₂, I₂, ICl, SOCl₂, PCl₅, PCl₃, KF ETC.)
- > Friedel – Craft Reaction
- > Knoevenagel Condensation
- > Biginelli Reaction
- > Clark-Eschweiler Reductive alkylation
- > Schiff Base Reaction
- > Arylation
- > Alkylation
- > Decarboxylation
- > Formylation
- > Oxidation (KMNO₄, CrO₃, HNO₃, O₂, H₂O₂)
- > Sandmeyer Reaction
- > Beckmann Rearrangement
- > Leuckart Wallach Reaction
- > Sarett Oxidation
- > Pinner Synthesis
- > Acylation
- > De-Alkylation Cleavage
- > Dehydration
- > Cyclization
- > Reduction (H₂, Pd, Ni, Pt, NABH₄, ZN, VITRIDE, SODIUM)
- > Perkin Reaction
- > Curtius Rearrangement
- > Darzens Glycidic Ester Condensation
- > Friedel-Crafts Reaction
- > Aldol Condensation

Quality Assurance

Committed to conforming to National and Global Regulations on Quality.

At Ami Lifesciences, we have the requisite infrastructure and expertise to ensure proper regulatory approvals of our clients and competent authorities such as EUGMP, TGA, KFDA, UKMHRA, EDM, ANVISA, COFEPRIS etc.

Our QA department ensures that every activity associated with the design, development, and manufacturing (Purchase, Warehousing, Production, Quality Control, Release and Distribution) of Active Pharma Ingredients and intermediates are carried out in a systematic and approved manner in compliance with the regulatory and cGMP requirements.



Highlights of Our Q&AA and Regulatory Systems

- > Implementation of Standard Operating Procedures (SOPs) and periodic review
- > Instrument and Equipment Qualifications
- > Process Validation and Method Validation
- > In process controls
- > Technology Transfer
- > Documentation Control
- > Audit of manufacturing facilities and auditing suppliers of the critical raw materials
- > Handling deviations, customer complaints, implementation of the corrective and preventive actions.
- > Capability to develop and file CTD DMF, US DMFs, CEP and other registrations required in the various markets.

Commercial Product List



Sr. No.	Pharmacological System	Product Name	Therapeutic Category	Filed					Under Filing
				DMF	CEP	WC	CFDA/KFDA	COFEPRIS	
01	Respiratory System	Ambroxol Hcl	Mucolytic Expectorant	DMF	CEP	WC	CFDA	COFEPRIS	KFDA
02		Acebrophylline	Anti-Asthmatic / Bronchodilator	DMF		WC	CFDA		
03		Doxofylline	Anti-Asthmatic / Bronchodilator	DMF		WC	CFDA	KFDA	
04		Benzonatate	Anti-Tussive	DMF					
05		Levopiperastine Fendizoate	Anti-Tussive	DMF					
06	Cardiovascular System	Azilsartan Medoxomil K Salt	Anti-Hypertensive	DMF		WC		CFDA	KFDA
07		Fimasartan	Anti-Hypertensive	DMF				CFDA	
08		Sacubitril Valsartan	Anti-Hypertensive	DMF					
09		Choline Fenofibrate	Lipid Lowering Agent	DMF		WC	KFDA	CFDA	CFDA
10		Olmesartan	Anti-Hypertensive	DMF					DMF
11	Gastrointestinal System	Rutoside Trihydrate	Capillary Stabilizing Agent	DMF		WC			
12		Ilopride HCL	Nonulcer Dyspepsia	DMF		WC	CFDA	CFDA	KFDA
13		Vonoprazan Fumarate	Anti-Ulcer	DMF					
14	Nervous System	Betahistine Di HCL	Anti-Vertigo	DMF	CEP	WC	CFDA		
15		Desvenlafaxine Succinate	Anti-Depressant	DMF		WC		CFDA	KFDA
16		Eslicarbazepine Acetate	Anti-Epileptic	DMF		WC			CFDA
17		Oxcarbazepine	Anti-Epileptic	DMF					CEP
18		Tapentadol HCL	Analgesic	DMF		WC			CEP
19		Brivaracetam	Anti-Epileptic	DMF					CEP
20	Venlafaxine HCL	Anti-Depressant	DMF					CEP	
21	Genitourinary System	Flavoxate HCL	Anti-Muscarinics	DMF		WC			
22		Pamabrom	Diuretic	DMF		WC			KFDA
23		Tadalafil	Erectile Dysfunction	DMF	CEP	WC		CFDA	CFDA
24	Nephrology	Dapoxetine HCL	Premature Ejaculation	DMF		WC			CFDA
25		Sevelamer Carbonate	Anti-Hyperphosphatemic	DMF		WC		CFDA	CFDA
26	Musculoskeletal System	Sevelamer HCL	Anti-Hyperphosphatemic	DMF		WC		CFDA	CFDA
27		Diacerein	Anti-Rheumatic	DMF	CEP	WC	KFDA	CFDA	CFDA
28	Endocrine System	Febuxostat	Anti-Gout	DMF		WC			CFDA
29		Gliclazide	Anti-Diabetic						CEP DMF
30		Teneligliptin Hbr Hydrate	Anti-Diabetic	DMF					CFDA
31	Vitamins	Vildagliptin	Anti-Diabetic	DMF				CFDA	CFDA
32		Benfoliamine	Vitamin	DMF		WC	KFDA		
33	Blood forming organs	Alpha Lipoic Acid	Anti-Oxidant						DMF
34		Tranexamic Acid	Anti-Fibrinolytic	DMF	CEP	WC		CFDA	CFDA
35	Liver Function	Obeticholic Acid	Liver Disease	DMF					

*Patent infringement is the responsibility of buyers. Products currently covered by valid patents are offered for R & D purposes only.

Awards & Achievements

