



Reliable CDMO Partner

DEVELOPEMENT

NCE

INNOVATION

MEDICINE

DRUG

CHEMISTRY

SCIENCE

R&D

CUSTOMER

SERVICE

RESEARCH

HEALTHCARE

SCIENTIST

ONCOLOGY

QUALITY

RELATIONSHIP

EXCELLENCE

SOLUTION

CONTRACT

TRANSFORMATION

HPAPIS

ENVIRONMENT

API



AMI Lifesciences CDMO Emerging Services



We are accelerating the next wave of new molecular entities, building our immunology and rare diseases capabilities, pursuing new scientific modalities, and driving R&D productivity.



Wanted to be Trusted CDMO partner for NCEs, advanced intermediates from early stages to commercial with broad scale, development sciences & delivery technologies manufacturing.



We help our clients navigate complex R&D and manufacturing challenges and find innovative, safe, economically, and environmentally optimal solutions.



We're uniting science, technology, and talent to get better at finding new, better medicines .



Reimagining what innovation looks like in development science and are committed to providing the technology and subject expertise to inspire infinite scientific solutions



Lifesciences companies depend on us as we are trusted and reliable partner for their custom development and manufacturing needs.



Our Experience

Innovation, Invention and Unique Solution

250+

R&D Team



50+

Senior
Scientist



140+

QA/QC
Experts

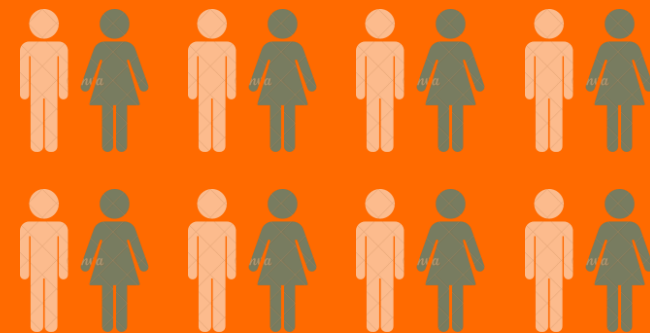


50+

Chemist &
Biologist

1250+

Employees



02

Production
Centre

Manufacturing Plants at
Karakhadi, Gujarat and
Raichur, Karnataka

60+

Export Countries

Manufacturing Capabilities up to 16 kL
reaction scale with batch sizes of 1500 Kgs &
11 batches /week



Our Clients-Partners in Success

 **INNOVATOR
COMPANIES**

 **LARGE
PHARMA &
Gx
COMPANIES**

| Why they choose us | Companies |
|--------------------|-----------|
|--------------------|-----------|

- Cost Savings
- Capacity and Resources for production
- Expertise and Experience
- Regulatory Compliance & Quality
- Focus on Core Competencies
- Access to Cutting-Edge Technology
- Flexibility
- Reduced Risks
- Project Management





Accreditations



Existing



European Directorate for the
Quality of Medicines and
Healthcare



Ministry of Food and Drug
Safety, Korea
(Formerly Korea FDA)



Pharmaceuticals and
Medical Devices Agency
(PMDA, Japan)



Agência Nacional de
Vigilância Sanitária
(Brasil)



National Medical
Products Administration
(Formerly China FDA)



Federal Commission for the
Protection against Sanitary
Risk (COFEPRIS, Mexico)



WHO cGMP



ISO 9001-2015



ECOVADIS - GOLD



EIR Received in Dec, 2024





SS Reactor Count & Capacity



| Sr. No. | Reactors | Count | Capacity |
|---------|------------|-------|----------|
| 1 | SS Reactor | 4 | 12.5 KL |
| 2 | SS Reactor | 1 | 10.0 KL |
| 3 | SS Reactor | 1 | 8.0 KL |
| 4 | SS Reactor | 6 | 6.3 KL |
| 5 | SS Reactor | 3 | 6.0 KL |
| 6 | SS Reactor | 3 | 5.0 KL |
| 7 | SS Reactor | 3 | 4.0 KL |
| 8 | SS Reactor | 6 | 3.0 KL |
| 9 | SS Reactor | 3 | 2.0 KL |
| 10 | SS Reactor | 2 | 0.1 KL |
| 11 | SS Reactor | 2 | 0.5 KL |
| 12 | SS Reactor | 3 | 0.25 KL |



Glass Lined Reactor Count & Capacity



| Sr. No. | Reactors | Count | Capacity |
|---------|-------------|-------|----------|
| 1 | Glass Lined | 1 | 12.5 KL |
| 2 | Glass Lined | 3 | 6.3 KL |
| 3 | Glass Lined | 2 | 5.0 KL |
| 4 | Glass Lined | 3 | 4.0 KL |
| 5 | Glass Lined | 5 | 3.0 KL |
| 6 | Glass Lined | 2 | 2.0 KL |
| 7 | Glass Lined | 1 | 1.6 KL |
| 8 | Glass Lined | 2 | 0.1 KL |
| 9 | Glass Lined | 3 | 0.25 KL |
| 10 | Glass Lined | 2 | 0.5 KL |



Manufacturing Equipment

| Sr. No. | Equipment | Count | Capacity |
|---------|-----------------------|---------|-------------------------------------|
| 1 | Agitated Nutch Filter | 1 | 4.0 KL |
| 2 | Sifter | 1 | 30" Dia |
| 3 | Centrifuge | 6+2+17 | 24" Dia, 48" Dia, 60" Dia |
| 4 | Candy Filter | 1 | 800 L |
| 5 | Leaf Filter | 2 | 100 L |
| 6 | Filter Press | 3 | 1500 L |
| 7 | Sparkler Filter | 3+3+2 | 12 Plate, 15 Plate, 18" Dia |
| 8 | Vacuum Tray Dryer | 3+1 | 24 Tray, 96 Tray |
| 9 | Air Tray Dryer | 2+2+1+8 | 24 Tray, 48 Tray, 96 Tray, 192 Tray |
| 10 | Rotocone Vacuum Dryer | 2+1+1+1 | 4.0 Kl, 3.0 KL, 0.25 KL, 0.5 KL |
| 11 | Agitated Nutch Filter | 1+1+1 | 6 KL, 5KL, 0.5 KL |
| 12 | Micro Pulveriser | 1+2+2 | 12KG/HR, 200KG/HR, 30-2000KG/HR |





Manufacturing Equipment

| Sr. No. | Equipment | Count | Capacity |
|---------|-----------------------|-------|-----------------------|
| 1 | Rotocone Vacuum Dryer | 1 | 0.25 KL |
| 2 | Multimill | 1+4 | 5 KG/HR, 52-200 KG/HR |
| 3 | Sifter | 1+6 | 12" Dia, 30" Dia |
| 4 | Micronizer | 2 | 5-200 KG/HR |
| 5 | Compactor | 1 | 100-200 KG/HR |
| 6 | Blender | 1+1 | 4.0 KL, 1.0 KL |





Type of Reactions in API Manufacturing

Acetal Formation

Acylation

Addition Reaction

Aldol Condensation

Alkylation

Arylation

Beckmann Rearrangement

Biginelli Reaction

Clark-Eschweiler Reductive Alkylation

Condensation

Curtius Rearrangement

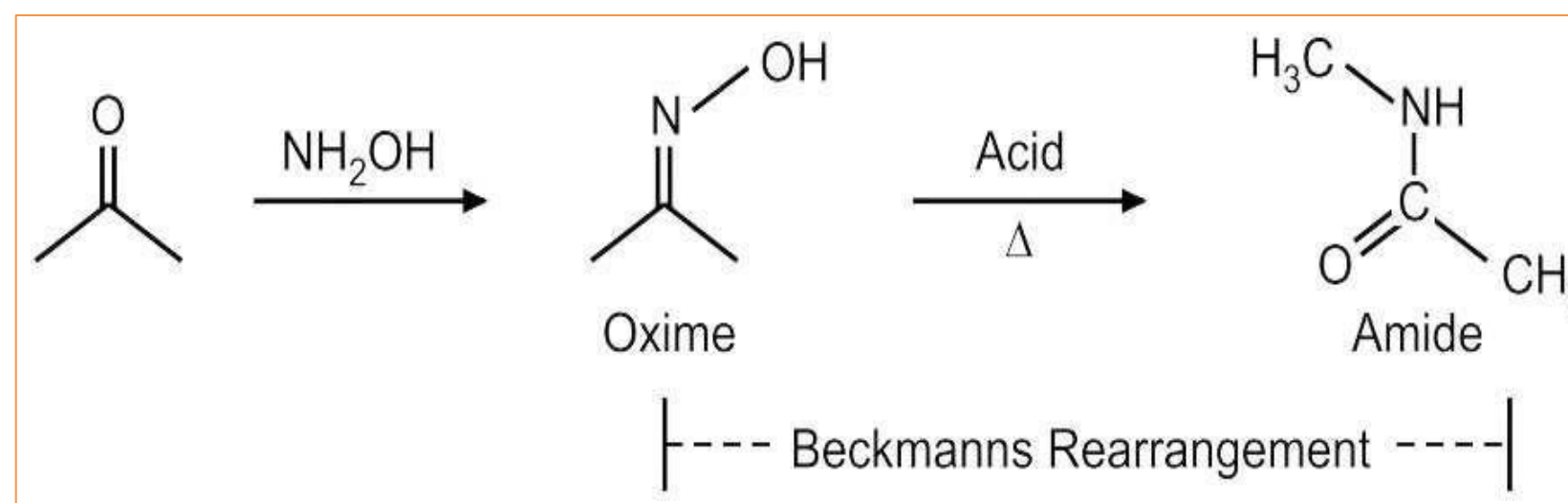
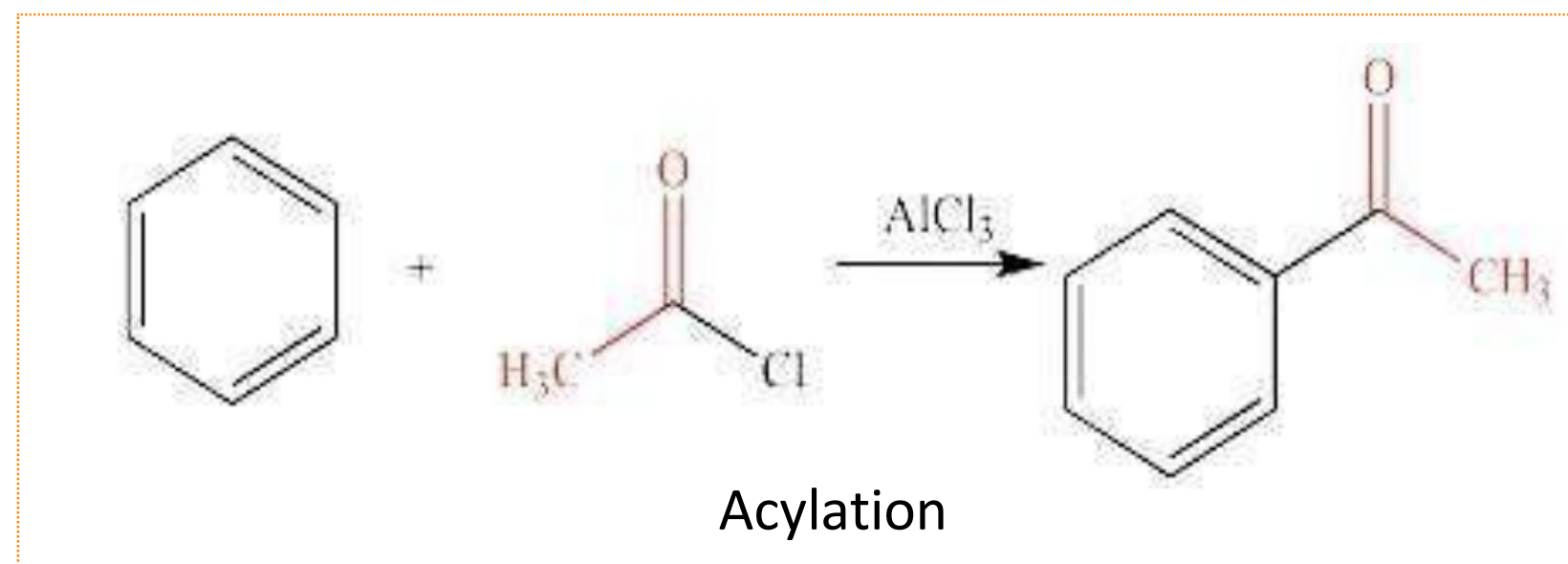
Cyclization

Darzens Glycidic Ester Condensation

De-Alkylation Cleavage

Decarboxylation

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





Type of Reactions in API Manufacturing

Dehydration

Esterification/ Trans-esterification

Formylation

Friedel – Craft Reaction

Halogenation (Br_2 , Cl_2 , I_2 , ICl , SOCl_2 , PCl_5 , PCl_3 , KF etc.)

Knoevenagel Condensation

Leuckart Wallach Reaction

Oxidation (KMnO_4 , CrO_3 , HNO_3 , O_2 , H_2O_2)

Perkin Reaction

Pinner Synthesis

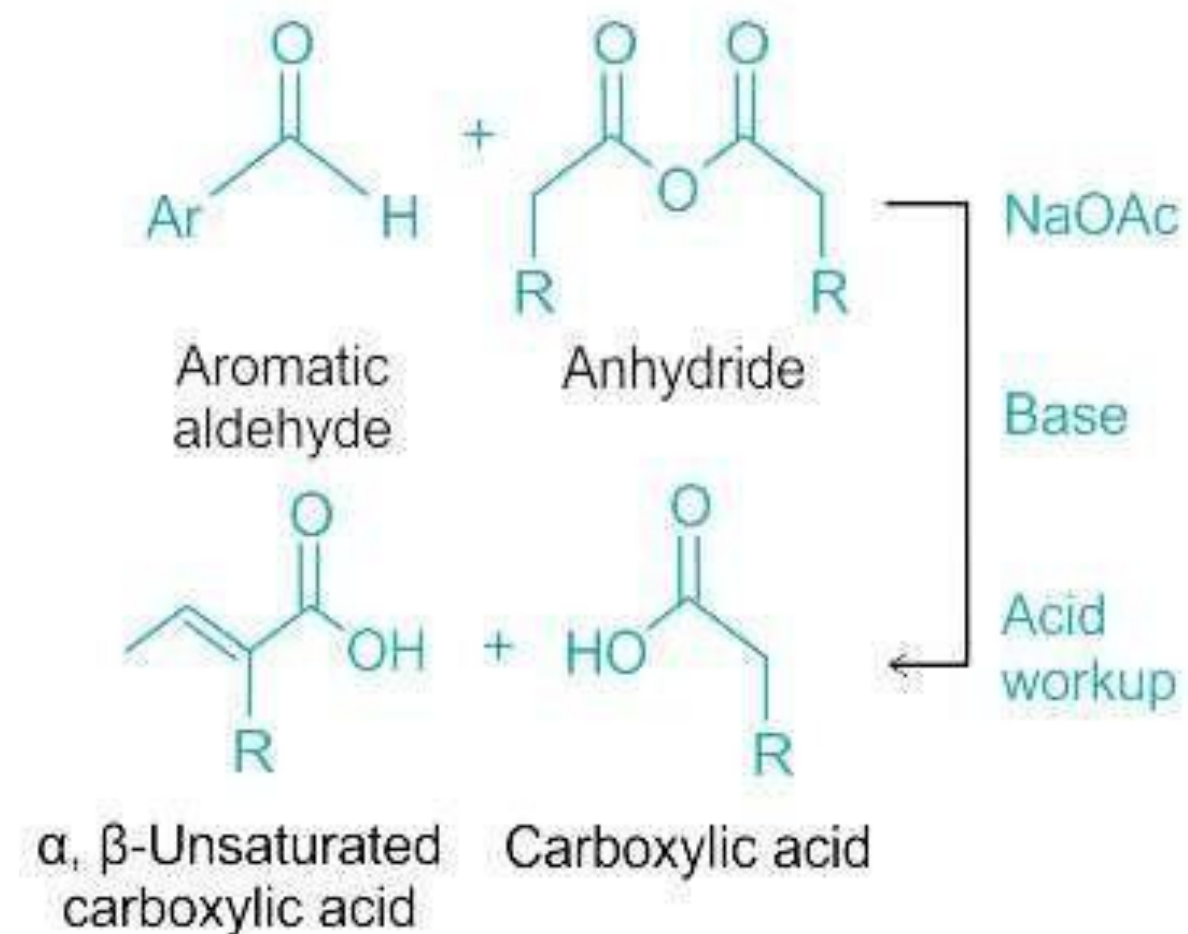
Reduction (H_2/Pd , Ni , Pt , NaBH_4 , Zn , Vitride, Sodium)

Sandmeyer Reaction

Sarett Oxidation

Schiff Base Reaction

Perkins Reaction



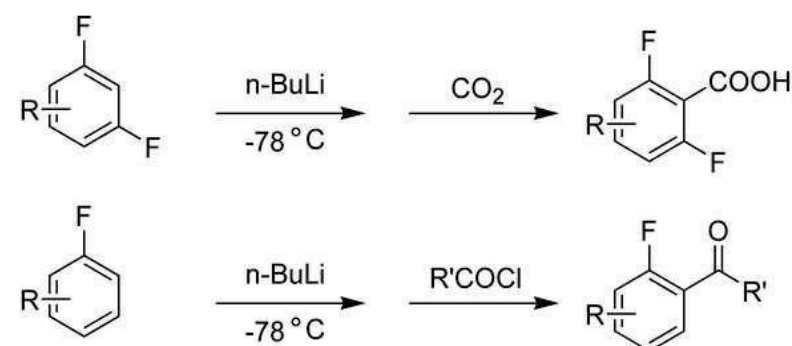


Reactions - That We Support

Cryogenic Reactions

We can perform cryogenic reactions in temperature ranges up to $(-80)^{\circ}\text{C}$

Cryogenic Reactions



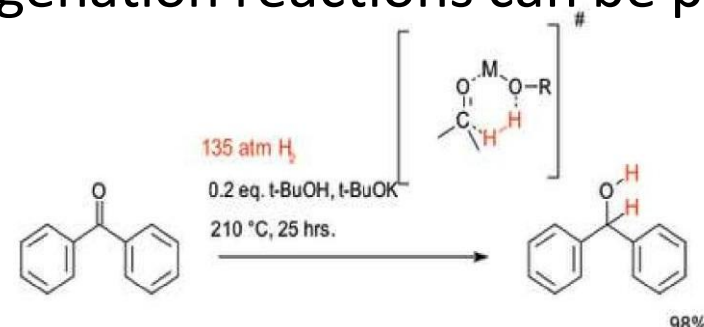
Pyrophoric and Sensitive Reactions

Capable to handle precious metal catalysts and pyrophoric materials at elevated temperature and high pressure.



Hydrogenation Reactions

With designed pressure range up to $30\text{kg}/\text{cm}^2$, temperature range up to 180°C and capacity ranging from 25 L to 12.5 KL, efficiently hydrogenation reactions can be performed.





Our Key Differentiators



Comprehensive services, including process development and optimization, formulation development, analytical testing, and clinical supply management.



Flexible to meet evolving client and regulatory demands for both large & small production runs.



Our Immuno-Oncology Expertise have **in-depth understanding** of Oncology Drug Manufacturing Challenges and Complexities



Project Management expertise by our high-performance teams for high-potency drugs manufacturing by ensuring effective communication & delivery.



Strong partnerships with leading research institutions and industry experts.



Experienced process engineers on hand to guide you every step of the way.



Solid supply chain relationships and experience, with scalability & Reliable handling of high potency APIs.



R&D in new technologies and automation, such as continuous manufacturing.



Why Choose Us

As every project is different and our clients may require different levels of support. That's why we offer **flexible service models** that can be tailored to meet the specific needs of each project.

We understand the importance of budget constraints and are committed to providing **cost-competitive solutions** that deliver results without breaking the bank.



Our team is made up of

- **Entrepreneurs**
- **Problem-solvers**
- **Innovation-driven individuals**

who bring a unique perspective to each project.

Our clients can trust that they will receive value for their investment.



Thank You

