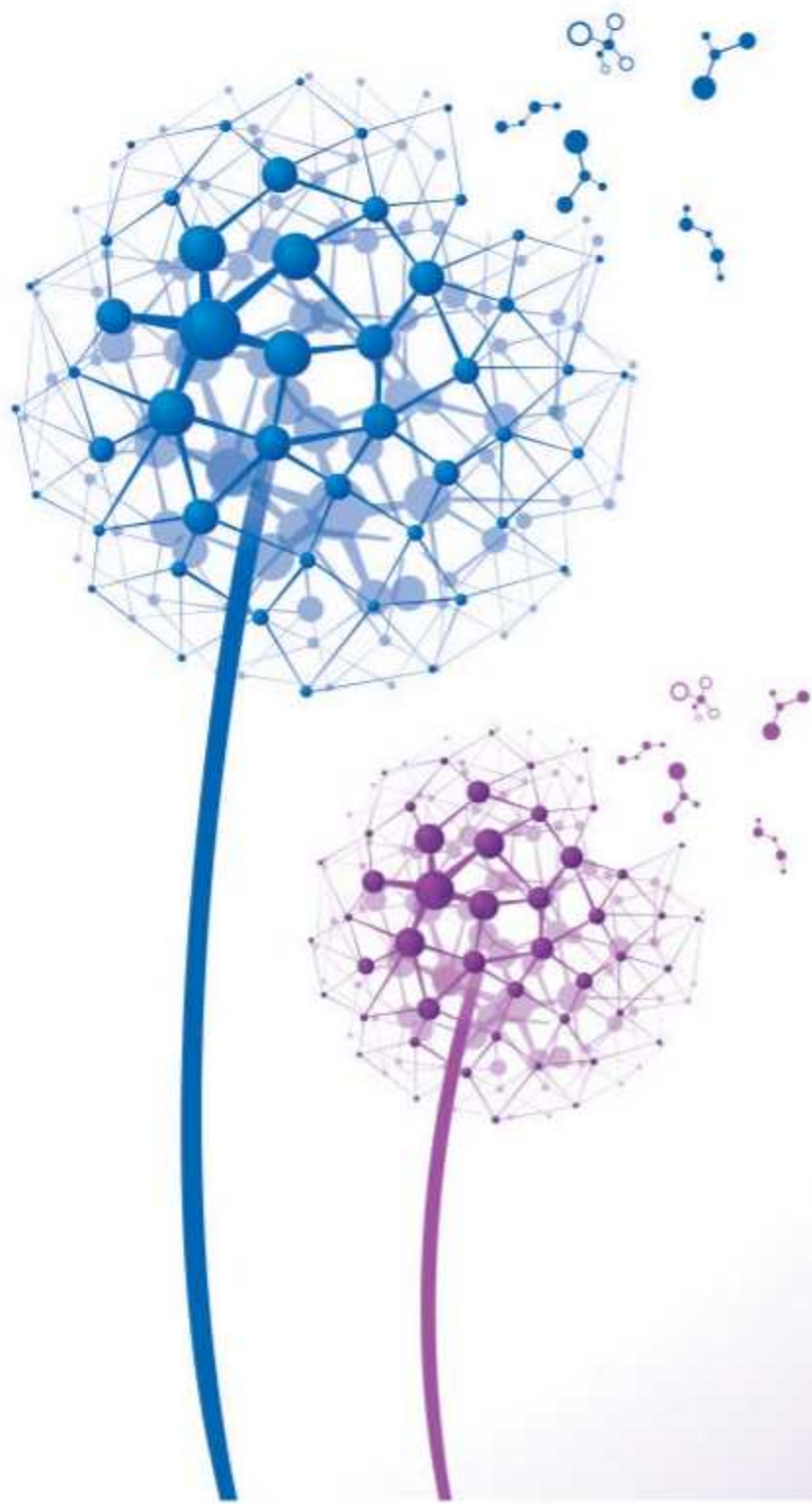
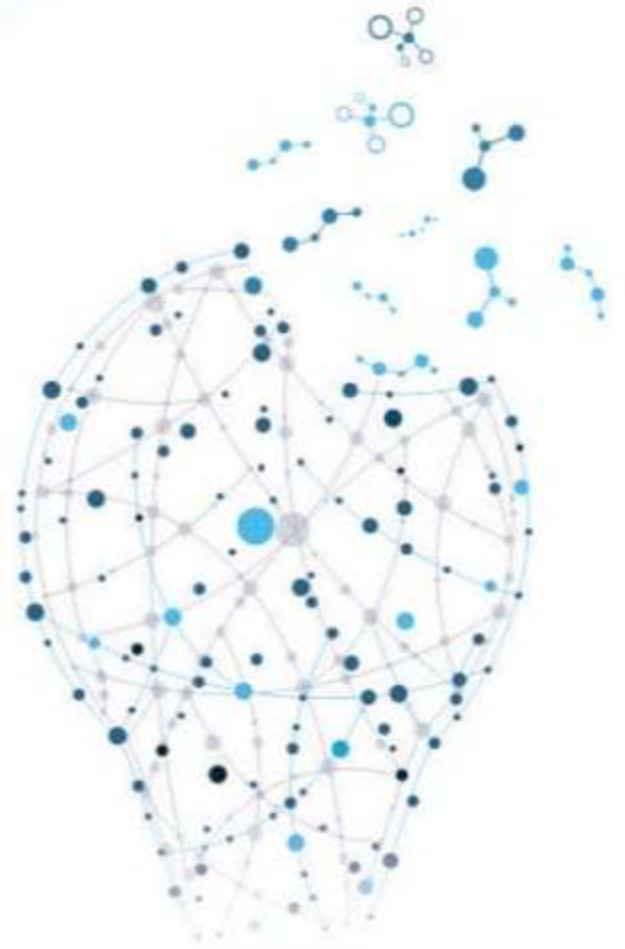


Leadership Through Quality,
Innovation & Technology



www.amoliindia.com

Broader **vision** lightens
our path of **success**



Mission

The purpose of business is to respectfully serve the needs of customers by providing products and services of international standards at an affordable price and to earn an adequate profit which is required for an organization to grow and also to provide reasonable opportunity for employees to grow.

- To provide customers with superior products and services
- To satisfy customer needs
- To provide employees a learning environment and advanced opportunities

Vision

To be recognized by our employees, customers and stakeholders as a reliable pharmaceutical company in the world, resulting in value for all.

Core Values

- Quality
- Integrity
- Respect for people
- Leadership
- Collaboration – “Teamwork”





About Us

Amoli Organics was incorporated in 1992. We manufacture Active Pharmaceutical Ingredients (APIs) in India and these are marketed across the globe.

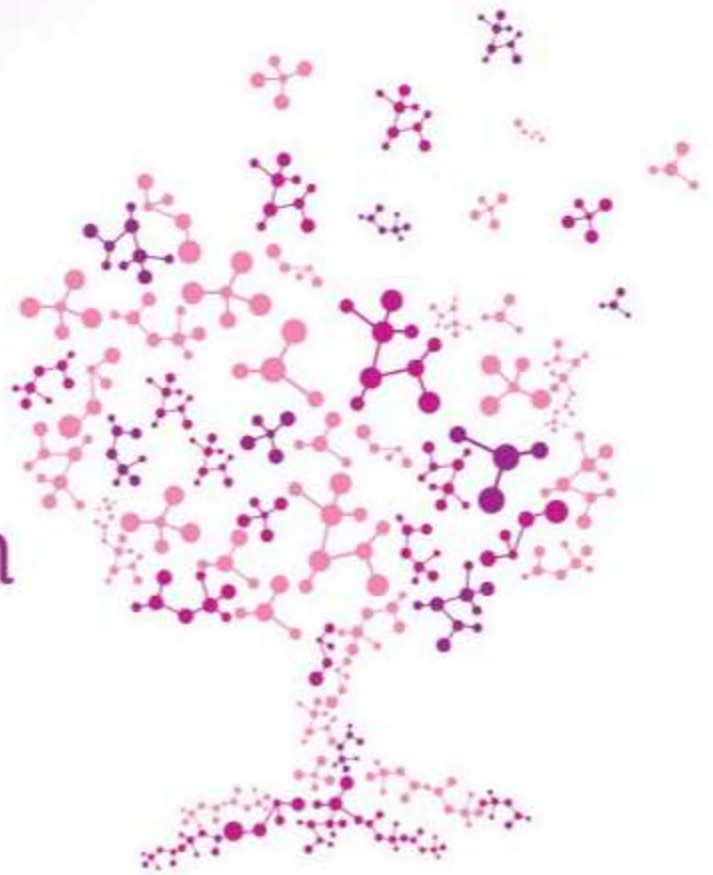
Amoli's foundation is based on the philosophy of **"Leadership through QUALITY, INNOVATION & TECHNOLOGY"**

- Our world class manufacturing sites are located at Baroda and Vapi
- We have leadership position in Diclofenac Sodium globally. We hold 35% market share as per IMS2010
- We currently operate in 85 countries with major focus in the regulated markets
- Our Chemical Research and Development Laboratory is located in Baroda
- We have aggressive R&D program to develop 8-10 molecules each year
- We partner with our customers by providing custom and contract manufacturing services.
- Amoli has been able to establish an image of high quality and service over a period of time, thus leading to customer satisfaction

Best is not **our choice...**
We seek for better than the **best**



We believe in
**manufacturing
reputation**



Manufacturing

BARODA site (approx. 435 kms north of Mumbai) comprises of 8 manufacturing facilities.

VAPI site (approx. 170 kms north of Mumbai) comprises of 3 manufacturing facilities.

- Both sites are cGMP compliant and are managed by highly skilled professionals
- Sites are being regularly audited and approved by Innovators and Top Global Generic companies
- SS and GL reactors (volumes ranging from 150 L to 25000 L)
- Total reaction capacity – 600 KL

Environment

- Full-fledged ETP for effluent treatment
- Conduct Environment Impact Study
- SHE compliant



Quality and Regulatory

QA & QC

- Quality Control and Quality Assurance are located at both the manufacturing sites
- Quality management systems are well established according to ICH guidelines
- Amoli has maintained a prime position in manufacturing of quality products of international standards
- Our QA/QC meets requirements of our customers by offering consistent quality products and services

RA

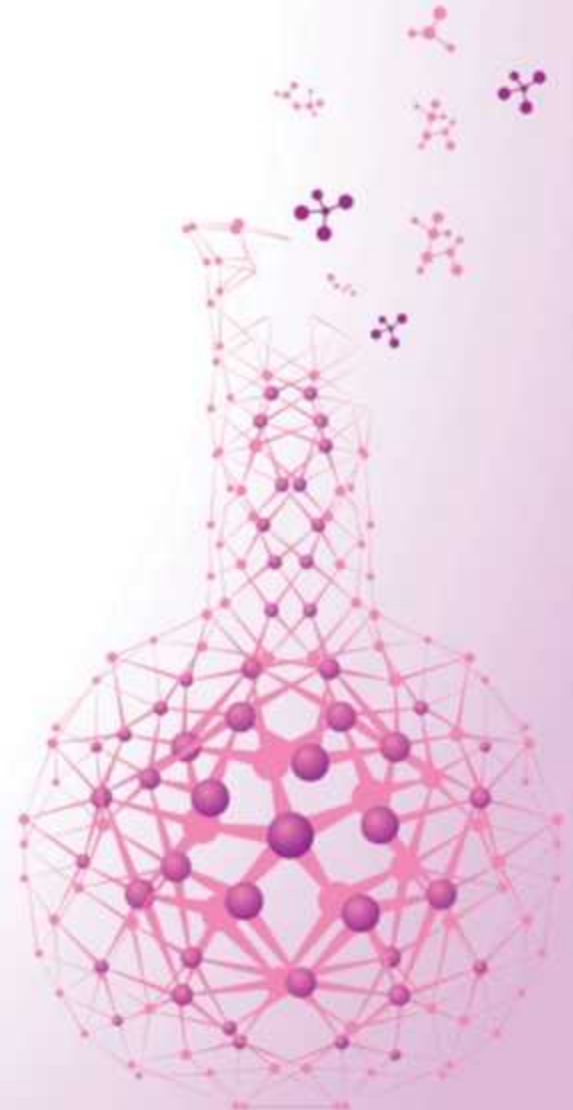
- Strong regulatory team is competent to prepare high quality technical packages and drug master files.
- Fully compliant with cGMP
- Drug master files are available for all commercial products
- 100% regulatory compliance with respect to manufacturing and dossier development.
- Regularly inspected by customers from all over the world.

Accreditations

- US FDA
- EDQM & EUGMP
- ANVISA, Brazil
- PMDA, Japan
- COFEPRIS, Mexico
- TGA, Australia
- WHO-GMP



We **research** to
develop healing touch



Great **innovation** needs greater **research** and **development**



R & D

Chemistry Lab

- Situated at Baroda, Gujarat, India, Amoli Research Centre is spread over 12,000 sq.ft.
- Well equipped with cGMP compliant 2 Synthetic labs, 2 Analytical labs and a pilot plant with SS and GL reactors (250 L to 1200L)
- Has a talented pool of 80 scientists including organic/analytical chemists.
- R&D centre is engaged in developing process technology for APIs.

Analytical Lab

Our Analytical Lab provide support to our R&D through documentation and validation of test results as per ICH guidelines and assist the regulatory affairs to prepare high quality technical packages and drug master files.

R & D Capabilities

- Polymorph Development
- Impurity Profiling
- Generation of Intellectual Property
- Chiral Separations
- Stereoselective synthesis
- Cryogenic reactions
- Particle sizing capabilities



Leadership pan globe



Our Reach

- Amoli group has 6 offices based across the globe
- Exports to more than 85 countries
- Has more than 450 satisfied customers globally
- Healthy relations with innovators and top global generic customers
- Leadership position in Diclofenac Salts, with 35% market share



Commercial Products

Product	Therapeutic Use	Regulatory Status
1 Aceclofenac BP / EP	Anti-inflammatory	CEP
2 Ascorbic Acid BP / EP / USP	Vitamin	USDMF
3 Atorvastatin Calcium Crystalline BP/ EP / USP	Anti-hyperlipidemic	USDMF, CEP
4 Aripiprazole USP	Anti-depressant/Anti-psychotic	USDMF
5 Carbamazepine BP / EP / JP / USP	Anti-Convulsant	USDMF, CEP
6 Celecoxib BP / EP / USP	Anti-inflammatory	USDMF, CEP
7 Clotrimazole BP / EP / USP	Anti-fungal	USDMF, CEP
8 Chlorthalidone EP / USP	Diuretic	USDMF, EDMF
9 Diclofenac Salts		
a) Diclofenac Sodium (Bromine Free) BP / EP / JP / USP	Anti-inflammatory	USDMF, CEP
b) Diclofenac Potassium BP / EP / USP	Anti-inflammatory	USDMF, CEP
c) Diclofenac Diethylamine BP	Anti-inflammatory	USDMF, EDMF
d) Diclofenac Free Acid	Anti-inflammatory	USDMF, EDMF
e) Diclofenac Epolamine	Anti-inflammatory	USDMF, EDMF
f) Diclofenac Deanol	Anti-inflammatory	EDMF
g) Diclofenac Resinate	Anti-inflammatory	EDMF
10 Dihydralazine Sulphate BP / EP	Anti-hypertensive	CEP
11 Dimethyl Fumarate	Multiple Sclerosis	USDMF, EDMF
12 Hydrochlorothiazide BP / EP / USP	Diuretic	USDMF, CEP
13 Levetiracetam EP / USP	Anti-Convulsant	USDMF, CEP

Customised particle size available

USFDA | EDQM | TGA | PMDA | ANVISA | COFEPRIS | MIT (Russia)

Patent note : All transactions are carried out in conformity with the patent laws applicable in the user country.
 Responsibility with respect to third parties patent rights in a specific country lies exclusively with the buyer

Amoli Organics Pvt. Ltd.

407, Dalamal House, Nariman Point, Mumbai - 400 021. INDIA.

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Commercial Products

Product	Therapeutic Use	Regulatory Status
14 Mesalamine / Mesalazine	Anti-Inflammatory (IBD)	Tech Pack (DMF-Q2 2020)
15 Olmesartan Medoxomil EP / USP	Anti-hypertensive	USDMF, CEP
16 Oxcarbazepine EP / USP	Anti-convulsant	USDMF, CEP
17 Pirfenidone	Fibrosis	USDMF, CEP Applied
18 Ranolazine	Anti-anginal	EDMF, USDMF
19 Rosuvastatin EP	Anti-hyperlipidemic	USDMF, CEP
20 Sertraline HCL BP / EP / USP	Anti-depressant	EDMF
21 Sildenafil Citrate EP/ USP	Erectile dysfunction	USDMF, CEP
22 Sodium Ascorbate EP/ BP/ USP	Vitamin	
23 Solifenacin Succinate	Overactive bladder	USDMF, CEP
24 Succinylcholine / Suxamethonium Chloride	Muscle Relaxant	Tech Pack (DMF-Q2 2020)
25 Tadalafil EP/ USP	Erectile dysfunction	USDMF, CEP
26 Venlafaxine HCL BP / EP / USP	Anti-depressant	USDMF, CEP

Pipeline Products

Product	Therapeutic Use	Regulatory Status (USDMF / CEP)
1 Apixaban	Anti-coagulant	Q II 2020
2 Apremilast	Psoriasis	Q II 2020
3 Deferasirox	Iron chelating agent	Q I 2020
4 Eslicarbazepine Acetate	Anti-convulsant	Q I 2020
5 Elagolix	Endometriosis	Q4 2020
6 Desvenlafaxine Succinate	Anti-depressant	Q4 2020
7 Sitagliptin Phosphate	Diabetes	Q4 2020
8 Mirabegron	Overactive bladder	Q4 2020

Customised particle size available

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Future Products

Product	Therapeutic Use
1 Dapagliflozin Propanediol Monohydrate	Diabetes
2 Empagliflozin	Diabetes
3 Linagliptin	Diabetes
4 Vortioxetine	Antidepressant
5 Tofacitinib	Rheumatoid Arthritis
6 Edoxaban	Anticoagulant
7 Ticagrelor	Antiplatelet

Customised particle size available

USFDA | EDQM | TGA | PMDA | ANVISA | COFEPRIS | MIT (Russia)

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