

Alkem Labs

Leading global pharmaceutical company

A single idea, which sprouts from a human mind, contains the potential to create marvels that can influence generations. It can redefine rules, it can transform the world. Back in the year 1973, a team of individuals came with such an idea – The idea was called Alkem. It was highly potent and resilient, like a spark that could ignite a thousand more ideas.

Fifty years ago, Alkem penned the first chapter of a remarkable journey with the vision of transforming India's pharmaceutical sector. Today, with a footprint in 40 countries, 19 manufacturing units, over 800 brands, and many, many milestones later, we have an assemblage of tales enriched with pioneering work. Alkem is one of the biggest names in the generic and specialty pharmaceutical sector in India. Our legacy is a testament to the sheer hard work, perseverance, and grit to take the path with barely any footprints and a lot of latent potential to make a difference. A single step, a single idea, led to Alkem – a journey driven by our commitment to people, innovation, and service to the community.

In the last five decades, Alkem Labs has been Meaningfully impacting lives through groundbreaking research and innovation, Transforming the conventional understanding of the pharmaceutical world, Writing exemplary chapters of good health by adhering to the best standards of quality, Making a significant contribution through remarkable healthcare solutions, Making the world a better place by ensuring accessibility and affordability, Raising awareness about different conditions and disorders, one initiative at a time, Achieving milestones while making a difference, and therefore, INSPIRING HEALTHIER LIVES.

Global Presence

The journey started with a small step that originated with the idea of increasing Alkem's global footprint. And it eventually turned into a giant leap. For Alkem Labs, the United States is the focal point of international operations. In this stride, we have cumulatively filed more than 125 ANDAs with the US FDA. Alkem markets and sells products in the United States under its wholly-owned subsidiary, Ascend.

Other international operations include markets like LATAM, Europe, Africa, CIS, Southeast Asia, and Australia. Our products are marketed in about 50 international markets, directly through our subsidiaries and indirectly through active engagements with other organizations.

We are constantly looking forward to product in-licensing and out-licensing opportunities in several emerging markets. This helps us leverage our product portfolio and sales and marketing infrastructure.

Investing today, for a healthier tomorrow

At Alkem, our path is clear and so is our purpose. With over 500 scientists working in 5 global R&D centres, we are empowering innovations that perpetually reinforce our philosophy of 'Extended Lifecare Beyond Boundaries'. This philosophy is at the heart of everything we do. It is driven by our uncompromised integrity, unparalleled solutions, commitment to innovation, and upholding the highest standards in safety and performance. This is what sets Alkem apart – the roots of great intent enhanced by an incredible team

of visionaries. With units across the nation, leaders with diverse backgrounds, and scientists from various parts of the world, everyone at Alkem is united by the same ardor to reciprocate the faith in our products with the promise of good health.

Manufacturing Facility

We as an organization focus on ensuring high quality, and that reflects in all our operations. Alkem's manufacturing operations focus on producing generics, branded generics, over-the-counter (OTC) products, Active Pharmaceutical Ingredients (APIs), and nutraceuticals. These are available in a full range of dosage forms, which include tablets, capsules, injectables, powder for oral suspension and liquids. This helps in furnishing quality formulations in India as well as 40 plus other countries.

We have state-of-the-art facilities that employ cutting-edge manufacturing techniques for producing the best-in-class products. Alkem has an extensive manufacturing footprint which has a total of 19 manufacturing facilities, out of which 18 are in India and 1 are in the United States of America.

We have various manufacturing facilities at Daman, Baddi, Indore and Sikkim. These possess regulatory approvals from agencies such as USFDA, MHRA – UK, TGA – Australia, ANVISA – Brazil, WHO – Geneva, TPD – Health Canada, PPB – Kenya, NDA – Uganda, MOH – Sudan, INVIMA – Colombia, TFDA – Tanzania, Zimbabwe, BfArM–Germany, SAHPRA–South Africa, and other African, Asian and CIS Countries. The facilities are audited by relevant regulatory agencies of the countries where products are marketed.

Our Production Team has over 3,000 capable individuals, who work in tandem with the Quality Team to deliver top-quality products. Our management furnishes adequate resources to ensure quality deliverance. All

manufacturing units are equipped with Quality Control Units that assure quality at each stage.

Manufacturing Facilities & Capabilities in India

Facilities	No. of Facilities	Manufacturing Capabilities
Baddi	3	Formulations – Tablet, Capsules & Dry Syrup
Daman	3	Formulations – Tablet, Capsules, Dry Syrup & Liquid
Sikkim	7	Formulations – Tablet, Capsules, Injectables, Dry Syrup, Respules, Oral Liquids, Neutraceuticals & WFI
Mandva	1	Active Pharmaceuticals Ingredients (APIs) & FOS
Ankleshwar	1	Active Pharmaceutical Ingredients (APIs)
Indore	1	Formulations – Capsules, Tablets, Dry Syrup, Ointment
Pune	2	Biosimilars

We are in moving towards automation of processes which results in optimum utilization of resources, Cycle time reduction & maximum capacity utilization. We have Introduced electronic Log books & batch cards in international manufacturing plants & this helps in avoiding manual transcriptions & errors. The technical training center is operational at Daman which is helping us to provide adequate training with practical experience.

Manufacturing Facilities & Capabilities in the US

Facility	No. of Facilities	Manufacturing Capabilities
California – Norac	1	Active Pharmaceutical Ingredients (APIs)

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Subsidiaries

Office Location	Type of Subsidiary
Alkem Foundation, India	Wholly Owned Subsidiary
Alkem Medtech Private Limited, India	Wholly Owned Subsidiary
Alixer Nexgen Therapeutics Limited, India	Wholly Owned Subsidiary
Alkem Wellness Limited, India	Wholly Owned Subsidiary
Connect 2 Clinic Private Limited, India	Wholly Owned Subsidiary
Cachet Pharmaceuticals Pvt Ltd, India	Subsidiary
Indchemie Health Specialities Pvt Ltd, India	Subsidiary
Enzene Biosciences Limited, India (Enzene)	Subsidiary
Enzene Inc., USA	Wholly Owned Subsidiary of Enzene
S & B Holdings S.a.r.l., Luxembourg (S & B)	Wholly Owned Subsidiary

ThePharmaNetwork, LLC, USA (TPN)	Subsidiary of S & B
Ascend Laboratories LLC, USA	Wholly Owned Subsidiary of TPN
S & B Pharma LLC, USA	Wholly Owned Subsidiary of TPN
Ascend Laboratories (Pty) Ltd, South Africa	Wholly Owned Subsidiary
Alkem Laboratories Corporation, Philippines	Wholly Owned Subsidiary
Ascend GmbH, Germany	Wholly Owned Subsidiary
Ascend Laboratories SDN BHD., Malaysia	Wholly Owned Subsidiary
Alkem Laboratories Korea Inc, Korea	Wholly Owned Subsidiary
Ascend Laboratories (UK) Ltd., UK	Wholly Owned Subsidiary
Ascend Laboratories Ltd., Canada	Wholly Owned Subsidiary
Ascend Laboratories S.A.S, Colombia	Wholly Owned Subsidiary
Ascend Laboratories SpA, Chile (Ascend Chile)	Wholly Owned Subsidiary
Pharma Network SpA, Chile	Wholly Owned Subsidiary of Ascend Chile
Ascend Laboratories S.A. DE C.V., Mexico	Wholly Owned Subsidiary of Ascend Chile
Pharmacor Ltd., Kenya	Wholly Owned Subsidiary
Pharmacor Pty Limited, Australia (Pharmacor)	Wholly Owned Subsidiary
Pharmacor Limited, New Zealand	Wholly Owned Subsidiary of Pharmacor
Pharmacor SpA, Chile	Wholly Owned Subsidiary of Pharmacor
The Pharma Network, LLP, Kazakhstan	Wholly Owned Subsidiary

Therapies

Anti-Infective

Anti-Infective is a Therapy Area (TA) that constitutes over 11.8% of the revenue of the total Indian Pharmaceutical Market (IPM).

Alkem holds the number one place in the sector of anti-infective TA with a wide range of medicines that fight against different kinds of infections.

We have expertise in an impressive range of formulations that includes tablets, dry syrups, and sterile dosage forms.

From the outset, brand building has been the greatest strength of Alkem. This has enabled us to become the only company with 9 anti-infective brands featuring among the top 300 brands of the Indian Pharmaceutical Market. It has played a pivotal role in propelling Alkem to the summit of anti-infective TA.

Some of the highlights of Alkem's Anti-infective portfolio are :

CLAVAM, TAXIM-O, TAXIM, PIPZO, MEROSURE, ZAXTER, SWICH, XONE & XONE-XP, the pillar brands of Alkem in anti-infective are the key contributors to Indian Pharmaceutical Market.

Redefined paediatric infection management with launch of Merosure-O DS (Feropenem).

Cardiology

Cardiovascular (CV) disease is the leading cause of death and disability in India, and is a significant burden on healthcare. Key risk factors of CV diseases in India are hypertension, generalized obesity and altered lipid levels which are seen in 35.5%, 28.6% and 81.1% of adult population respectively. This CV disease epidemic in Indians is characterized by a higher relative risk

burden, an earlier age of onset, higher case fatality and higher premature deaths compared to global counterpart^{1,2}. Thus, Cardiovascular therapy is the second largest Therapy Area (TA) following anti-infective.

A quarter of all deaths in the country can be attributed to cardiovascular diseases. The burden of CVD is growing at a morbid rate. Therefore, cardiovascular therapy is the second largest Therapy Area (TA) following anti-infective.

Alkem is an emerging player in this TA. Our presence in Cardiology TA is through 2 divisions – Alkem Aspiria and Alkem Imperia. These help us in reinforcing our resolve to ensure healthier lives through quality care. We aim at emerging as the most significant name in the cardiovascular TA by paving the way for enhanced solutions for hypertension, dyslipidemia and thereby managing CV diseases holistically.

Some of our key brands are:

- Olkem (Olmesartan)
- Jupiros (Rosuvastatin)
- Cilnikem (Cilnidipine)
- Dabiclote (Dabigatran)
- Tsart (Telmisartan)
- TICAVIC (Ticagrelor)

Dermatology

Dermatology and Aesthetics has always been an important Therapy Area (TA) for Alkem. We cater to this segment through integration, innovation, and enhancement of our diverse Dermatology and Cosmetology portfolio. It includes moisturizers and products for acne, vitiligo, skin infections, melasma, dermatitis, alopecia, and skin revitalization. Our incredible range of formulations makes us stand out in this TA, for all the right reasons. Keeping

up with our principle of not stopping and confining ourselves, we impart updated medical education through national symposiums, international and domestic conference participation, round table discussions, and live webcasts for online discussions for the medical fraternity.

Highlights of Alkem's Dermatology portfolio:

Melbild (our brand of Decapeptide) was the biggest launch of the segment in 2015.

Alkem acquired Clindac-A – a leading brand in the Clindamycin topical market from Galderma.

Renocia (our range for alopecia available as serum, shampoo, and conditioner) is an in-licensed product from South Korea – a known leader in this sector.

We launched Olesoft—an emollient catering to various needs of moisturization.

Olesoft Max is emerging as one of the top choices of moisturizer for atopic dermatitis.

Kojiglo Gold is a unique combination with the promise to lighten up acne-induced hyper-pigmentation.

Some of key brands are:

- LILITUF
- PRUCROS
- RENOCIA
- CLINDAC A
- CLINDAC AP
- SUNHEAL
- HYMOS

Gastroenterology

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Alkem has always believed to evolve as per the need of the therapy and currently, Alkem holds 7% of the total revenue generated by this TA.

At present, Alkem is the 3rd largest company in the GI Therapy Area (TA) of IPM. Alkem has built its trust by developing several products for GI disorders like GERD, gastric ulcers, anti-emetic, constipation, hyperacidity, diarrhea, worm infestation, etc.

Some of the highlights of Alkem's Gastroenterology portfolio are

- PAN is the No.1 ranked brand in sales value in PPI market*
- Extending treatment options in Refractory GERD with a new launch PAN 80.
- PAN-D is the No.1 ranked brand in sales value in PP I+ Domperidone market*
- Obetohep is the No.1 ranked brand in sales value in Obeticholic acid market*
- Ondem is the most preferred antiemetic and has been maintaining its leadership position in the respective segment.
- Emty is the 3rd largest value brand in the Lactulose market*
- Rifakem, an intelligent gut antibiotic is focusing on infectious diarrhea/IBS-D.
- Noworm, a brand of Albendazole, is holding the 2nd position in the respective market.

Oncology

Cancer is characterized by uncontrolled cell growth. In some cases, cancer can metastasize i.e., spread to different parts of the body. It is one of the deadliest diseases and requires immediate medical attention. Despite the availability of several anticancer drugs (oncology drugs), a lot is yet to be discovered.

Oncology is the branch of medicine that deals with the prevention, diagnosis, and treatment of cancer. Alkem has dedicated a division for anticancer products, which is christened 'Oncology Division'. The Oncology division has been in existence for over 17 years. As far as anticancer medicines are concerned, Alkem Oncology has hormonal preparations, cytotoxic drugs, and targeted therapeutic drugs in its portfolio.

Alkem Oncology offers three biosimilar drugs i.e., Rituximab (Cytomab), Bevacizumab (Advamab), and Trastuzumab (Hersima). All of these are monoclonal antibodies. Rituximab is highly recommended by oncologists as the targeted therapy for the treatment of non-Hodgkin lymphoma (NHL) and autoimmune disorders like rheumatoid arthritis (RA). Bevacizumab is used as a targeted therapy in the advanced stages of colorectal cancer and recurrent ovarian cancer.

Trastuzumab is used as a targeted therapy in HER2 +ve Breast Cancer and HER2 +ve Gastric Cancer. Enzene Biosciences, a dedicated research unit of Alkem Laboratories, is currently working on a number of monoclonal antibodies. Also, there are several other biosimilar drugs in the pipeline. Alkem Oncology offers three biosimilar drugs i.e. Rituximab (Oncology), Bevacizumab (Advamab), and Trastuzumab (Hersima). All of these are monoclonal antibodies.

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