SCL Lifesciences Limited

About Us

SCL Lifesciences is a reliable supplier and CDMO services provider for Pharmaceutical APIs and Intermediates.

SCL was incorporated on 20th December 1993 as a Private Limited Company. It initially began its operations by manufacturing Intermediates. Later, on 1st July 1997, the Company was reconstituted as a Public Limited Company and subsequently was renamed to its present name. In 2004, SCL set up a new facility for API manufacturing and currently offers a wide range of APIs and Advanced Intermediates to its Customers. These APIs and Advanced Intermediates cater to diverse Therapeutic segments such as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Cardiovascular System(CVS), Anti-Diabetes, Anti-cholinergic, Central Nervous System (CNS), Anti-filarials, Anthelmintics, etc.

SCL caters to both Domestic as well as International Market. It derives ~75% of the total revenue from the international market and the remaining ~25% from the Domestic market. SCL is engaged in manufacturing of Bulk Drugs/ Active Pharmaceutical Ingredients (APIs) and Advanced Intermediates. We provide CDMO Services to our clients in regulated markets of Europe, USA and Japan.

SCL has over the years expanded its presence across the globe with key export markets being Europe (France, Spain, Germany, Italy, Greece, Austria, Portugal, Slovenia, Netherlands, Denmark), the United States of America (USA), Turkey, Japan, Korea, Brazil, Russia & CIS countries, South & Central America, Middle East & Northern Africa (MENA) region & other Asian countries.

The Company is headquartered at Panchkula (Haryana) near Chandigarh and has 2 Manufacturing facilities (one each for intermediates & APIs) located at Derabassi, Mohali (Punjab) about 200Kms from Delhi. Marketing headquarter for the company is based out of Delhi NCR. Company has acquired 22acres of land for adding new facilities near the existing site.

The Manufacturing facilities of the Company comply with the United States Food and Drug Administration (USFDA), European Union Good Manufacturing Practices (EU-GMP), TGA Australia, MFDS Korea & Japanese Pharmaceutical and Medical Devices Agency (JPMDA).

Major Milestones

1990's — First manufacturing facility (for intermediates) set up in late 90's

2002 — Becomes largest supplier of Cephalosporin & Penem Intermediates in India

2004 — API manufacturing site set up

2005-2008 — First EU GMP Certification of API site in 2005, Subsequent approvals by Danish and German Authorities in, 2008, 2011, 2012 & 2015

2013 — Joint Venture with Mitsubishi Corporation, Japan

2014 — SCL receives WHO Geneva GMP approval

2015 — AFM registration with PMDA, Japan EU GMP by Danish Medicine, TGA Empanelment

2016 — USFDA Approval received, WHO GENEVA Empanelment, KFDA Approval, First CEP

2017 — Second USFDA audit conducted (Zero 483s), Second KFDA approval

2018 — Third USFDA audit, EIR received, Third WHO GMP audit

2022 — Second CEP

2023 — CBPF (Brazil) Approval, NMPA (China) Approval, Third CEP

2024 — Fourth CEP, EDQM Audit Cleared EUDRA GMP received

CDMO Services

We are leading provider of Custom development and manufacturing services to clients across Europe, USA and Japan and have more than a decade of successful experience of delivering the services on both Contract and FTE basis.

Some references of our CDMO partnerships:

- CDMO project for advance intermediate for European innovator Company.
- Development, Scale up and Contract manufacturing of APIs for large European Generic Pharma company for more than a decade.
- Collaboration for New Drug Application in Brazil for top Innovator.
- CDMO project for NCE and 505(B)2 filings in US for multiple clients.
- CDMO project for Niche/Orphan products, Co-development on an end to end model, exclusive basis for US based customer. Collaborative agreement for sales in defined territories.
- Development and Contract manufacturing of Advanced Intermediates (for NCE) for a Japanese MNC.
- Development, scale up and Contract manufacturing of five APIs for a Japanese MNC.

Research & Development

- With robust experience of over 29 years, the process research and development team of SCL Lifesciences have proven track-record of having executed the synthesis of complex active pharmaceutical ingredients (API) and intermediates. SCL Lifesciences have 100 + highly qualified scientists with strong scientific and academic background with rich experience. Our team excels at resolving complex scientific problems with a systematic approach in a time-bound manner while assuring the quality of all processes and product.

- Our experts devise the most effective route for the synthesis of novel/complex intermediate and API's and delivered value-added results for various API synthesis and process validations.
- Analytical Chemistry team at SCL Lifesciences provides analytical support to process development teams and carry out analytical method validations. Our analytical chemists apply chromatography, spectroscopy, mass spectrometry and nuclear magnetic resonance techniques to a wide range of chemical testing and analysis applications. Using highly sensitive instruments, the team conducts analytical studies at a high level of accuracy and consistency to accelerate the development of complex products.

SCL Knowledge Centre

- With an idea to encourage and enable creativity, SCL has set up a new Knowledge Centre in the hub of Pharmaceuticals in Hyderabad in the Genome Valley.
- The Centre houses development facilities to aid the emerging needs of preventive medicines and to help SCL overcome the volatility caused by worldwide events through parallel development of several Value-added Business streams.
- One of the key verticals at the SCL Knowledge Centre is focused on development of a portfolio of Ingredients /Components for the new applications in the Vaccine industry.
- Over the next few years, this Centre will create a pipeline of products for CDMO/CRO clients, focusing on niche API segments and develop key APIs for SCL's launch portfolio.

Quality Assurance

At SCL Lifesciences we are committed to provide Intermediates & Active Pharmaceutical Ingredients at utmost customer satisfaction through Quality Management System with respect to current Good Manufacturing Practices, by fixing quality objectives and reviewing these periodically for continual improvement.

- Quality Assurance at SCLensures compliance to National and International Regulatory cGMP requirements.
- The primary responsibility of Quality Assurance is to evaluate and assure the quality of all incoming materials, intermediates and finished products.
- Quality Assurance ensures that the quality systems, manufacturing procedures, warehousing practices, other connected support systems are in compliance with the current Good Manufacturing Practices.
- Qualification / Validation Program are planned throughout the life cycle of the product and facility.
- Computerized systems with potential for impact on product quality are effectively managed under a quality system which is designed to ensure that systems are protected from acts of accidental or deliberate manipulation, modification or any other activity that may impact on data quality and integrity.

Quality Control

We have a Fully equipped in-house laboratory including:

- Wide range of sophisticated 21-CFR-Part-11 compliant analytical instruments.
- Chromatographic instruments are hooked to Empower 3.
- Dedicated microbiological lab.
- Lab is well equipped to comply to upcoming ICH Q3D requirements of "Elemental Impurities" with In-House "ICPMS"

Manufacturing Units

API Facility

- API Plant (ZERO LIQUID DISCHARGE FACILITY)
- 3rd US FDA approval received in March 2018
- EDQM audit cleared in 2024
- AFM by Japanese PMDA, EUGMP, & WHO Geneva GMP compliant
- FDA and TGA Compliant
- Fine (8+1) Pharma blocks of class 100,000 including 2 Pilot and 1 Kg Scale facility
- High pressure reaction vessel block
- No. of reactors: ~100, Capacity: ~268 KL varying
- From 63 L to 6,000 L
- Capability for multistage, cryogenic reactions & high pressure and temperature reactions.
- Capability under addition – Cyanation

Small Volume Facility

KG Scale & Pilot Facility

- Equipment's' ranging from 63 L to 1000 L
- KG Scale HPAPI (High Potent API) facility
- Dedicated facility for production of low volume and high value APIs
- Facility compliant to cGMP and used for filings in USFDA, PMDA, EDQM, etc.
- Capability for multistage, cryogenic reactions & highpressure reactions and HPAPIs
- Independent powder processing and finishing area

Intermediate Facility

Intermediate Plants

- Largest facility in India for manufacturing of Cephalosporin and Carbapenems Intermediates
- Large capacity for Bromination (Bromine Handled: 3 MT/ day)
- Capability for multistage, cryogenic reactions & high-vacuum distillation Fully equipped laboratory with HPLC and GCs
- No. of reactors: 28, Capacity: 61 KL varying from 250 L to 5,000 L

Regulatory Approvals

USFDA
2015, 2017, 2018

PMDA AFM Registration
2014

PMDA
2019

EUGMP
2005, 2008, 2011, 2012, 2015, 2024

edqm
2024

TGA Australia
2018

KOREAN MFDS
2016

WHO GENEVA
2014, 2016, 2019

ANVISA
CBPF Approval Year (2023)


SCL

API Product List

PRODUCT NAME	CATEGORY	REGULATORY APPROVAL / FILING				
		USDMF	CEP/ ASMF	NMPA	ANVISA	Others
COMMERCIAL APIs						
Atropine Sulfate*	Mydriatic and Cycloplegic	✓	✓	✓	✓	MFDS, TGA, Health Canada
Carglumic Acid	Treatment of Hyperammonaemia	✓		✓		
Celecoxib	Analgesic, antipyretic and anti-inflammatory agent, NSAID	✓				
Chlorzoxazone	Muscle Relaxant	✓				
Clopidogrel Besylate	Antiplatelet		✓			
Clopidogrel Bisulfate (Form II)*	Antiplatelet		✓			MFDS
Dapagliflozin Propanediol Monohydrate	Type-II Antidiabetic	✓	Q4 2025			
Dexketoprofen Trometamol	Analgesic	✓	✓	✓	✓	MFDS, Russia
Diethyl Carbamazine Citrate	Anthelmintic	✓				WHO
Febuxostat	Xanthine Oxidase Inhibitor		✓			
Homatropine Hydrobromide	Anticholinergic medication Mydriatic and Cycloplegic		✓			
Homatropine Methylbromide	Anticholinergic medication Mydriatic and Cycloplegic	✓	✓		✓	
Ibandronate Sodium	Treatment of Osteoporosis					
Ipratropium Bromide*	Bronchodilator	✓	✓	✓	✓	
Ketoprofen*	Non-Steroidal Anti-Inflammatory Drug	✓	✓	✓	✓	Russia, MFDS
Ketorolac Tromethamine	Analgesic		✓		✓	MFDS, Russia, Health Canada, Kenya
Levofloxacin Hemihydrate*	Broad Spectrum Antibiotic		✓			
Nitisinone	4-hydroxyphenylpyruvate Dioxygenase	✓				
Obidoxime Hydrochloride	Antidote: Acetylcholinesterase Reactivator		✓			
Papaverine HCl	Erectile Dysfunction	✓		✓		MFDS
Pregabalin	Anticonvulsant Drug					
Probenecid	Treatment of Gout and Hyperuricemia	✓				
Ticagrelor	Antiplatelet		Q4 2025			
Tiotropium Bromide	Bronchodilator		✓	✓		
Vildagliptin	Anti-Hyperglycemic Agent		Q4 2025		Q4 2025	

* CEP Available

Disclaimer: Products protected by valid patents are not offered for sale in countries where the sale of such products constitutes a patent infringement. The liability of any sale into such protected markets is at buyer's risk.

API Product List

PRODUCT NAME	CATEGORY	REGULATORY APPROVAL / FILING				
		USDMF	CEP/ ASMF	NMPA	ANVISA	Others
APIs LAUNCHING						
Daprodustat	Treatment of Anaemia due to CKD	Q1 2026				
Bempedoic acid	Lipid Lowering Agent	Q1 2026				
Ketoprofen Lysinate	Non-Steroidal Anti-Inflammatory Drug	Q4 2025				
Tribenoside	Anti-inflammatory, analgesic, and wound healing properties	Q4 2025				
Empagliflozin	Antidiabetic	Q4 2025				
APIs UNDER DEVELOPMENT						
Ozanimod	Treatment of relapsing multiple sclerosis and ulcerative colitis	Q1 2026				
Edoxaban Tosylate	Direct oral anticoagulants (DOACs)	Q2 2026				
Tafamidis Meglumine	Transthyretin kinetic stabilizer	Q2 2026				
Vonoprazan	Potassium-competitive acid blockers (PCAB)	Q2 2026				
Isavuconazonium Sulfate	Azole antifungals	Q3 2026				
Upadacitinib Hemihydrate	Janus kinase (JAK)1-selective inhibitor	Q3 2026				
Finerenone	Treatment of Cardio-renal diseases	Q1 2027				
Ivacaftor	Cystic Fibrosis Transmembrane conductance Regulator (CFTR)	Q1 2027				
Resmetirom	Treatment of moderate to advanced Liver Fibrosis	Q2 2027				
Fezolinetant	Treatment of moderate to severe vasomotor symptoms due to menopause	Q2 2027				
Vibegron	Treatment of overactive bladder	Q3 2027				
Omaveloxolone	Used to treat Friedreich's Ataxia (A rare genetic neurodegenerative disorder)	Q3 2027				
Sparsentan	Genitourinary Agent (Reduce proteinuria in adults with primary immunoglobulin A nephropathy)	Q3 2027				
Cenobamate	Anticonvulsant	Q4 2027				
Atogepant	Oral CGRP antagonist; Anti-migraine	Q4 2027				
Solriamfetol HCL	Dopamine and norepinephrine reuptake inhibitor (DNRI)	Q4 2027				

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Intermediates List

Carbapenem Intermediates

- Benzylformimidate Hydrochloride [60099-09-4] Meropenem Intermediate
- 4-Nitrobenzyl Diazoacetoacetate [82551-63-1] Imipenem intermediate
- Mg salt of Mono 4-Nitrobenzyl Malonate [83972-01-4] Meropenem Intermediate
- 4-NitroBenzyl Alcohol [619-73-8] Carbapenem Intermediate

Cephalosporin Intermediates

- (z)-4-Bromo-2-methoxyimino-3-oxobutyric acid [79232-66-9] Cefpodoxime Proxetil Intermediate
- (z)-4-Chloro-2-methoxyimino-3-oxobutyric acid [111230-59-2] Cefpodoxime Proxetil intermediate
- 1-Bromo ethyl acetate [40258-78-4] Cefuroxime Axetil intermediate
- 4-Nitrobenzyl Bromide [100-11-8] Cefaclor intermediate
- Ethyl (Z)-2-(2' (tritylamino) thiazol-4-yl)-2-(trityloxyimino) acetate [69689-86-7] Cefdinir Intermediate

Tiotropium Intermediate and API

- Scopine di (2-thienyl) glycolate [136310-64-0]

Valsartan Intermediates

- 4-(Bromo Methyl) Biphenyl-2-Carbonitrate) [114772-54-2]
- L-Valine Benzyl Ester Hydrochloride [1462-34-2]
- L-Valine Benzyl Ester P-Toluenesulfonate [16652-76-9]
- L-Valine Methyl Ester Hydrocholoride [6306-52-1]

Lisinopril Intermediate

- L-Proline Benzyl Ester Hydrocloride [16652-71-4]

Aripiprazole Lauroxil Intermediate

- Chloro Methyl Laurate [61413-67-0] Aripiprazole Lauroxil intermediates

Naftifine Hydrochloride Intermediates

- Cinnamyl chloride [2687.- 12. -7]
- N-Methyl napthalene-1-methylamine [14489-75-9]

Epalrestat Intermediate

- Alpha Methyl cinnamaldehyde [101-39-3]

Lorcaserin Intermediate

- 2-Chloro-N-4- chlorophenylethyl) propane-1-amine hydrochloride [953789-37-2]

Zopiclone Intermediate

- 6-(5-Chloropyrid-2-yl)-5-hydroxy-7-oxo-5, 6-dihydropyrrolo [3, 4-b] pyrazine [43200-81-3]

Eprosartan Intermediates

- diethyl 2-((thiophen-2-yl)methylene)malonate [60-29-7]
- diethyl 2-((thiophen-2-yl)methyl)malonate [26420-00-8]

Dapagliflozin Intermediates

- 1-(4-bromo-2-chlorobenzyl)-3-ethoxybenzene [1996-30-1]
- Tetramethyl silyl gluconolactone [32384-85-9]

Dexetoprofen Intermediates

- ethyl 3-(1-cyanoethyl)benzoate [64-17-5]
- Ketoprofen [2271-15-4]

Clopidogrel Intermediate

- (S)-methyl 2-(2-(thiophen-2-yl)ethylamino)-2-(2-chlorophenyl)acetate hydrochloride [1258938-54-7]

Ticagrelor Intermediate

- benzyl (3aR,4S,6R,6aS)-4-(2-hydroxyethoxy)-tetrahydro-2,2-dimethyl-3aH-cyclopenta[d][1,3] dioxol-6-ylcarbamate [274693-55-9]

Methotrexate Intermediate

- Methylamino benzoyl Glutamic acid diethyl ester [2378-95-2]

Empagliflozin Intermediate

- 3-(4-(5-Bromo-2-chlorobenzyl) phenoxy) tetrahydrofuran [915095-89-5]

Other Intermediates

- 5-Chlorosalicylic amide [37893-37-1]
- 1-(2-Ethoxyethyl) benzimidazolone [101953-61-1]
- Para bromobenzldehyde [1122-91-4]
- 4-Nitrobenzyl Alcohol [619-73-8]

SCL Lifesciences Limited

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