SKANTTR LIFESCIENCE LLP — COMPANY PROFILE

Pioneering Precision in Cancer Care

CYTOTOXIC ANTICANCER APIS | GMP CERTIFIED — SCHEDULE M | CGMP COMPLIANT SYNTHESIS | CDSCO & DRDO APPROVED

Innovating Oncology API Solutions

GMP-Certified Manufacturer (Revised Schedule M) · Specialized in Cytotoxic Anticancer APIs

COMPANY INTRODUCTION

Delivering Uncompromising Quality for Life-Saving Therapies

Skanttr Lifescience LLP is a dynamic pharmaceutical company at the forefront of oncology API manufacturing. Our core mission is to significantly impact global cancer care through dedicated research, development, production, and worldwide marketing of high-quality cytotoxic anticancer Active Pharmaceutical Ingredients (APIs). We are driven by a commitment to innovation, stringent regulatory excellence, and the unwavering goal of providing accessible and effective solutions for patients worldwide. Our strategic foundation is built upon cutting-edge science and a deep understanding of the intricate needs of cancer treatment, ensuring every API we produce meets the highest standards of purity, potency, and safety.

20+	200kg	GMP	IP·BP USP
Oncology APIs in Portfolio	Monthly Production Capacity	Revised Schedule M Certified	Pharmacopoeial Compliance

RESEARCH & DEVELOPMENT

Innovating new synthetic pathways and optimising existing ones for enhanced efficiency and purity in API production.

PRODUCTION EXCELLENCE

State-of-the-art manufacturing facilities designed for high-containment and cGMP-compliant synthesis of cytotoxic compounds.

GLOBAL MARKETING & DISTRIBUTION

Establishing a robust supply chain to ensure timely and secure delivery of critical APIs to pharmaceutical partners worldwide.

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CORE FOCUS — CYTOTOXIC ANTICANCER APIS: 20 MOLECULES ACROSS 6 CATEGORIES

Targeting haematological & solid tumours · IP, BP & USP pharmacopoeial standards · cGMP manufactured

At Skanttr Lifescience LLP, our expertise lies in the meticulous manufacturing of a diverse and critical portfolio of oncology APIs — spanning alkylating agents, targeted tyrosine kinase inhibitors, antimetabolites, taxanes, hormonal therapies and novel targeted agents — developed and tested to IP, BP and USP standards.

ALKYLATING AGENTS — 4 APIs

Bendamustine HCL
CAS: 3543-75-7
Non-Hodgkin lymphoma (NHL), blood cancer and multiple myeloma.

Cisplatin
CAS: 15663-27-1
Widely used chemotherapy; forms DNA adducts causing apoptosis in cancer cells.

Carboplatin
CAS: 41575-94-4
Platinum-based agent; forms DNA adducts causing crosslinking and apoptosis.

Oxaliplatin
CAS: 61825-94-3
Platinum-based chemotherapy primarily for colorectal cancer.

TARGETED THERAPIES — TYROSINE KINASE INHIBITORS (TKIS) — 6 APIs

Imatinib Mesylate
CAS: 220127-57-1
Blood cancer and chronic myeloid leukaemia (CML); first-generation BCR-ABL TKI.

Dasatinib
CAS: 302962-49-8
Second-generation BCR-ABL/Src inhibitor for blood cancer and CML.

Nilotinib
CAS: 641571-10-0
Second-generation TKI for CML; effective in imatinib-resistant cases.

Gefitinib
CAS: 184475-35-2
EGFR TKI for non-small cell lung cancer (NSCLC).

Lapatinib
CAS: 231277-92-2
Dual TKI (HER2/EGFR) for HER2-positive advanced breast cancer.

Lorlatinib
CAS: 1454846-35-5
Third-generation ALK/ROS1 inhibitor for NSCLC; active against resistant mutations.

ANTIMETABOLITES — 3 APIs

Methotrexate
CAS: 59-05-2
Blocks DNA & RNA synthesis; used in various cancers and Rheumatoid Arthritis.

5-Fluorouracil (5-FU)
CAS: 51-21-8
Antimetabolite for colorectal, breast, stomach and pancreatic cancers.

Cytarabine
CAS: 147-94-4
Treatment of acute myeloid leukaemia and lymphomas; interferes with DNA synthesis.

TAXANES — 2

Paclitaxel
CAS: 33069-62-4
Breast cancer, ovarian cancer and lung cancer.

Docetaxel
CAS: 114977-28-5
Taxane for breast, lung and prostate cancers.

HORMONAL THERAPIES — 3

Letrozole
CAS: 112809-51-5
Aromatase inhibitor for breast cancer in post-menopausal women.

Anastrozole
CAS: 120511-73-1
Aromatase inhibitor for HR-positive breast cancer.

Fulvestrant
CAS: 129453-61-8
ER antagonist for HR-positive advanced breast cancer.

NOVEL TARGETED — 2

Olaparib
CAS: 763113-22-0
PARP inhibitor for BRCA-mutated ovarian and breast cancers.

Bortezomib
CAS: 179324-69-7
Proteasome inhibitor for multiple myeloma and mantle cell lymphoma.

✓ DMF READY

All **20 APIs** are **Drug Master File (DMF) Ready** — Fully Documented & Available for Immediate Global Regulatory Submission and Supply

✦ CDMO SERVICES

Contract Development & Manufacturing Organization (CDMO) Services Available — Leverage Our cGMP-Certified Facility & Expertise to Develop & Synthesise **Custom APIs Beyond Our Listed Portfolio**

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STATE-OF-THE-ART MANUFACTURING & QUALITY CONTROL FOR CYTOTOXIC APIS

Schedule M & cGMP compliant · SS 316-grade stainless steel · 100–200 kg/month capacity · Advanced in-house QC laboratory

MANUFACTURING INFRASTRUCTURE & EQUIPMENT

Our manufacturing infrastructure at Skanttr Lifescience LLP is built upon a foundation of unparalleled quality and safety, adhering strictly to Schedule M and current Good Manufacturing Practices (cGMP) guidelines. This commitment ensures the high-efficiency and contamination-free production of our cytotoxic anticancer APIs, a critical requirement for these sensitive compounds. Our facilities are designed with dedicated containment zones and advanced filtration systems to prevent cross-contamination and ensure the purity of each batch. We employ sophisticated process controls and meticulous monitoring to maintain optimal environmental conditions, safeguarding both product integrity and personnel safety.

KEY MANUFACTURING EQUIPMENT

200L, 50L & 20L Glass Assemblies — GMP Model: Essential for controlled chemical reactions, offering visibility and inertness crucial for API synthesis.

Vacuum Tray Dryer: For drying and removing moisture from APIs, ensuring product quality and batch-to-batch consistency.

20" Sifter — SS 316: Ensures particle size uniformity and removes all foreign matter, vital for API purity.

Octagonal Blender — SS 316: Provides efficient and homogeneous blending of powders, critical for consistent API batches.

Air Jet Mill — SS 316: Fine particle size reduction, enhancing API bioavailability and dissolution properties.

PLANT CAPACITY
Monthly Production Output

100 – 200 kg / month

PRODUCTION STANDARDS & COMPLIANCE

Schedule M (Revised) GMP	cGMP Compliant Synthesis
IP / BP / USP Standards	SS 316 Grade Equipment
High-Containment Zones	CDSCO & DRDO Approved

QUALITY CONTROL & ANALYTICAL CAPABILITIES

At Skanttr Lifescience LLP, our commitment to excellence is underpinned by an advanced, in-house Quality Control (QC) Laboratory. This state-of-the-art facility is the cornerstone of our operations, providing robust and reliable testing protocols that ensure every batch of API meets the most stringent quality standards. Our QC processes are integrated throughout the entire manufacturing lifecycle — from raw material inspection to in-process checks and final product release — guaranteeing unparalleled purity, potency, and safety of our cytotoxic anticancer APIs.

HPLC — Shimadzu 2050 Auto Injector

High-Performance Liquid Chromatography provides precise quantitative and qualitative analysis of API purity and impurities, ensuring adherence to pharmacopoeial limits. The auto-injector system enhances efficiency and reproducibility.

Gas Chromatography (GC)

Detection and quantification of residual solvents and volatile impurities in APIs, critical for ensuring product safety and compliance with international regulations.

IR Spectroscopy — Bruker

Confirms identity of raw materials and final API products by analysing molecular vibrations, providing a unique spectral fingerprint for each compound.

Stability Chambers

Precise control across three environmental conditions: 25°C/60% RH, 30°C/65% RH, and 40°C/75% RH — crucial for accelerated and long-term stability studies and determining API shelf-life.

Wet Lab with Titration Capabilities

Equipped for traditional chemical analysis including acid-base, redox and complexometric titration methods, essential for determining API assay and excipient compatibility.

Dedicated RO Plant

Reverse osmosis plant ensures a continuous supply of highly purified water for all laboratory operations, eliminating potential contaminants that could affect analytical results.

COMPREHENSIVE ANALYTICAL SUITE

This comprehensive suite of analytical tools and dedicated facilities enables us to provide precise, accurate, and reproducible results, reinforcing our reputation as a trusted manufacturer of high-quality oncology APIs. Every batch is subjected to rigorous multi-parameter testing before release, ensuring complete confidence in product quality for our pharmaceutical partners worldwide.

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OUR VISION

To become a global leader in the development and manufacturing of high-quality oncology Active Pharmaceutical Ingredients (APIs), dedicated to advancing cancer care through innovation, integrity, and excellence.

We envision a future where life-saving oncology treatments are accessible, affordable, and driven by science and precision. Through sustainable practices and cutting-edge technology, we aim to empower healthcare systems worldwide to make a meaningful difference in the lives of cancer patients.

- Excellence in quality — APIs meeting the highest international standards
- Sustainable innovation in all that we do
- Global accessibility — cost-effective oncology APIs for emerging & regulated markets

OUR MISSION

Skanttr Lifescience LLP's mission is to deliver high-quality, reliable and affordable APIs that empower global healthcare solutions.

- Adhering to highest standards of quality, safety & compliance
- Driving innovation through continuous R&D and technology adoption
- Building sustainable manufacturing capabilities with global scalability
- Collaborating with healthcare stakeholders to address unmet medical needs
- Upholding ethical practices and patient-centric values in all that we do

CERTIFICATIONS & COMPLIANCE

- GMP Certified — Revised Schedule M
- cGMP Compliant Manufacturing
- CDSCO & DRDO Approved Facility
- IP / BP / USP Pharmacopoeial Standards
- Pursuing USFDA & EUGMP Approvals

CLEAN ROOM & UTILITY SYSTEMS: MAINTAINING ASEPTIC ENVIRONMENTS

At Skanttr Lifescience LLP, the integrity of our cytotoxic API manufacturing process is critically dependent on maintaining highly controlled and sterile environments. Our state-of-the-art cleanroom and utility systems are engineered to meet the most rigorous international standards, ensuring the prevention of contamination and the safety of our personnel. These systems are meticulously designed for complete control over environmental and microbial parameters, which is paramount when handling active pharmaceutical ingredients used in oncology where purity is non-negotiable.

Class D Clean Room

Manufacturing facilities feature a Class D cleanroom, fully compliant with ISO 14644-1 standards. Meticulously controlled for airborne particulate counts, temperature and humidity, with advanced HEPA filtration minimising contamination risk from environmental sources.

Purified Water System

Robust PW system with a 0.5KL U-Loop online setup, ensuring a continuous supply of high-purity water for pharmaceutical processes including washing, rinsing and reagent preparation. Regular microbial and chemical testing guarantees pharmacopoeial compliance.

Fire Hydrant System

Facilities are equipped with a comprehensive, fully compliant fire hydrant system, strategically designed for rapid response to potential fire incidents. Regular drills and dedicated personnel ensure its operational readiness at all times.

Advanced Containment Zones

Dedicated high-containment zones for sensitive cytotoxic compounds ensure operator safety and product integrity. Advanced HVAC with pressure differentials, interlocked airlocks and continuous monitoring prevent cross-contamination.

Future Expansion: Towards a Global Oncology API Powerhouse

Skanttr's strategic vision for the next 3–5 years is ambitious and forward-looking, aiming to solidify our position as a preeminent global leader in oncology API manufacturing. By 2030, our goal is to evolve into a comprehensive global oncology API powerhouse — a trusted partner for life-saving cancer therapies worldwide.

FACILITY EXPANSION

Scaling up manufacturing capacity with advanced high-containment zones for cytotoxic compounds, to meet growing global demand and quality standards.

GLOBAL REGULATORY APPROVALS

Actively pursuing USFDA and EUGMP approvals to unlock access to major regulated markets, reinforcing commitment to global quality standards.

ADVANCED R&D CENTRE

Establishing a state-of-the-art R&D facility to drive innovation in oncology API synthesis and discover novel compounds.

GLOBAL PARTNERSHIPS

Forging strategic joint ventures and oncology formulation partnerships to expand our reach and integrate vertically within the pharmaceutical value chain.

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