cohance
lifesciences

Accelerating Advantage

Avra
CDMO Platform
Technology Division

Who we are

Cohance Lifesciences specializes in the research, development, and manufacturing of antibody-drug conjugate (ADC) payloads and derivatives aimed at revolutionizing targeted cancer therapies. Leveraging cutting-edge technology and expertise, Cohance Lifesciences delivers innovative solutions to meet the chemistry and technology challenges for the development and manufacturing of highly potent and complex Camptothecin and Auristatin derivatives.

Key Offerings

- Our expertise in the field of synthetic Camptothecin and Auristatin derivatives allows us to collaborate with innovators for process development of novel payloads.
- Our R&D has the expertise and capability to handle molecules in the range of OEL level ~20 nanogram /m3. This allows us to support our partners in process development, optimization, and material supply in the total product development process (from clinical study to phase studies)
- Our State-of-the-art GMP Cytotoxic manufacturing facilities are fully equipped to supply products from 500 gm to multiple kgs. from a single batch.
- Regulatory accreditation from the US and EU authorities and strong in-house expertise allow us to serve our partner in the registration phase of the product.
- Adherence to stringent regulatory standards ensures compliance with global quality and safety regulations.

ESG- Shaping Our World

ESG framework is an integral part of our operations. Silver Medal rating in the 2023 EcoVadis Global Sustainability Assessment along with ISO 14001, ISO 45001, and ISO 9001 accreditations.

- 17% Reduction in Water Consumption per MT produced
- 6% Reduction in Coal Consumption and CO2 Emission per MT produced.

- 12% Reduction in treated effluents per day.
- 33,000+ Tree Plantations since the acquisition, i.e. 30/day.

unity | simplicity | passion | accountability | agility

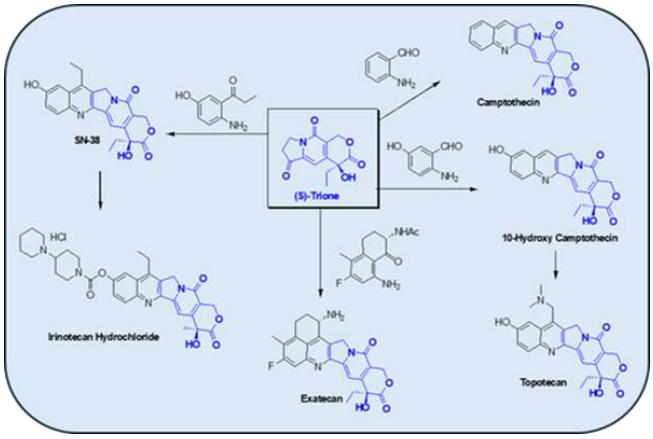
Development Capabilities:

Synthetic Camptothecin

- Cohance is the global pioneer in developing a fully synthetic route for the large-scale production of Camptothecin derivatives
- Our proprietary technology allow us to develop robust process through S-Trione intermediate for synthesis of different Camptothecin related war heads.
- Camptothecin derivatives such as Irinotecan, SN-38, Exatecan, Camptothecin, 10-Hydroxy Camptothecin, Topotecan, developed using the above technology.
- Supporting customers in both development and manufacturing of customized Campthothecin-based payloads

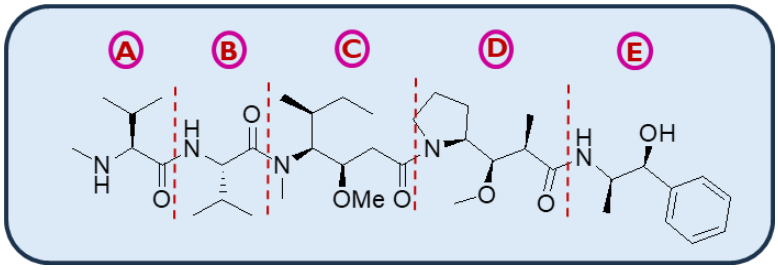
Exatecan

- Cohance has developed a fully backward integrated manufacturing process for Exatecan.
- All potential impurities are identified and controlled through the Quality by Design (QbD) approach with an appropriate specification in line with ICH small molecule acceptance criteria.
- Process validation is planned by Q3 2024.
- Exatecan mesylate (API) as well as 2 KSM/Intermediates ((S)-Trione (CAS# 110351-94-5) and Tetralone derivative ((CAS# 182182-31-6) are available.



Auristatins: Monomethyl Auristatin E (MMAE)

- Auristatin derivative (MMAE) is under development
- All potential impurities are identified and controlled through the Quality by Design (QbD) approach with an appropriate specification in line with ICH small molecule acceptance criteria.
- Process validation are planned by Q4 FY 24.



Our Manufacturing capabilities

DESIGN PHILOSOPHY OF ONCO FACILITY

MEN ENTRY / MATERIAL MOVEMENT

- Entry and exit are handled via different change rooms with door interlocks.
- The exit has a mist shower to decontaminate operational suits in case of a breach in the manufacturing area.
- At the exit, lesser pressure is maintained w.r.t manufacturing area pressure with 100 % exhaust.
- Only Dynamic Pass-boxes with door interlocks are used to bring materials into the facility.

TWO MANUFACTURING BLOCKS HANDLING CYTOTOXIC PRODUCTS

CAPABILITIES OF HANDLING CYTOTOXIC PRODUCTS ARE DEFINED BASED ON THE SURROGATE STUDY

MANUFACTURING AREA /LAB AREA

- The manufacturing facility is maintained with lesser pressure than atmosphere by BIBO HEPA equipped AHU's.
- Washrooms are also maintained with 100% exhaust through BIBO.
- Manufacturing areas are maintained as per ISO- 8 class standards.

ISOLATORS

- Negative pressure is maintained compared to room pressure. (-75 to -125 mm of WC)
- Material entry is done through intake pass box and through continuous linear port in exit.
- Wash liquid is collected in the catch pot. (filled with detoxification solution) after neutralization and detoxification it will be sent to the main effluent stream for further treatment.

Manufacturing facility- Kilo Scale facility (~1kg scale Batch size)

Sampling, dispensing & Pack-off isolator

Isolator with Reactors, PNF, VTD & Powder processing

Equipment details in Isolator-2	Capacity
All Glass Reactors- 2 No's	20 L
Hastelloy PNF- 2No's	7 L
VTD with Hastelloy trays	2 Trays
SS - Miller	ANA
Hand Sifter	NA

Equipment details in Isolator-1	Capacity
All Glass Reactors	20 L
Hastelloy PNF	7 L
VTD with Hastelloy trays	2 Trays

Manufacturing facility- Multi-kilo facility

Powder Processing Isolator

Reactor with Charging Isolator

Equipment details	Capacity
Glass Lined Reactor	630 L
SS Reactor	1500 L
SS ANFD	350 L
Hastelloy ANFD	350 L
Reactor Charging Isolator/ANFD Discharge Isolators- 2 No.	NA

Equipment Available in Powder processing & VTD Isolators	Capacity
SS-316 Vacuum Tray Drier with Isolator	6 Trays
Multi-Mill	10-24 kg/hr
Air-Jet Mill	100 mm Dia
Sifter	10-24 kg/hr

End-to-end Capabilities with

Development

Preclinical | Phase-I | Phase-II & III

- Supply of payload in gm scale during Preclinical studies – ensure the highest standards of quality and delivery timelines
- Strong In-house capability in Process and Analytical Development
- Process Chemistry and Optimization
- Unique expertise in Camptothecin Platform Technology
- New Capability in Auristatin Chemistry

Multiple Areas of Collaboration

Registration

Registration and Launch

- Multi-kilo facility with infrastructural and manpower capability to handle complex payload manufacturing
- Strong In-House Regulatory Expertise for global market entry
- Cohance platform offers facilities accredited by various regulatory authorities globally: US, EU, China, Japan, etc

Manufacturing

Commercial and late-stage Manufacturing

- Proven capabilities in scale-up and capacity enhancement to facilitate market expectation
- Proven regulatory expertise in lifecycle management (amendment approvals) and getting approval in new markets
- Infrastructure available to provide dedicated manufacturing lines as per business requirement

Registered Office

215 Atrium, C Wing, 8th Floor, 819-821, Andheri Kurla Road, Andheri (East), Mumbai – 400093, Maharashtra, India Tel: +91 22 61539999 Fax: +91 22 61539997

Corporate Office

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WEBSITE: www.cohance.com

API Manufacturing Sites

API Unit-IV
Cohance Lifesciences
Plot No.A-21, Road No. 10, IDA Nacharam, Uppal -500076
Telangana, India.

API Unit-V
Cohance Lifesciences
Plot No.48, Road No.7,
J.N.Pharmacity, Parawada,
Anakapalli District - 531021
Andhra Pradesh, India.

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