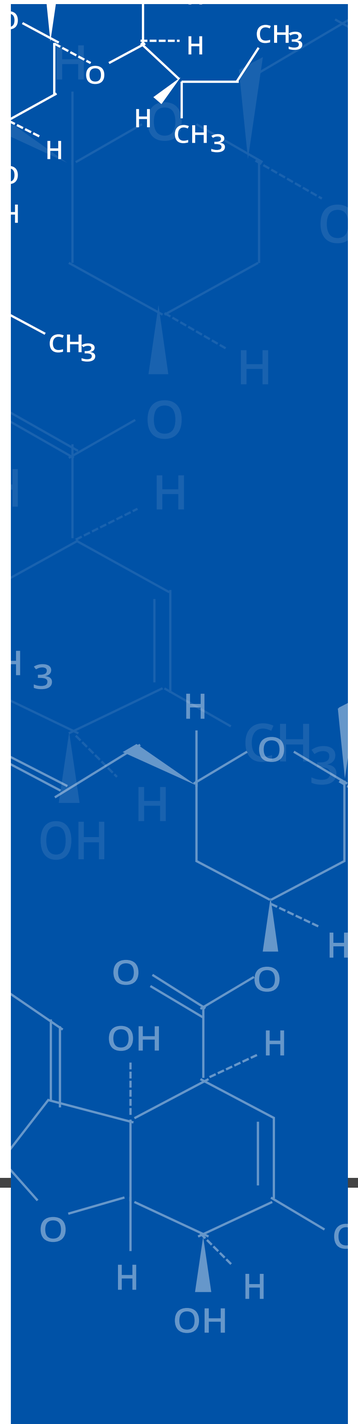
GlobeSynth
Pharma Tech



Specialized in the Synthesis of Pharmaceutical Impurity Reference Standards, API Impurities , Execution of pharmaceutical development, Product launch and analytical services

GlobeSynth
Pharma Tech

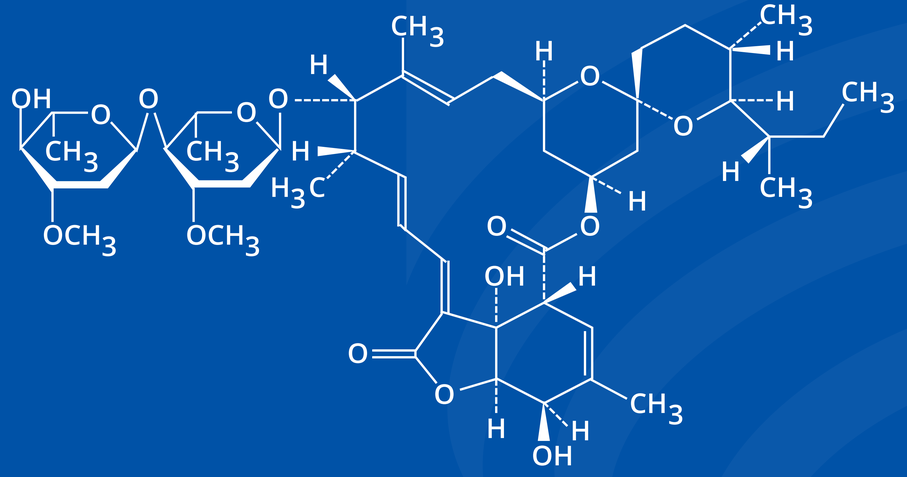
4/155 Soolaimedu,
Uthamacholapuram,
Salem 636010,
Tamilnadu, India

+(91)-82830 85118
+(91)-9115796473

contact@gspharma.tech
info@gspharma.tech

Scan me

Ivermactin EP Impurity D



WHO WE ARE?

GlobeSynth Pharma Tech is a CRO based company located in Salem, Tamilnadu, India. GSPT is a team chemists are well experienced with Ph.D. / M.Sc. degree.

We are expert in providing complex chemistry solutions to our customers from areas such as Pharmaceutical Impurity Reference Standards (Pharmacopeial and non-Pharmacopeial) , Process Impurities, API impurities, Degradation Impurities, Potential Impurities, Building Blocks, metabolites of active ingredients and excipients, Medicinal Discovery Chemistry, Custom Synthesis, Materials Chemistry, Library Design and Synthesis, Chiral Synthesis, Peptide Synthesis, Nucleic Acids Chemistry and Process Chemistry. Additionally we provide the accommodation of DMF Filling, Analytical Method Development and Validation to avail customers on Analytical quandary solving activities.

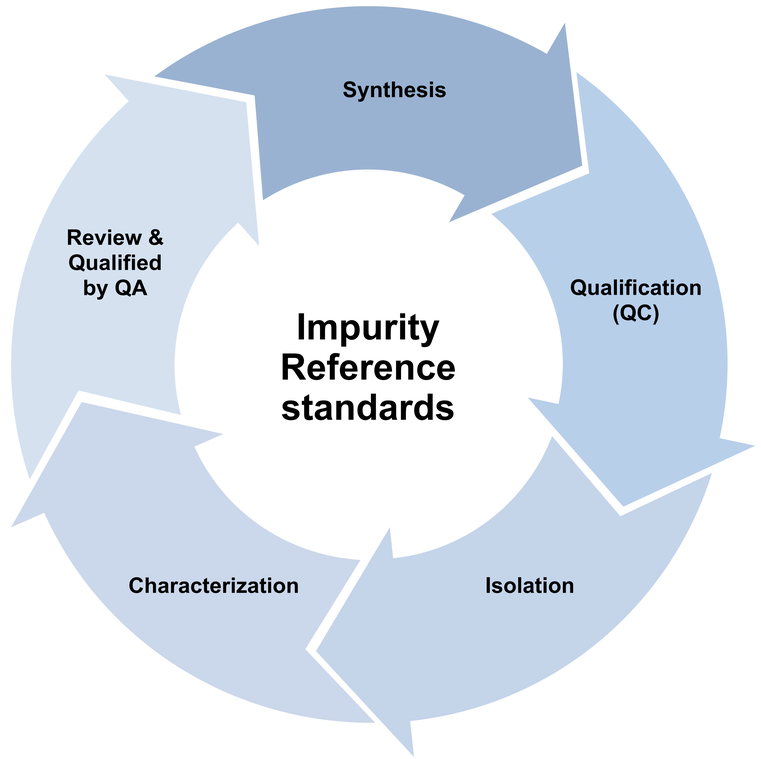
BULK QUANTITIES

We also supplies Bulk quantities of API, Fine chemicals, custom synthesis and impurities can be supplied for your toxicity testing and product development requirements.

QUALITY AND RELIABILITY

GlobeSynth Pharma Tech standards understand the industry's need for quality and reliability. Our analytical standards are thoroughly characterised and prepared in accordance with a robust quality system. We not only meet, but surpass the exacting pharmaceutical manufacturing standards necessary for the success of your project.

WHAT WE DO?



We are manufacturing impurity in mg-gm level. We also do Custom synthesis of complex organic molecules is our core business & competence with cost effectiveness.

The leadership team has more than seventeen years of drug development, Impurity Reference Standards, Contract Research and Manufacturing Services, API intermediates, Analytical method development, Validation and regulatory filing experience drawn from various well known reputed pharmaceutical companies.

GSPT also maintains a senior advisory committee, having very depth knowledge expanding their depth of expertise in pharmaceutical product development.

OUR SERVICES

CUSTOM SYNTHESIS

Our Custom Synthesis services are,

- Pharmaceutical Impurities Reference Standards
- Custom Synthesis of Impurities (mg to gm)
- Drug Metabolites, Photochemical & Gluconorides
- Custom Synthesis of complex organic molecules
- Large Scale API intermediates & Fine Chemicals
- API products from milligram to Kilo gram quantities
- Computation evaluation of Genotoxic impurities
- New NDDS molecules & Traceable Working Standards
- Process related impurities Degradation Products
- Contract Research Services
- API route scouting & process development
- Stable Isotope Labelled Products Isolation & Structure Elucidation of Unknown Impurities
- Isolation Purification of known and unknown Impurity from APIs and Drug products

OUR MISSION

Our main mission to help our clients will be the Active Pharmaceutical ingredients manufacturers who are willing to procure reference standards and intermediates which is either pharmacopeia or non-pharmacopeia with high quality standards of Data carrying Certificate of Analysis as per Standards.

2018

Reference Standards, Synthetic Research, Analytical Research, DMF Filling, Analytical Method Development Analytical Validation

2019

Labelled Compounds, Contract Research Services

2020

Photochemical & Gluconorides, LargeScale API, intermediates & Fine Chemicals

OUR VISION

"To become leading global Impurity Reference Standard Company and one among the top 10 by 2022" and mainly focus on sustainable and profitable growth to achieve our target customers are, India, US and Europe based markets.

ANALYTICAL SERVICES

Our Analytical services are

DMF Filling.

Analytical Method Development and Validation Services.

Method validations are performed to meet current ICH (International Conference on Harmonisation) guidelines. We can develop and write the protocol for method validations and protocols are prepared and experiments are executed to FDA/ICH guidelines for method validation.

Analytical problem solving activities.

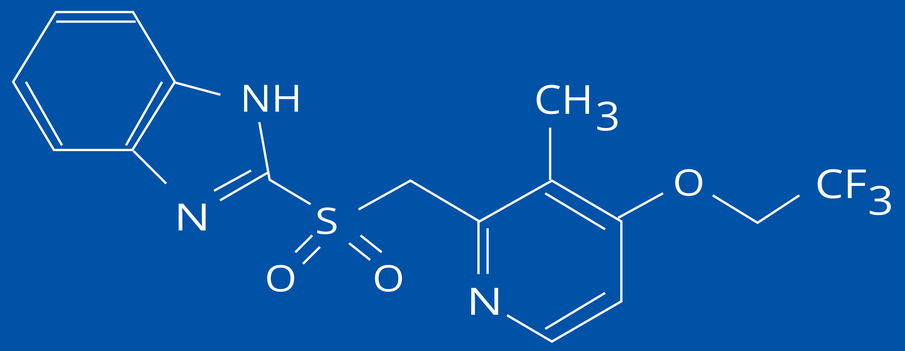
We followed Standard operating procedures (pharmacopoeial known method) are prepared and methods transferred to client laboratories, in case method is unknown we developed in-house method which relates with parent molecule by literature search or on the basis of customer method (Vendor qualification). Analytical problem solving activities include identification of unknown peaks, evaluation of methods with new products or processes, and investigation of faster and simpler analytical alternatives. The same tools are frequently used to troubleshoot processes, development and manufacturing a Compliance Analytical Lab.

Lansoprazole Sulphone

IMPURITY

EP Lansoprazole EP impurity B
USP Lansoprazole USP RC A

C No. 07.LAN.02
P No. L-056



CAS No.	131926-99-3
Appearance	Off-White Solid
Mol.Weight	385.36
Mol.Formula	C16H14F3N3O3S
Storage	2 to 8°C, Dark
Assay 'as is'	99.02%

IDENTITY

The identity of the reference substance was established by following analysis

S.No	Test	Result	Specification
1	HPLC Purity(%)	99.02% (Chromatogram Attached)	NLT 95%
2	IR	Conforms (Spectra Attached)	To Conform to Structure
3	HNMR	Conforms (Spectra Attached)	To Conform to Structure
4	LC/MS	Conforms (Spectra Attached)	To Conform to Structure

CERTIFICATE OF ANALYSIS (COA)

All products offered are thoroughly characterization and supply to our valuable customer with certified Certificate Of Analysis (COA) and supported by comprehensive analytical data like IR, HPLC purity, Mass and NMR. All data are looking closely reviewed and each project undergoes a R&D Head and technical QC review before releasing to our valuable clients. Our COA includes

FT-IR , HPLC Purity/ GC Purity, HNMR & MS (Mass Spectroscopy)

Apart from this, the customized reports with any of the following analysis are withal available on request

Chiral Purity

LC-MS

Thermo Gravimetric Analysis (TGA)

Loss on Drying (LOD), Moisture Content

CMR (Carbon-13 nuclear magnetic resonance), COSY (Correlation Spectroscopy)

HMQC (Heteronuclear Multiple Quantum Coherence)

Residual Solvents

Specific Optical Rotation (SOR)

Elemental Analysis(C,H,N)

Halide Content By Ion Chromatography (IC Purity)

Capillary Electrophoresis Analysis (CE Purity)

Preparative HPLC (separation)