

## Analytical Services & Solutions

Our full service state-of-the-art, USFDA registered, Maharashtra State FDA approved and ISO 9001:2015 certified analytical GLP and material testing laboratories are well equipped to characterise your materials and products. We provide clients with highly sophisticated testing support throughout product lifecycle.

### Extractable and Leachable studies

- For Pharmaceutical and Bio Pharma packaging material and process components.

### Method Development/Validation.

- Including Nitrosamines and other impurities.

### Medical Device testing

- Chemical Characterisation of medical device
- Gas pathway testing of breathing devices

### Failure Investigations

Testing is done as per following regulatory standards and guidelines:

- USP 661.1, 661.2, 665
- USP 1663, 1664
- USP 1660
- PQRI – OINDP & PDP
- ICH Q2: Validation of Analytical Procedures
- ICH Q3D: Elemental Impurities
- ISO 10993 – 18 for medical devices
- ISO 18562 – Gas Pathway.



## Our Vision

At GVS Cibatech we believe in a Safe and Sustainable future for Industry and all its stakeholders at large.

By working in partnership with our clients and applying our structured and practical approach. we strive to mitigate our client's risks and protect their brand value.

### Other Analytical Services offered:

Environmental risk assessment of Effluents from Pharmaceutical Industries – Testing of waste waters for trace amounts of API upto ppb levels.

Testing for VOCs from various matrices including automobile interior components, 3D printers etc.

## Our Instrumentation tailored for E/L and investigative analysis

Instrument	Make
TDS – GC/MS (TD-20)	GL Science/Shimadzu- QP2020
TDS – GC/MS (TD-30)	Shimadzu - 8050NX
HS – GC/MS	QP-2020EI with HS 20
LC/MS/MS	Shimadzu - 8045
Triple Quad – GC/MS	Shimadzu
Triple Quad Orbitrap LC/MS/MS	Sciex – 5500
ICP – AES	Shimadzu - 9820
HPLC	Shimadzu - LC 203C3D

## Our Experience

- Vials for Injection, Pre-Filled Syringes & Infusion Bags.
- Metered Dose Inhalers (MDI) & Nasal Sprays.
- Single use systems for Biologics.
- Ophthalmic solutions & suspensions.
- Transdermal ointments and patches.
- Liquid Orals and tablets.
- Medical Devices including implants, tubings, IV kits.
- Labels, Inks and Adhesives.
- Process tubing materials and filters.

For more details on the above or to request a visit from our experts please contact:

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## GVS Cibatech Pvt. Ltd.

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