

One Stop Hub for GMP Testing Requirements





Method Development & Validation



**Microbiological Testing** 



**Biowaiver Studies** 



**Impurity Qualification Studies** 



Extractables & Leachables



**Stability Studies** 



**Physical Characterization** 



**Bioassays** 







**Biologics** 



**Medical Devices** 



### **Our Services**



### **Specializations**

- » Extractables & leachables
- » Glass delamination
- » Ink and gum migration
- Method development & validation
- » IVRT & IVPT
- >> Impurity profiling studies
- » Dissolution profiling
- » Genotox impurities
- » Pepsin enzyme activity
- » Elemental Analysis
- » Population BE study

- » In vitro microbial kill rate studies
- » In vitro bioequivalence (BE) studies
- » Physical characterization (XRD, DSC, TGA, PSD)
- » Nasogastric studies
- » SEM analysis
- » Disinfectant efficacy studies
- » Bovine serum albumin studies
- » Human serum albumin studies
- » Batch release assays for recombinant protines & peptides
- » IIRMI studies

## **Routine Services**

- » Pharmacopoeia testing (IP/USP/BP/EP/JP)
- » Release testing, COA
- » Water testing as per USP/BP/EP/IP
- » Raw material analysis
- » Excipient analysis
- » Osmolality
- » Elemental analysis by AAS
- » Microbiology: MLT, BET, AET, sterility, environmental monitoring, water testing as per regulatory requirement, method development & validation
- » Water content
- » Liquid particle count
- » SOF





## **Stability Studies**

- » Clinical stability
- » Developmental stability
- » Follow-up stability studies
- » Registration stability studies
- » Transport stability studies
- » Freeze thaw cycling stability studies
- » Photo stability studies



Customer Specific Contract Labs

- » An extension of customer's own facility
- » Dedicated lab space, equipment, manpower
- » Co-management
- » Infrastructure for round the clock operations
- » Full Time Equivalent (FTE) model
- » Fee For Service (FFS) model

## Faclities & Technologies

- » Modern analytical laboratory spaces
- » Validated Laboratory Information Management System (LIMS) for sample tracking and results reporting
- » Large number of cold rooms dedicated for samples custody before, during and after analysis
- » Large stability storage capacities for conducting stability studies

# Instumentation

- » HPLC UV, PDA, RI, FL, ELSD
- » Prep -HPLC
- » UPLC UV-VIS PDA
- » UHPLC UV-VIS PDA
- » GC FID, TC, MS
- » GC-HS
- » GC -MS/MS
- » GC MS -TOF
- » GC-MS
- » LC MS TOF
- » HRGCMS

- » LC MS/MS
- » LC Q TOF
- » LC MS Triple TOF
- » CHNS
- » IC
- » DSC
- » TGA
- » pXRD
- » FT RAMAN
- » SEM
- » PSD
- » Zetasizer

- » Particle counter
- » FTIR, Near IR
- » DNA sequencer
- **»** qPCR
- » Capillary electrophoresis
- » i3X multimode reader
- » Particulate matter tester
- » ICP MS
- » ICP OES
- » AAS
- » Dissolution I, II, III, IV

## **Quality Management System**

An independent quality assurance unit comprising of trained and experienced professionals with analytical, quality assurance and regulatory compliance expertise is commi ed to Vimta's Quality Management System through:

- » Compliance to cGMP and ISO/IEC 17025:2005 requirements and ICH guidelines
- » Strong induction and continuous training programs
- » Routine process audits, internal quality audits and continuous improvements

## Accreditations, Licenses & Approvals

Vimta is routinely and successfully inspected by regulatory and accreditation authorities. Vimta is also audited by several customers every year. As a part of its commitment to continuous improvement external audits are actively encouraged by Vimta.















#### **About Vimta**

Highly experienced, modern laboratory with wide range of cGMP compliant analytical capabilities and large capacities are the strengths of Vimta's pharmaceutical analytical laboratories. Vimta is a service innovator and market leader in contract testing and analytical R&D services catering to the outsourcing needs of pharmaceutical, medical device, biotech and animal health industries across the globe.

Vimta has customers at the heart of its operations through pro-active project management, timely and transparent communications, scalable capacities to meet challenging time lines as well as large outsourcing needs, and adaptability to customer requirements, Vimta delivers signicant added value to the customers.



#### **Get in touch**

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