



Analytical Services at Calyx

The Spectrum

- Stability testing
- Analytical method development and Validation
- Force degradation
- Residual solvent validation
- Spectral data – NMR (400MHz), GC-MS, LC- MS, CHONS,
- Bio-Analytical services

Stability Testing

- Long term stability 250C/ 60%RH
- Intermediate stability 300C/65%RH
- Accelerated stability conditions 400C/75%RH
- Photo stability testing
- Conducted as per ICH Q1 A(R2) guidelines

Method Validation

- Pre validation study
- Preparation of validation protocol
- Conduct of validation study as per the protocol
- Validation Report
- Conducted as per ICH guidelines Q2B

Parameters for method validation:

- Specificity
- Linearity
- Accuracy
- Precision
- Limit of detection
- Limit of Quantification
- Robustness
- Ruggedness
- Solution stability.



A select list of Instruments for Analytical Services

Instrument	Specifications
NMR	400 MHz-
HPLCs	Detector - UV/ECD/PDA/RI/Chiral detector
GCs	Detector - FID/ Autosampler/Direct Injection, Headspace
CHONS	Estimation of Carbon, Hydrogen, Nitrogen and Sulphur
Ion Chromatograph	For cations and anion analysis
LC-MS with Trap	ESI/APCI Modes
GC-MS	EI / NCI / PCI & direct probe modes
FTIRs	with DRS 8000 system no requirement for pelleting
Flash Chromatography	For impurity isolation
Karl-Fischer (KF Apparatus)	For Moisture Determination
Potentiometer	Digital with direct printout
Stability Chambers	400+ liter capacity each
Preparative HPLC	For impurity isolation
UV-VIS Spectrophotometer	Double Beam, 0.001 nm resolution
Digital polarimeter	For Optical Measurement
Micro-Balances	6 Digit / 5 Digit
Analytical-Balances	4 Digit +
Ultra Pure Water Purifiers	TOC less than 1 ppb