



## Analytical Services at Calyx

### The Spectrum

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

### Stability Testing

- Long term stability 25°C/ 60%RH
- Intermediate stability 30°C/65%RH
- Accelerated stability conditions 40°C/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
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	As per ICH guidelines
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	Ultra high purity water