

In-vivo Pharmacokinetic Assays

1. Bioanalytical Method Development and Partial Validation.

For estimation of analyte concentration in biological matrix like plasma or brain, etc a quantitation method will be developed using MRM technique in LC-MS/MS system with adequate sensitivity. Method will be validated for Selectivity, Recovery, Linearity, Accuracy, Precision, Stock Solution Stability (24 hr), Dilution Integrity and Long Term Stability (1 week). Typically requires around 200 samples for completion.

2. Single Dose PK in rat

One test item, Three rats, oral or iv, fasting, 10 sampling points upto 24 hr, method development, one day validation and estimation using LC-MS/MS

3. Bioavailability in rat

One test item, Three rats, oral & iv, fasting, 10 sampling points upto 24 hr, method development, one day validation and estimation using LC-MS/MS

4. Intravenous Cassette dose in Rat

Four Test Item (+ one reference), three rats, iv cassette dosing, 10 samplings points upto 24 hr, method development, one day validation and estimation of five analytes in single method using LC-MS/MS

5. Brain Penetration Study in rat

One test item, Three rats per sampling points, oral, iv or ip dosing, fasting, 10 sampling points upto 24 hr, collection of blood and brain samples, estimation analytes in plasma and brain using LC-MS/MS (method development and one day validation charges as defined in 1)

6. Single Dose PK in dog

One test item, Three dogs (non-naïve), oral or iv, fasting, 10 sampling points upto 24 hr, method development, one day validation and estimation using LC-MS/MS

7. Bioavailability in dog

One test item, Three dogs (non-naïve), oral & iv, fasting, 10 sampling points upto 24 hr, method development, one day validation and estimation using LC-MS/MS

Suven Life Sciences Limited

Serene chambers, Road No - 5, Avenue-7 Banjara Hills, Hyderabad 500 034, INDIA

Tel: 91-40-23556039/38 Fax: 91-40-23541152

Contact : nvsrk@suven.com, knvishu@suven.com

8. Reactive Metabolite Identification in Rats

One test item, bile duct cannulated rat, IP dosing, fasting, 1 or 2 sampling points at 0.5-2 hr, collection of bile and LC-MS/MS analysis of extracted sample for presence of glutathione conjugates in either positive or negative mode.

9. CSF Pharmacokinetic Study in Rats

One test item, Three rats per sampling point, oral or iv, fasting or fed, collection of CSF by sacrificing the rat for each sampling point, method development, one day validation and estimation of compounds using LC-MS/MS

10. Free Drug Estimation in brain dialysate fluids (Microdialysis)

One test item, Three rats, oral or sc, subjected to stereotaxic surgery to implant a semi-permeable membrane probe into specific region of brain (hippocampus, cortex, striatum, etc), perfused with aCSF and collected dialysates will be quantitated for compound concentrations using LC-MS/MS method.

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