KYMOS

Stability
Services

- Testing of drug products or drug substances
- Small molecules and Biologics
- GMP & GLP compliance, EMA and FDA inspected

KYMOS PHARMA SERVICES, S.L.

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WIDE OFFER OF SERVICES

We use comprehensive method validation designs fit for purpose depending on test type and pharmaceutical development phase, being flexible to adapt our protocol to different client's requirements. Regulatory validations are carried out following relevant ICH guidelines and published USA and EU compendia guidances. We have large experience with methods used for different purposes such as:

- Preliminary stability studies for API and FDF
- Stress Testing studies
- Development & Validation of stability indicating methods
- ICH stability testing (long term, intermediate and accelerated)
- Photostability studies
- In use stability studies for multidose containers and parenteral solutions compatibility
- Holding time studies for bulk products
- Temperature cycle test, frezze-thaw and transportation
- On-going stability programs
- Determination of leachables migrated from packaging

MULTIPLE CONDITIONS

Walk-in climatic chambers available for conditions corresponding to ICH zones II and IVb and for semipermeable containers:

- 25° ± 2°C / 60% RH ± 5% RH
- 30°C ± 2°C / 75% RH ± 5% RH
- 30° ± 2°C / 65% RH ± 5% RH
- 40° ± 2°C / 75% RH ± 5% RH
- 25°C ± 2°C / 40% RH ± 5% RH
- 30°C ± 2°C / 35% RH ± 5% RH
- 40° ± 2°C / NMT 25% RH
- 5°C ± 3°C
- -20°C ± 5°C

Delta Controls® SCADA system for climatic chambers monitoring. Alarm system connected to maintenance services to keep operational conditions 24x7x365. Back up chambers available for disaster recovery plan.

QUALITY ASSURANCE

LIMS LabWare® management for the whole operation: protocol writing, specifications, sample reception, sample check up, storage location, pulling, sample analysis, data entry, OOS, OOT and incidence management, partial and final reporting.

FULLY EQUIPPED LABS

Laboratories in Europe, inspected by EMA and FDA authorities, with experience in development, validation and testing of small molecules and biologics.

Full equipped lab with more than 30 HPLC instruments of different models (Agilent 1100, 1200, 1260, 1290, Waters Alliance, HClass and Acquity) with a wide range of detectors (DAD, VWL, RI, FLD, LSD, MSD, AMPD), 6 GC instruments (TCD, FID with HS) and many other capabilities such as LC-MS, GC-MS, QTof, ICP-MS, AAS, CE, KF. Microbiological testing lab available including endotoxins and sterility testing.