

Formulation Service specialising in HFA 152a

Koura have launched a new formulation service designed to support early-stage development studies specialising in HFA152a with internal capability to formulate and test pMDI products at bench and pilot (5L) scale.

Services

Research and Development

- Analytical expertise in HPLC, HPLC-MS, GC, moisture
- MDI characterisation techniques
- Bench scale formulation optimization
- Materials compatibility with propellant
- Leachable testing
- Stability testing
- Expertise in lab scale flammable gas handling

Pilot scale manufacturing

- pMDI manufacturing facilities in Zone D/ISO 8 capable cleanrooms designed around filling of flammable propellants
- Production capacity
 - 200-2000 units per batch Single Stage or Dual Fill
- Facilities to sample/dispense APIs in low oxygen/humidity atmosphere
- Separate facilities for check weighing/stress testing/packing/storage

Quality Control laboratories and Quality Assurance Systems

- Capability and instrumentation to support pMDI incoming inspection and finished product testing
 - HPLC
 - GC
 - FTIR
 - Moisture
 - Aerodynamic Particle Size (Cascade Impaction)
 - Dose Uniformity
- Electronic GMP qualified systems implemented across business
 - Electronic Pharmaceutical Quality System (Documentation, CAPA, Deviation, Change Control)
 - Openlab CDS
 - LIMS

Dedicated expert team in

- Analytical chemistry
- Materials science
- MDI Characterisation
- Propellant handling and testing

Contact us today to see how we can work together

Get in touch at:



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