Advande Labs

Company Presentation

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Introduction

Advande Labs is an Analytical Laboratory offering testing services to the Pharmaceutical, Nutraceutical and Veterinary Industry.

We offer a complete line of analytical solutions across all stages of the drug life cycle, ensuring the highest quality (GMP and US FDA) standards with condensed timelines.

Modern facility, strategically located in Central Europe in the old city of Prague to capture a growing Global Pharma market.

Advande Labs has experienced staff using the latest techniques to provide a high-quality service in a timely manner to its clients.

Services

Analytical R&D (RDD)

- **Development of analytical methods**
  - HPLC, LC-MS, GC-FID, GC-HS, UV, Dissolution
  - Developed methods are prevalidated
  - Provided methods can be improved/adopted and checked before validation
- **Development of methods for determination of trace levels of organic impurities in API and dosage forms**
  - content of genotoxic impurities (GTIs) like nitrosamines, alkylmesylates, etc.
  - Mostly using LC-MS triple quadrupole
- **Analytical support of formulation development**
  - Excipient compatibility studies, pre-formulation samples

Services

Analytical R&D (RDD)

- **Identification of synthetic or degradation impurities, or contaminants in chemical substances and dosage forms**
  - Identification by LC-MS(UV), NMR, etc.
  - Impurity synthesis or isolation from the mixture
  - Full characterization by LC/MS (UV), NMR, IR - CoA of the impurity provided
- **Degradation studies of drug substances/products**
  - For the purpose of purity method development
  - For the purpose of physical and chemical stability check of the given drug
  - Mass balance study

Services

Analytical R&D (RDD)

- **Deformulation**
  - Analysis of qualitative and quantitative composition
- **Extractables & leachables studies**
  - Various pharmaceutical formulations
  - Various analytical techniques available
- **Drug permeation studies**
  - Skin permeation tests via Franz cell

Services

Quality Control / GMP (QCD)

- **Method validations and method transfers**
  - Preparation of method validation/transfer protocols
  - Validation according to the ICH and FDA guidelines
  - Reporting in method validation/transfer reports

Services

Quality Control / GMP (QCD)

- **ICH Stability studies**
  - Primary stability studies (long term, intermediate and accelerated)
  - Photostability studies
  - Temperature cycle studies
  - Transport studies
  - Ongoing stability studies

Services

Quality Control / GMP (QCD)

- **General Quality control testing**
  - Testing of process validation samples
  - Cleaning validation – method development/validation and routine sample testing
  - In-vitro dissolution studies (pH profiling)
  - Analytical support of manufacturing process
  - Testing of veterinary products and dietary supplements

Advande Labs features

- Analytical method development, validation/transfer, impurity identification
- Low level impurity determination, including GTIs
- Stability studies, QC testing
- Dedicated lab area specialized for highly potent drugs (incl. hormones)
- Certification – GMP, US FDA registration
- Fast exchange of information, data provision and reporting
- Excellent expertise in analytical chemistry
- Direct connection to responsible analysts

List of basic equipment

- HPLC – Agilent 1260 UHPLC Agilent (2), 1290 Infinity II (Agilent), Vanquish Core (Thermo) (2), Acquity H-Class (Waters) (6 in total)
- GC – Agilent 7890A (FID, HeadSpace)
- LCMS LTQ XL High Performance Linear Ion Trap - Thermo (1)
- LCMS TSQ Quantis – Thermo (2 in total)
- Dissolution – Sotax AT Xtend, Sotax AT (2 in total)
- UV/VIS Specord – Analytik Jena (1)
- Luminex™ 200™(flow cytometry) – Luminex (1)
- Osmolality - Wescor Vapro® Model 5600 Vapor Pressure Osmometer
- Stability Cabinets – 25°C/60%, 30°C/65%(75%), 40°C/75% - Memmert
- Light Exposure stability Cabinet - Memmert
- Highly potent drugs laboratory area with air lock system

Contacts

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