

Analytical services

Introduction

RPD TOOL focuses on products and services to support formulation R & D. However classical analytical services are an integrated part of our service offer. If you are looking for analytical services to support your formulation activities RPD TOOL is the expert. If you are analytical support in other fields there's no need to worry. Don't hesitate to benefit from our broad experience and discuss your needs with us. In most cases we will be able to offer you a package either based our automated sample preparation systems or in the classical way using manual operations. Both solutions meet highest quality and cost efficiency requirements.

Analytical services

The following list contains examples of our analytical service packages:

Physico chemical characterisation

RPD offers physico-chemical characterisation of drug substances, pre-formulations and formulations. Typically services include but are not limited to:

- Assay and impurities
- Solubility (aqueous and non-aqueous)
- Acid and base constants (pKa)
- Partition coefficient (log P)
- Compatibility with excipients and packaging material
- Solid state properties
- Titrations
- Physical parameters such as density, DSC, TGA
- Vibrational spectroscopy (Raman, Near- and Mid-infrared)
- X-Ray powder diffraction (XRPD)

Physical and chemical storage stability testing

Our unique lab automation tools and consumables enable the determination of the chemical and physical storage stability under a wide range of storage conditions (temperatur, humidity, light).

Photo- and oxygenation stability testing

Our unique lab automation tools and consumables enable the determination of the photo and oxygenation stability in accordance to relevant guidelines and under different conditions.

Method development and validation

We provide reliable analytical methods for various purpose such as

- Quality control of starting materials, ingredients, active materials and formulations
- Storage stability testing
- Drug characterisation and formulation development

All methods are initially validated to ensure and to document that the method is scientifically sound. When used in GMP environment, method validation and if required method transfer can be performed in accordance to the corresponding guidelines (i.e. ICH, Ph. Eur.).

High potent and cytotoxic substances

RPD TOOL is equipped with the latest technology and know how to handle high potent and cytotoxic substances. We place great emphasis on technical safety, staff training and education and last but not least well defined processes including systematic analysis of potential safety risks.

Analytical characterisation of reference substances

RPD TOOL provides a comprehensive service for the characterisation of reference substances of small molecules:

- Isolation, purification or enrichment the active ingredient or by-products if needed as reference substance for example by crystallisation, extraction, distillation or chromatography.
- Characterisation of the reference substance.
- Certification of the reference substance, meeting GMP requirements
- Packaging, storage and logistic according to customers need

Quality Control Analysis

Quality control analyses can be performed according to GMP quality standards for

- Drug substances and formulations
- Starting materials, intermediates and excipients

Method and sample transfer can be proceeded in a simple way and in accordance to GMP standard, ICH guidelines or bilateral agreements.

Please do not hesitate to contact us for further details of our unique analytical service packages!

Your RPD TOOL Team