



Dissolution: Testing in Pharmaceutical Analysis

Introduction

Why is dissolution testing important?

Dissolution testing is an essential part of pharmaceutical quality control and product development. It provides reliable information on the release profile of an active ingredient and supports the assessment of efficacy and expected bioavailability. In many areas of pharmaceutical quality control, it is an integral part of regulatory requirements.

Dissolution testing (also referred to as an in vitro release test) is used to quantitatively determine the rate and extent of active ingredient release from a solid dosage form under defined conditions.

Applications

Dissolution testing is well established for marketing authorisation procedures, batch release and stability studies. It covers tablets, capsules, pellets and granules.

- Quality assurance and quality control: verification of batch consistency
- Formulation development: optimisation of tablet and capsule release profiles
- Comparative studies / bioequivalence testing: dissolution as a surrogate for bioavailability

Practical implementation:

Dissolution testing requires controlled conditions, reproducible and traceable procedures, and precise analytical execution. At Interlabor, specialised dissolution systems and clearly defined test procedures provide reliable analytical data under controlled and reproducible conditions.

Dissolution testing at Interlabor Belp AG

Different dissolution systems are used depending on the dosage form and testing requirements.

Testing is performed according to Ph. Eur. 2.9.3 / USP Apparatus I (Basket) for capsules and unstable tablets, and USP Apparatus II (Paddle) for tablets, pellets and other solid dosage forms.

Active ingredient release takes place under reproducible conditions defined by medium, volume, temperature, stirring speed and time. Automated sampling with integrated filtration enables direct transfer into analytical vessels. Quantification is performed using appropriate analytical methods.

Centralised software with user management, audit trails and LIMS integration supports transparent workflows and full data traceability. Its modular design and different media options allow flexible adaptation to various dosage forms and product requirements.

Principle of operation

- USP Apparatus I (Basket) for capsules and unstable tablets
- USP Apparatus II (Paddle) for tablets, pellets and solid dosage forms
- Quantification of active ingredient release under reproducible conditions
- Standardised according to USP <711> and Ph. Eur. 2.9.3
- Measurement after automated sampling using UV, HPLC or other suitable techniques

Key Data for Dissolution testing at Interlabor Belp AG

Interlabor offers dissolution testing under the following conditions:

- Analysis quality: GMP-compliant and ISO 17025-oriented analytical services
- Methods: USP, Ph. Eur. and customer-specific methods using Basket or Paddle apparatus
- Sample amount: minimum 12 tablets
- Delivery time: depends on matrix and analyte
- Analysis price: on request

For further information or a tailored quotation, we will be pleased to assist you.

Conclusion

Dissolution testing provides valuable insight into the release behaviour and quality of pharmaceutical formulations. At the same time, it requires sound methodological expertise, reproducible testing conditions and high analytical precision.

Interlabor Belp AG supports its customers with extensive experience in pharmaceutical analysis, modern dissolution systems and clearly defined test procedures. This ensures reliable and traceable results for development, quality control and stability assessment.

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