Device Support

ERWEKA and Quasaar provide comprehensive advice on the necessary laboratory equipment.

- Design of customized dissolution apparatus for special dosage forms
- Design of specific adapters
- Adjustment or extension of relevant device parameters (temperature, volume, rotation speed, etc.)
- Provision and execution of qualification concepts
- On-site support by an experienced technical team

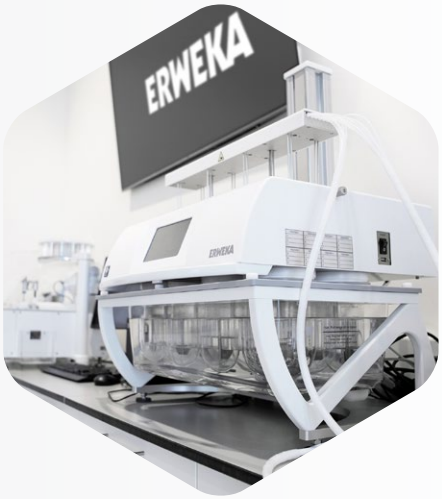
Contact

ERWEKA:
sales@erweka.com
+49 6103 924 26-200
www.erweka.com

Quasaar:
request@quasaar.de
+49 6826 818962-0
www.quasaar.de

ERWEKA

Quasaar



LABORATORY SERVICES

Access an extended range of tablet testing devices and pharmaceutical services with ERWEKA and Quasaar

Are you looking for comparative measurements and method transfers? Do you need a partner for method development and validation? Do you require dissolution studies under GMP conditions?

Then we are your partner to take your pharmaceutical project to the next level.

Comparative Measurements and Method Transfer

Together with Quasaar, ERWEKA offers a variety of services related to comparative measurements and method transfers - under GMP conditions and with the preparation of all relevant documents.

- Performance comparison of dissolution apparatus from different manufacturers and models
- Preliminary studies or formal method transfer under GMP conditions
- Experienced laboratory team provides on-site support and training if required
- Preparation of all relevant GMP documents and SOPs

Method Development and Validation

Method development is a complex process, and we can assist you throughout. ERWEKA and Quasaar also support revalidation, optimization, and troubleshooting.

- Complete development of dissolution methods from solubility testing and selection of apparatus type to definition of method parameters and demonstration of discriminatory power
- Development and validation of analytical methods for dissolution evaluation (e.g., U-HPLC, photometry), including full documentation
- Revalidation of methods following changes to method parameters (e.g., filters, sinkers, media, concentration range, formulation, etc.)
- Feasibility assessment for transitioning manual methods to automation (including validation)
- Optimization of dissolution methods (duration, media, robustness, etc.)
- Troubleshooting of dissolution methods
- Creation of test specifications and SOPs

Dissolution Studies

Do you require comprehensive dissolution studies, bioequivalence testing, or biopharmaceutical characterization? We can help.

- Determination of dissolution behavior for quality control and stability studies under GMP (including CoA or result report)
- Execution of profile dissolution studies in various media / pH values
- Bioequivalence testing via dissolution comparison of originator and comparator products (including SUPAC studies)
- Biopharmaceutical characterization of formulations
- Special dissolution testing: gastric resistance, buffer transitions, enzyme addition, infinity test, intrinsic dissolution, simulation media, influence of food, alcohol, stress conditions, etc.