HHAC
Labor Dr. Heusler GmbH

Analytics

Made in Germany

- Release Testing
- Stability Testing
- Climate Storage
- Highly Active Substances
- Method Development and Validation
- Release of active ingredients
- Analytics of Narcotics
- Scientific and Technical Advice

Managing Directors **Robert Scheurle** and **Thomas Walter**

Rapid **development** and **implementation** of methods for **pharmaceuticals** and **pharmaceutical raw materials**!

Our core competence

Labor Dr. Heusler

Since 1992, HHAC Labor Dr. Heusler has been one of the most renowned contract laboratories for the chemical and physical testing of pharmaceuticals and their raw materials in the European market. As a GMP-certified facility, we perform both release testing and stability studies. We offer sufficient capacity for storing stability samples under all standard temperature and humidity conditions. Our range of services also includes scientific and technical consulting services for analytics, stability studies, and GMP-relevant issues in general. The basis of our success is our highly motivated team of pharmacists, chemists, biologists, food chemists, chemical engineers and laboratory assistants, chemical-technical and medical-technical assistants, as well as administrative staff.

Our Competencies:

- Analytical expertise
- A confident and transparent relationship with our customers
- Scientific and technical feedback beyond the scope of the task
- Strict customer data confidentiality
- On-time delivery

Release Testing

Solid analytical expertise, state-of-the-art laboratory technology, and a wide spectrum of methods form the basis of HHAC's quality control testing on pharmaceuticals and raw materials in strict compliance with national and international regulations.

Each year, we analyze a broad range of samples for purity, content, active ingredient release, and other parameters. Our experience spans more than 500 active ingredients and excipients, ranging from chemically defined substances and antibiotics to vitamins and herbal drugs in a wide array of dosage forms.

GC

Our gas chromatographs are equipped with flame ionization detectors. We routinely use headspace sampling to determine residual solvents or other highly volatile components in pharmaceutical raw materials or finished products.

HPLC AND UHPLC

Our high-performance liquid chromatographs are optionally equipped with sample cooling, binary or quaternary pumps, and column switching valves.

We have an appropriate selection of detectors (UV-VIS, diode array, fluorescence) available for analysis work. Existing methods are adapted for UHPLC to improve chromatographic separation and to shorten the analysis time.

DISSOLUTION TESTING

Testing the in vitro release of an active ingredient from a dosage form is one of the common methods for routine quality control. HHAC has dissolution equipment from a variety of manufacturers with both manual and automatic sampling. Manual approval also allows tests to be carried out that are difficult to automate due to the media used.

HHAC tests the release of active ingredients from solid dosage forms using baskets, rotating cylinder and paddles as well as other applications, such as basket over paddle. Our dissolution testers are comprehensively calibrated according to USP specifications/FDA guidelines/Ph. Eur. or JP. We test dosage forms with unchanged, prolonged, or delayed release of the active substance. We also offer a wide range of dissolution profiles—from short-term profiles with sampling every five minutes to long-term profiles extending to 16 or 24 hours.

UV-VIS SPECTROSCOPY

For photometric measurements, we have several UV-VIS spectrometers with different applications at our disposal.

- Regular photometric measurements
- Photometric measurements with fiber optic probe
- Multi-component measurements

IMPURITY PROFILE

Active ingredients and finished products may contain impurities such as synthetic by-products, stability-related degradation products, or residual solvents. Complex HPLC or GC methods, including those used for antibiotic release testing, are routinely and rapidly established by our HPLC team.

We carefully evaluate impurity profiles during stability analyses and promptly check them for plausibility. If necessary, impurities can be identified using a diode array detector.

LABORATORY FOR HIGHLY ACTIVE SUBSTANCES

High-potency substances, including cytostatics, hormones, and antibiotics, are analyzed in a separate, isolated laboratory area secured by a lock system.

Stability Studies

We manage all aspects of executing stability studies from the planning to the documentation. We are also happy to take on in-use stability projects, stress tests, and photostability studies. This allows our customers to benefit from our many years of experience and from the opportunity for transparent cost controlling over the entire duration of a stability study.

For ICH-compliant test sample storage, we offer climatic chambers and cabinets, refrigerators and freezers, with the following storage conditions:

<-20°C	5°C	25°C / 60% RH
30°C / 65% RH	30°C / 75% RH	40°C / 75% RH
Specialized climate conditions can be arranged upon request.		

Method Development and Validation- Method Transfer and Verification

For customers who require it, we develop robust methods for routine operation and validate these to be ICH compliant. We also validate existing methods according to customer-specific SOPs or validation plans.

After successfully developing and validating the methods, we organize a fast and smooth process for their transfer to ensure their quick integration into routines. Customer test methods or pharmacopoeia methods are routinely implemented and verified according to a defined plan.

Scientific and Technical Advice

HHAC is on hand to provide its customers with advice on all areas of quality control from analytical questions to planning stability tests. Pharmaceutical manufacturers receive competent GMP consultation and support on setting up and further developing quality management systems.

Narcotics

In general, analytical testing of narcotics holds a special position, as in addition to the GMP and ICH requirements, the Narcotics Act must also be fully implemented.

Starting with the authorization and the permit to handle narcotics, this affects all subsequent steps in the process flow: from analysis and storage to the destruction of the narcotics samples.

Quality Management

HHAC operates a comprehensive quality management system based on GMP and DIN EN ISO/IEC 17025. The numerous measures include regular participation in interlaboratory comparisons, method transfers, staff training through seminars and training courses, and laboratory audits by external assessors. Our auditors regularly confirm that our quality management is not only a part of our manuals, but that it has been internalized by our employees.

RELEASE TESTING

Whether release tests for raw materials, intermediate products or finished medicinal products. Only optimal methods guarantee valid and maximally precise results. This is our area of expertise. For existing (customer-side) test procedures we organize the analytical method transfer.

STABILITY TESTS

From planning to final documentation: we are specialists in carrying out stability tests on active ingredients, medicinal products, medical devices and cosmetics.

CLIMATE STORAGE

For the storage of test samples according to ICH, HHAC provides you with qualified climate facilities under controlled storage conditions.

HIGHLY ACTIVE SUBSTANCES

Handling highly active and toxic substances requires both specific know-how and a specially designed working environment. HHAC offers you both.

METHOD DEVELOPMENT AND VALIDATION

We develop customized methods for robust, reliable routine operation and carry out the validation of purity, assay and dissolution methods, for example.

DISSOLUTION

We have many years of experience in the development and validation of methods for testing the in vitro release of active ingredients.

CONSULTING

We are your sparring partner for scientific and technical advice on analytics or stability tests, chemical-physical issues and QM topics.

PHOTO STABILITY TESTING

A light/climate cabinet is available for carrying out photostability tests in accordance with the ICH guideline

SCIENTIFIC AND TECHNICAL CONSULTING

Chromatography Equipment

- HPLC with DAD, UV/Vis and fluorescence detector and UHPLC devices
- Gas chromatographs (GC/FID) with headspace application
- Thin-layer chromatography with DC applicator and densitometer

Analytical devices

- Titrators, Karl Fischer titrators (volumetric, coulometric)
- Refractometer
- Density meter (oscillating U-tube)
- Moisture analyzer (infrared dryer)
- Turbidimeter
- Particle viewing station
- Distillation apparatus (Kjeldahl, steam, rotary evaporator)
- Conductometer
- Cone-plate viscometer
- Osmometer
- pH meter
- Incubator shaker
- Drying ovens
- Vacuum drying oven

Technical equipment:

Our goal is to provide optimal support to our customers. Therefore, we work under light-protected conditions when required and analyze highly active substances in specially shielded and secured laboratory areas.

Spectroscopy

- UV/VIS spectrometer
- IR spectrometer

Special devices for pharmaceutical analysis

- Dissolution testers with basket, paddle, rotating cylinder or special equipment
- Disintegration testers
- Resistance to crushing testers
- Friability testers

Auxiliary equipment

- Mills, muffle furnace, shakers, water and ultrasonic baths

Short Overview of HHAC **Services**

Release testing (chemical-analytical) **within 3 days**

- Raw materials testing
- Qualitative and quantitative determination of active ingredients and excipients in the finished product
- Testing for release specifications
- Pharmacopoeia compliance testing
- Development and validation of product-specific test methods for release testing
- GMP-compliant testing and documentation

Stability studies

- Test planning/logistics
- ICH guideline-compliant storage of stability samples under controlled climatic conditions
- Stress tests
- Developing and validating stability-specific methods
- Stability analysis with modern analytical instruments
- Stability report and complete documentation for approval documents

Certification

- Good Manufacturing Practice (GMP)
- Manufacturer's Authorization for human and veterinary medicinal products
- Permit from Federal Opium Agency Germany

Stability Storage

Storage in accordance with ICH guidelines.
The following storage conditions are available:

-20°C	5°C	25°C / 60%RH
30°C / 65%RH	30°C / 75%RH	40°C / 75%RH

Specialized climate conditions possible on request.

Photostability tests

A light/climate cabinet is available for carrying out photo-stability tests in accordance with the ICH guideline.

Method development and validation as well as method transfer and verification

Scientific and technical advice

Analysis of:

- Active pharmaceutical ingredients
- Finished medicinal products
- Active ingredients and excipients in pharmaceutical manufacturing incl. highly active substances
- Medical products
- Narcotics
- Chemical-physical testing of further substances

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