Solutions to control your quality processes

PHARMACEUTICAL ANALYSIS

Chromatography & mass spectrometry
Conventional equipment
Physicochemical tests
Inorganic analyzes
Molecular spectroscopy

HTDS
Hi-Tech Detection Systems

TECHNOLOGY, EXPERTISE AND SUPPORT ....
... TO GUARANTEE YOUR SUCCESS

The pharmaceutical industry uses intensively the majority of recognized analytical techniques both in the research and development phases of new molecules and in the produtction and quality control of drugs. For each production, thousands of analyzes are carried out daily following the main stages below:

SUPPLY AND STORAGE
For the identification, and the characterization of the raw materials before their integration into the production process : purity, concentration, water content, granulometry, ...

QUALITY CONTROL
To ensure the quality of all manufacturing processes using various and regulated techniques.

RESEARCH AND DEVELOPMENT
For analyses at each stage of the R&D processe : molecular screening, toxicology, formulation, Physical testing, dissolution, ...

PRODUCTION
To control all stages of production with online systems such as TOC, press hardness test and blending.

CONDITIONING
For the checking of the contents, the stability and the physicochemical properties of the finished products.

Most of the analysis techniques are available at every stage to ensure a production process that guarantees the quality of finished products and a quick release of batches:

	SUPPLY AND STORAGE	QUALITY CONTROL	R&D	PRODUCTION	CONDITIONING
ICP		•	•		
ICP-MS		•	•		
Raman spectrometry	•	•		•	
IR microscopy			•		
FTIR	•	•	•		•
GC	•	•			
GC-MS		•		•	
HPLC-UPLC-UHPLC	•	•	•	•	
LC MS MS			•		
TOC		•		•	
Thermal analysis		•	•		
Particle analysis		•	•		
Physicochemical tests		•	•	•	
Balances	•	•	•	•	
Titrators / pH meters		•	•		
Refractometers		•	•		
Dissolution		•	•		
pharmacotechnical controls		•	•		

For each technology, HTDS offers suitable solutions and provides its expertise at each stage of the implementation of your solution : consulting, installation, validation and qualification of equipment, training (on site or in training centers) and maintenance.

CHROMATOGRAPHY & **MASS SPECTROMETRY**

Historically, chromatography is the main analytical technology of the pharmaceutical industry. The chromatography techniques coupled with mass spectrometry are becoming more and more popular with pharmaceutical companies because of the increased focus of research into biochemical and biological substances for the elaboration of new drugs.

CHROMATOGRAPHY IN LIQUID PHASE (HPLC / UHPLC / UPLC)

Apply Pharmacopoeial methods in HPLC, UPLC or UPLC without revalidation.

- Reduced time and cost of analysis, solvent saving and simplified solvent management
- Transfer without revalidation of the isocratic Pharmacopeia methods on particle sizes 2.x µm
- Double fluidic circuit (HPLC and UHPLC) allowing the exact reproduction of your gradient HPLC analysis carried out on your HPLC chains whatever the brand is
- A complete consumables range for all your LC analysis and sample preparation

MASS DETECTOR

Reduced time spent on research and development with simple quadrupole mass detection.

- The size of a UV detector, combines with HPLC, UHPLC, UPLC Waters solutions.
- Time saving during method development : identification by the «peak tracking» mass
- Detection of impurities without chromophores
- Detection of coelutions
- Compatible with Empower 3 without compromise
- Does not require any specialist
- Quick start : < 20 min
- Option with diversion valve to reduce system maintenance

Focus on

Chromatographic Data Software LC & GC EMPOWER 3

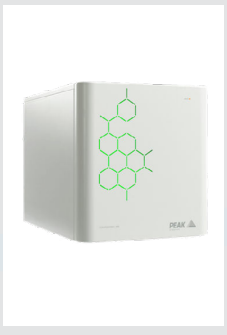
The Empower 3 chromatographic data processing and data management software facilitates sample analysis and reliable results. The Empower 3 software interface is designed to maximize your productivity by improving the acquisition, processing, and editing of chromatographic data. Software features include custom reports and calculations, task management defined and optimized by user and analysis ...

Equipped with features to ensure compliance with 21CFRChapter 11, Empower3 enhances data integrity, security, and traceability. Empower3 software is designed to integrate with existing IT infrastructures. It offers high performances in network configuration.

GAS CHROMATOGRAPHY (GC - GC / MS)

- Adapted for quality control of raw materials and finished products (eg identification and quantification of impurities, residual solvent in the active ingredients)
- Time saving during methodes development with GC / MS
- GC/MS able to identify very small quantities of impurities
- GC/MS ideal for analysis of toxicology, pharmacological screening or bio-availability (search for active principle in blood, urine or other tissues)

Focus on



Gas Generators for GC and LC / MS / MS

Our gas generators meet GC, LC/MS applications requirements. For greater safety and autonomy of your laboratories, we offer a complete range of gas generators:

- Nitrogen generators
- Hydrogen generators
- High purity nitrogen generators
- Zero air generators
- Combined nitrogen / air

HTDS can also assist you with specific needs in gas generators to meet a large number of applications beyond the laboratory (nitrogen and oxygen of high purity in pharmaceutical manufacturing).

CONVENTIONAL **EQUIPMENT**

TITRATION & KARL FISCHER

The new generation of our Titrators and Karl Fischer ensure you safety, simplicity of use, reliability and traceability essential to the pharmaceutical industry for the determination of daily contents (acid-base, oxidation-reduction, argentimetry, water content ...).

- Simplified routine use in one click!
- Simple, modular and evolutive instruments (Evolution to multiparametric analyzes)
- Possibility of automation
- Sample preparation / integrated solvents
- Traceability of analysis and samples (Printer, CFR21 Dual Mode Software, Smart Sample RFID)

DENSITY MEASUREMENT AND REFRACTION INDEX

- Portable, benchtop or multiparameter solutions for simultaneous quality control of density refractive index, pH and color
- Possibility of automation
- Traceability of analysis (Printer, CFR21 Software in Dual Mode)
- Pumping sequence, cleaning, integrated CheckCell
- Simplified one click routine use

pH / COND / DO

- Benchtop or portable instruments (waterproof)
- Single-parameter or multi-parameter scalable systems (pH, dissolved oxygen conductivity)
- Routine models or GLP traceability (printers, software ...) with administration levels (4)
- Plug'N Play recognition of electrodes and calibration monitoring
- Creation of flexible methods and customizable calculations
- Simplified one click routine use
- Full compliance with pharmaceutical regulations (EP or USP)

BALANCES AND MICROBALANCES

Crucial steps in throughout an analysis, the weighing operations carried out with the Excellence Balances guarantee reliable and repeatable results in the long term.

- Perfect ergonomics for fast and accurate weighing
- Tray iInterchangeable and adaptable tray to all containers (weighing shoe, beakers, eppendorf tube, standard HPLC bottle ...)
- Automatic drift control (electrostaticity, temperature change, leveling, etc.)
- Protection of the weighing cell
- Possibility of upgrading to the automated QUANTOS standard preparator

TOC **TOTAL ORGANIC CARBON**

We offer dedicated instruments for the surveillance of pure or ultra pure water networks. The unique selective membrane technology ensures reliable and non-interfering results. Our TOCs are available in laboratory, portable or online versions. TOC (Total Organic Carbon) is a fast, and inexpensive solution that will guarantee a reliable procedure for cleaning validation with a detection of all contaminants : active ingredient, excipients, detergents, recombination products, etc.

Compliance with Standards: CFR 211.676 / ICH Q7 (Cleaning Validation / EP 2.2.44 / USP27 (TOC)..

PHYSICO-CHEMICAL **TESTS**

Physicochemical tests on pharmaceutical products (tablets, suppositories, capsules ...) are essential steps before being able to release the batches. Having solutions that meet pharmaceutical (EP or USP) standards, robust and reliable is the priority of HTDS.

DISSOLUTION TESTS

To edit dissolution profiles in accordance with USP regulations.

- Reliability and robustness of results with Easytouch screen control with 100 protocols, totale visibility with circular bath
- Modular and scalable design for adaptation to all products (USP1 / 2/3/4/6/7) and rates
- Manual version, ON / OFF line UV or HPLC, or fully automatic on bench or independent
- Ideal for reputedly difficult analyzes like dissolving suppositories with a continuous flow bath (USP4)

PHYSICAL TESTS

A full range of physical testing for IPC and QC.

- Hardness, friability, disintegration, torque meter, flow, settlement
- Modular device, adjusting to the number of your samples, manual, semi automatic or automatic mode, coupling to any presses with different parameters
- Intuitive software, CF21 part 11 and respected data integrity with multi-instrument software (Sotax and others) Q Doc

SAMPLER PREPARATOR FOR UNIFORMITY TESTING

Assurance of reproducibility and time savings in sample preparation.

- Automatic range for dilution, centrifugation, uniform mixing and weighing with management. of 100 to 300 samples to reduce your preparation time
- Ease of transferring methods with feasibility study

ANALYSIS **OF PARTICLE SIZES**

LASER GRANULOMETRY

For particle size control of excipients and APIs.

- Wide size range: 0.01µm to 3500µm
- Range of Plug'N Play samplers in dry or liquid process
- Simple and fast measurements: results in less than a minute
- Compliance with pharmaceutical regulations : EP 2.9.31, USP776

ZETAMETER

For stability control of suspended particles or emulsions.

- Precise and fast determination of the stability of the formulations and control of the performances
- Effective screening of candidates (vaccines, bio-medicines, ...)
- Automated measurement of Zeta potential as a function of temperature, pH ...
- Zeta potential handsets and particle size

ANALYSIS OF SPRAYS

For the control of the size of the droplets emitted by the sprays.

- Rapid analysis of sprays and aerosols
- Flexible system : measurement of sprays, MDI, DPI, nebulizers ...
- Full measurement chain control (actuation, measurement, evacuation) for better repeatability

ANALYSIS OF GELS AND CREAMS

For the control of the physical characteristics of creams, gels and emulsions.

- Rheometers for the characterization of syrups, emulsions, creams, pasty products
- Determination of viscoelasticity parameters : viscosity, pour point, stability over time or under stress, influence of temperature, vibration and time on a product performance
- Modular and scalable design for adaptation to all products (plan, cylinder systems ...)

INORGANIC **ANALYSIS**

In the process of production, some inorganic elements are part of the actual composition of drugs (Li, Mg ...), while others must not exceed a certain threshold of concentration. For decades, unreliable colorimetric methods have been the only tests available for the control of elemental impurities. Today, the US (USP 232 and 233), European (EP5.2, EP2.4.20), Japanese, and ICH (ICH Q3D) common pharmacopoeia have enlisted and use modern elementary control technologies : ICP, ICPMS and microwave mineralization for sample preparation.

ATOMIC ABSORPTION (AA)

- Flame technology for major element analysis and furnace technology for trace analysis
- Mono elementary technology remaining fast in flame mode
- Examples of pharmaceutical applications : determination of lead in sugar using flame mode

Focus on

Definition of the limits of conformity

The new standards for the analysis of metallic elements in drugs take into account several parameters to define the limits of conformity :

- The toxicity of the elements: Hg, As, Pb and Cd being the essential elements
- The Galenic form: oral, parenteral, inhalation, LVP
- The daily dose

OPTICAL ICP

- Recommended solution to ensure compliance with new standards
- Multi-elemental technology allowing a fast assay of all the elements of interest in an analysis
- Better Detection limits than those achieved by SAA flame
- Argon consumption reduced by 50%

ICP-MS

- Ideal solution to meet the new standards because it is the only technology which will make it possible to reach the concentration limits described in the standards, whatever the galenic form is
- ICP-MS allows the detection of the lowest levels for the determination of elements, often less than the ppt
- Fast multi-elemental technology

Focus on

Sample preparation

The standards describe several methods of sample preparation:

- Dilution for fully soluble drugs either in aqueous media or in organic media
- Acid mineralization for which the use of microwave digesters is required

HTDS offers suitable solutions for both of the methods

THERMAL **ANALYSIS**

A powerful set of methods for the characterization of pure substances and mixtures. Ideal for purity studies, determination of melting or glass transition temperatures, polymorphism studies, determination of phase diagrams ...

Versatile tool to solve problems including research & development, quality assurance and packaging control.

MOLECULAR **SPECTROSCOPY**

In the pharmaceutical industry, the need to control each product, identify and qualify (purity, content) each raw material, pushes scientists to search for fast and reliable methods of identification and analysis, minimizing the steps of sample preparation. HTDS offers a choice of spectrometers to suit different applications.

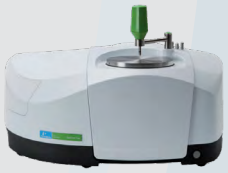
Focus on

Portable Raman Spectrometer - TRUSCAN RM
Compliance with pharmaceutical regulations PE 2.2.48

Raman spectroscopy is a reliable and efficient technology for instant authentication of incoming raw materials. HTDS offers the first portable raw material analyzer specifically designed to meet the needs and standards of the pharmaceutical industry. This technology offers the advantages of FTIR and NIR without its disadvantages: simple methods, no sample preparation!

The «Point and Shoot» system allows the measurement to be carried out through various packages. With a weight of less than 0.9 kg, TruScan RM can be used wherever fast material verification is required. An ideal solution for your quality control applications to avoid the multiplication of samples. The Truscan RM is also available for identification of counterfeit medicines with its own library and allows you to quantify your mixtures of materials (semi-finished products, finished products, blister products, ...).

FT-IR & FT-NIR



FTIR
- Traditionally for quality control of pharmaceutical products
- Sample preparation and simplified data analysis (ATR accessory, atmospheric correction, AVI)

NIR
- Does not require any sample preparation
- Allows even higher rates
- Offers the possibility of multi-parametric analyzes

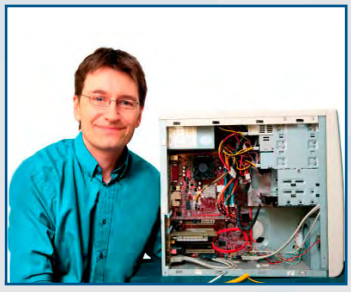
IR MICROSCOPY & IR IMAGING

- Spectral method giving access to a large amount of information
- Ideal for checking the homogeneity of powder mixtures, identifying the compounds present in pharmaceutical tablets or the distribution of the active ingredient on the tablets

SPECTROSCOPIE UV-VIS

- Ideal for OD measurements, assay, spectra, kinetics or for more precise applications such as DNA melting point, enzymatic kinetics, purity assay, etc
- Solution approved by laboratories subject to validation and qualification requirements

Focus on



Installation Qualification (IQ) Validation - Qualification Operational (QO) - Performance Qualification (QP)

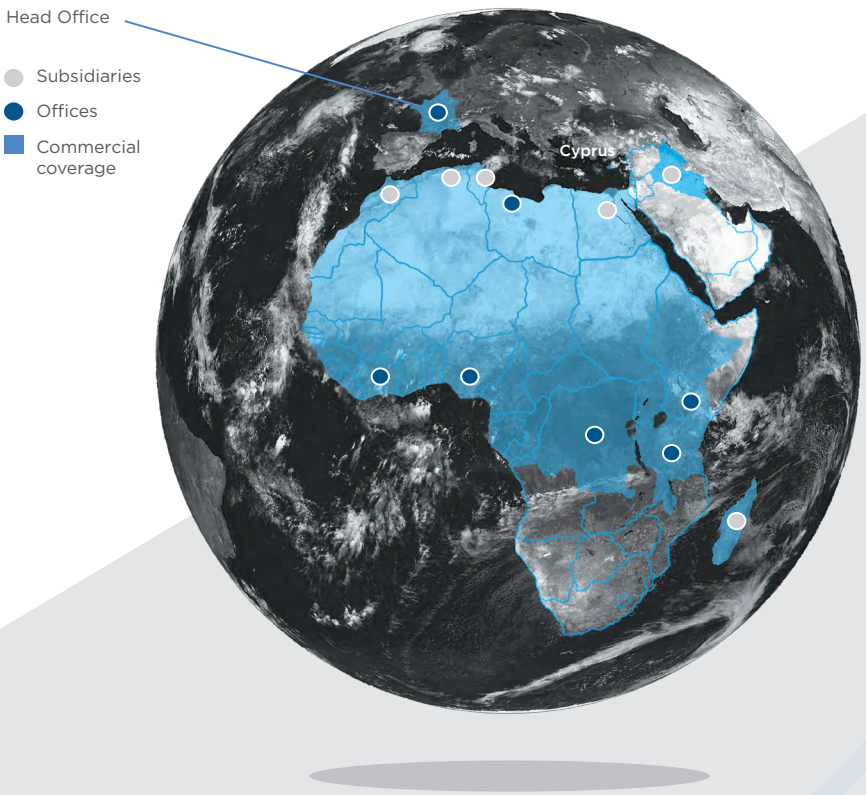
To meet the quality requirements of pharmaceutical companies operating in a controlled environment, we offer QI, QO, QP validation procedures for all our equipment. We elaborate with you a complete file of validation of each step in the respect of the recommendations ICH and FDA :

Validation Protocol - Installation Qualification - Operational Qualification - Performance Qualification - Nonconformity Processing Sheet - Annual Certification.

OUR INTERNATIONAL NETWORK

HTDS (Hi-Tech Detection Systems) is a company specialized in the distribution and maintenance of high-tech detection systems in France and abroad.

HTDS offers a full range of detection solutions dedicated to the following areas:
Security - Product Control - Analytical Sciences -
Nuclear and Radiation Protection - Signal Processing - Optoelectronics
HTDS's exclusive partners for pharmaceutical analyzes are recognized as world leaders in their field.



For a responsive service, tailored to your needs, HTDS has a network of subsidiaries, each with a team of specialized technicians and a complete stock of spare parts. A dedicated stock of equipment for your occasional rental needs is also available.

ALGERIA
(ex-Chemin de La Touche) 18 lotissement
Doudou-Mokhtar Ben Aknoun
Algiers - Algeria
Tel : +213 23 23 84 01
Fax : +213 23 23 84 00

EGYPT
91 El Meghani St - App 11
Heliopolis Cairo - Egypt
Tél : +20 222 90 53 06
Fax : + 20 222 90 53 07

MADAGASCAR
Immeuble Hi-Pôle - Lot Pres,
71 bis Antanetibe Antehiroka
Ambohidratrimo - Madagascar
Tel : +261 326 170 443

LIBYA
Khalifa Zaidi St. - City Building Office
503 - 5th Floor P.O. Box : 3913 Tripoli
G.S.P.L.A.J. - Libya
Mob : +218 91 69 50 70 8
Fax : +218 21 333 79 74

MOROCCO
7 rue Hatim Al Assam
20500 Casablanca - Morocco
Tel : +212 522 27 49 59
Fax : +212 522 20 83 74

TUNISIA
50 rue de l'Artisanat, ZI Charguia II
2035 Carthage Aéroport - Tunisia
Tel : +216 70 836 961
Fax : +216 70 836 561

www.htds.fr

HTDS
Hi-Tech Detection Systems

afaq ISO 9001 Qualité AFNOR CERTIFICATION

Parc d'Activités du Moulin de Massy - 3, rue du Saule Trapu - BP 246 91882 Massy cedex - France
Tel : +33 (0)1 64 86 28 28 - Fax : +33 (0)1 69 07 69 54 - info@htds.fr