Pharma Service Catalogue

Pharmaceutical Laboratory Services

Mérieux NutriSciences

One-stop shop pharma facility

MÉRIEUX NUTRISCIENCES

ASSETS

- Scientific Excellence dedicated to chemical and microbiological tests on food, pharmaceutical products, biocides, medical devices, cosmetics and food products
- Top Level Quality Accreditations
- GMP & GLP Authorization
- Unique Technological Platform
- Global European Front Office

PHARMACEUTICAL GMP LABS

Mérieux NutriSciences is a **valued partner to the global pharmaceutical industry**, offering R&D and quality control testing of pharmaceutical products.
From **active ingredients to finished products**, **we offer a complete range of analytical and research services for API and pharmaceutical products**. Our services include safety and quality control, development and validation of analytical methods. Our fully equipped, state-of-the-art laboratories offer **comprehensive testing services in compliance with euGMP/cGMP**. Investigation studies and contract research services are provided according to customer specifications.

The quality standard

In our GxP Laboratories each test is set-up in a **fully validated Laboratory Information Management System (LIMS)** compliant to CFR 21 Part 11 and Eudralex Annex 11.

The dedicated GMP/GLP area of about 2800 sqm:

- 4 independent laboratories and huge storage capacity in the same facility:
  - R&D Lab
  - Chemical Lab
  - Microbiological Lab (equipped with 2 Cleanrooms)
  - Cell biology, Toxicology and Virology Labs
- Climatic Chambers (>320 m^3, all ICH conditions covered)

The key facts

+40 yearly GMP audits
+ 300 international pharmaceutical customers

The Pharma Team

+140 scientists in the pharma facility
+20 researchers dedicated to **R&D activities**
+10 experts dedicated to **Quality Assurance**

ANALYTICAL TECHNIQUES

A
- Amino Acid Analyzer
- Atomic Absorption Spectroscopy

B
- BET (Brunauer–Emmett–Teller)

C
- Cell Culture Techniques

D
- Differential Scanning Calorimetry (DSC)
- Dissolution System for solid forms (Apps 1&2)
- Dissolution System for Chewing-gums
- Densimetry (included Tapped Density)
- Disintegration System

E
- Elecrophoresis (capillary & gel)

F
- Flow Cytofluorimetry

G
- Granulometry (Analytical sieving) (micro)
- Granulometry (Dynamic light scattering) (nano)
- Granulometry (Laser light diffraction) (micro)
- Granulometry (Dry powder laser diffraction)
- Gas Chromatography (GC-FID/TCD/ECD)
- Head-Space Gas Chromatography (HS-GC)
- Gravimetry

I
- ICP Atomic Emission Spectroscopy (ICP-AES)
- ICP Mass Spectroscopy (ICP-MS)
- Ionic Chromatography (ED/PAD)
- IR Spectroscopy (ATR/µFT-IR)

K
- Karl-Fisher (coulometric & semi-micro)

L
- Liquid Chromatography (DAD/ELSD/RID)

M
- MALDI-TOF
- Mass Spectrometry (GC-MS/MS)
- Mass Spectrometry (LC-MS/MS)
- HR Mass Spectrometry (Orbitrap & TOF)
- Melting Point (metal block)

N
- Nucleic Acid Sequencing

O
- Optical Microscopy
- Osmometry

P
- pH-metry
- Polarimetry

R
- Rifractometry
- Real Time PCR

S
- SDS-PAGE
- Spectrofluorimetry
- Spectrophotometry (UV-Vis)
- Scanning Electron Microscopy (SEM/EDS)

T
- Tensiometry
- Thin Layer Chromatography (TLC)
- Titrimetry
- Transmission Electron Microscopy (TEM)
- TOC

V
- Viscosimetry (capillary and rotational)

W
- Western blot

X
- X-Ray Diffraction (XRD)
- X-Ray Fluorimetry (XRF)

Analytical Techniques available in GxP Facilities

PHARMACEUTICAL SERVICES

QUALITY CONTROLS

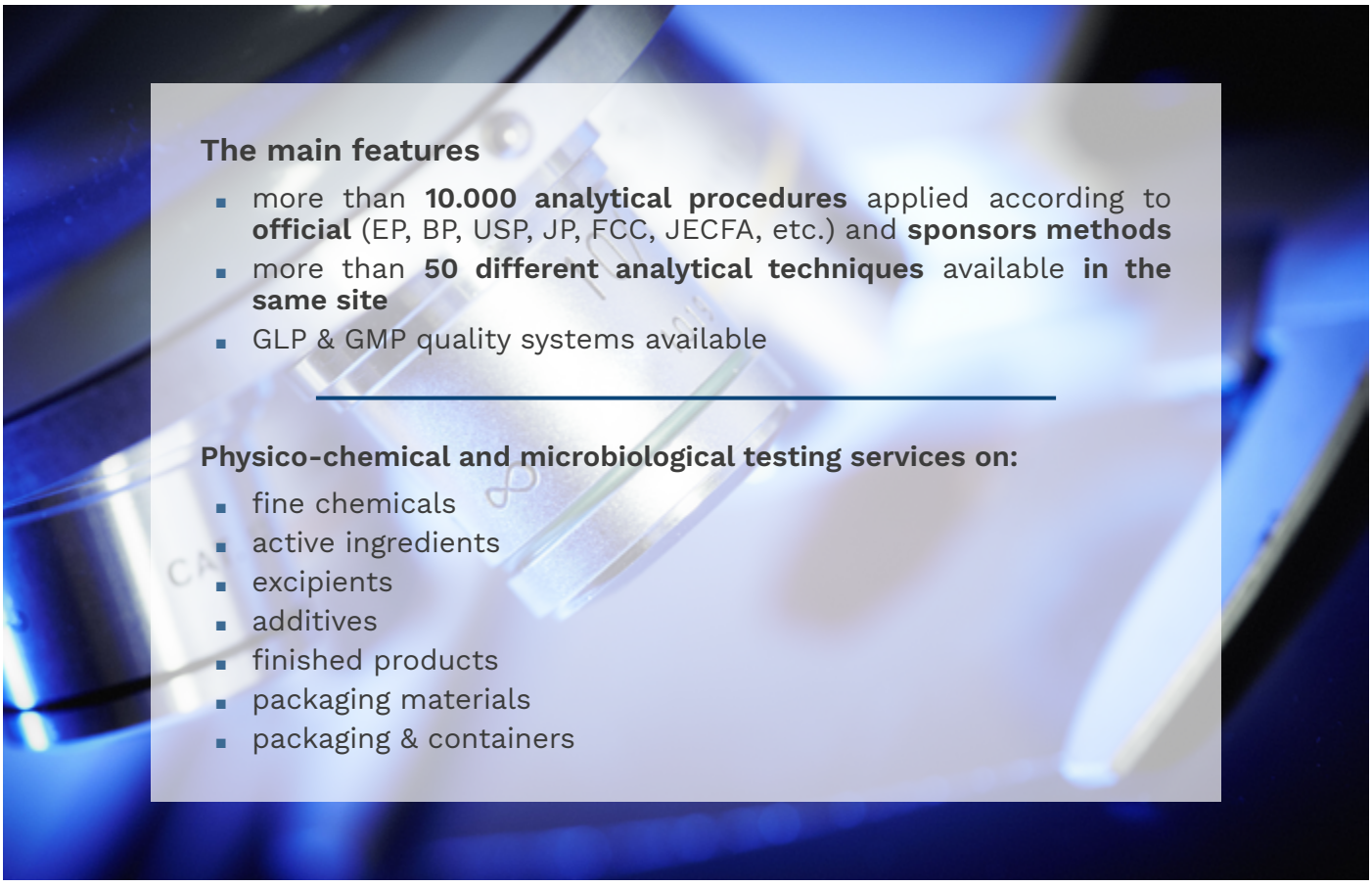
The QC Labs of Mérieux NutriSciences offer a complete portfolio of GxP-compliant studies and laboratory analyses useful for the **release of raw materials** (API and excipients) and **finished pharmaceutical products**, as required as part of the drug development manufacturing and commercialization process.

Physical testing

- Dissolution and disintegration tests
- Particle size
- Spectral analyses
- Polymorphism (XRD)
- Visible and sub-visible particle counting

Chemical testing

- Chemical Characterization
- Related substances
- Elemental impurities
- Nitrosamine impurities
- Ninhydrin-positive substances
- Residual analyses (solvents, mycotoxins, genotoxic impurities)
- Other residues and contaminants



The main features

- more than **10.000 analytical procedures** applied according to **official** (EP, BP, USP, JP, FCC, JECFA, etc.) and **sponsors methods**
- more than **50 different analytical techniques** available **in the same site**
- GLP & GMP quality systems available

Physico-chemical and microbiological testing services on:

- fine chemicals
- active ingredients
- excipients
- additives
- finished products
- packaging materials
- packaging & containers

Microbiological testing

- TAMC and TYMC
- Sterility Test
- Bioburden Test
- Challenge Test
- Microbial Assays for Antibiotics
- Bacterial endotoxins detection (LAL Test) - PHEUR 2.6.14 and USP<161>
- Monocyte Activation Test (MAT) *in vitro test* for pyrogen detection - EP 2.6.30

Microorganism identification

Microorganism Identification by MALDI-TOF - Matrix Assisted Laser Desorption Ionization-Time of Flight.

MALDI-TOF systems available

- BrukerDaltonics-BiotyperSoftware
- Vitek-MS (Biomerieux)-SaramisSoftware

If identification by MALDI-TOF, is not reliable, we apply **identification by 16S rDNA for bacteria and D2LSU for yeast and molds**.

Biopharmaceuticals characterization

- Amino acids composition
- Terminal amino acid sequence
- Peptide mapping
- Accurate mass

INVESTIGATION STUDIES

Thanks to a long-standing collaboration with Pharmaceutical companies at international level, the Pharma Labs can investigate the pharmaceutical sample to ensure its safety, **identifying the presence of impurities, foreign particle** or **unknown impurities**.

QUALITY ISSUE	POTENTIAL INVESTIGATION	METHODS
IMPURITIES	Controls of impurities Quantification of genotoxic impurity	▪ LC-MS/MS (APCI/ESI) ▪ LC-HRMS ▪ GC-MS ▪ GC-MS/MS
FOREIGN PARTICLES	Identification of foreign particles	▪ traditional optical equipment ▪ microscope-ATR-FTIR ▪ µFTIR / chemical imaging ▪ SEM-EDS ▪ TEM-EDS
OOS UNKNOWN IMPURITIES	Identification of unknown impurities	▪ LC-HRMS (LC-UHPLC-Q Exactive Focus) ▪ GC-HRMS (GC-SPME/HS-Q Exactive) ▪ NMR (in outsourcing with a specialized partner)

Controls of Impurities

Mérieux NutriSciences GxP Facilities could **develop and validate suitable and high sensitive methods** to detect, identify and quantify organic and inorganic impurities at trace levels. Impurities are identified and quantified by means of state-of-the-art analytical equipment's.

Organic impurities

- Control of starting materials, by-products, intermediates (including chiral impurities) in compliance with pharmacopoeia requirement or Sponsor specifications.
- Degradation products characterization by means of forced degradation studies (stress test) under acidic, basic, oxidative, and various heat and light-exposure conditions.

Analytical techniques

- LC-MS/MS, LC-HRMS
- GC/MS, GC-MS/MS, GC-HRMS
- ICP/MS, ICP/OES
- XRD
- MALDI-TOF/TOF
- IC
- AAA

and many others

Inorganic elemental impurities

Elemental impurities need to be monitored in drugs as they could be toxic for humans, interfere with drug stability and shelf-life, and cause unwanted side effects to humans. **ICH Q3D guideline** aims at **limiting** the presence of elemental impurities in drug products using the principles of risk management as described in **ICH Q9: risk-based quality control strategy**.

Our testing services

- screening tests
- methods development and validation according to Eur. Ph. 2.4.20 or USP <233>
- quality controls
- analytical batch release

Moreover, Mérieux NutriSciences supports customers to define the most appropriate:

- testing strategy
- sample preparation procedure
- analytical technique (e.g. ICP/MS, ICP/AES, GF-AA, AA-FIAS, XRF, etc.)
- suitable testing plan to determine all the requested
- elemental impurities at the required safe level/LOQ

Mérieux NutriSciences is registered at the US FDA as Testing Facility in compliance with cGMP requirements and guarantees data integrity in compliance with the requirements of CFR 21 part 11 and Eudralex Annex XI.

Residual solvents according to pharmacopoeia and ICH Q3C specifications

Genotoxic impurities

Mérieux NutriSciences' long-standing experience in residual analysis can **support the Pharmaceutical Companies for the genotoxic impurities identification and determination following a tired approach**:

- Search for in-house/official suitable methods already available
- Method development by means of high sensitive and state-of-the-art technologies
- Method validation in full compliance with ICH Q3A/B and ICH Q2 guidelines

Genotoxicity safety tests

- Bacterial reverse mutation test (Ames test) - OECD 471 (*in vitro test*)
- Mammalian cell micronucleus test - OECD 487 (*in vitro test*)
- Mammalian cell gene mutation test using thymidine kinase gene - OECD 490 (*in vitro test*)
- Mammalian erythrocyte micronucleus test - OECD 474 (*in vivo test*)

Other safety tests are available in our Toxicological Labs for Cytotoxicity, Toxicity, Sensitization, Irritation.

Identification of unknown impurities

Merieux NutriSciences proposes different analytical approaches for the identification of unknown impurities following customized testing strategies:

- Method Analytical Transfer
- Non-MS compatible method adaptation for MS analysis
- HRMS MS/MS analysis for accurate mass determination
- Structure estimation based on accurate mass and fragmentation
- Isolation and/or enrichment of the impurity (if needed)

Analytical techniques

- LC-HRMS (LC-UHPLC-Q Exactive Focus)
- GC-HRMS (GC-SPME/HS-Q Exactive)
- NMR (outsourced to specialized partner)

Determination of Nitrosamine Impurities (NI)

Our GMP facility is equipped with a dedicated lab equipped with the most sensitive analytical techniques available for nitrosamine impurities in APIs and DP (i.e. LC-MS/MS, LC-HRMS, GC-MS/MS, GC-HRMS).

Applicable testing for different phases of NI evaluation

RISK EVALUATION

- GMP or NON-GMP screening limit tests on raw materials of drug products supporting the Risk Assessment process in case of missing information:
  - Multiresidual nitrosamines analysis
  - Single nitrosamine analysis (with or without reference standard)
  - Nitrosation Assay Procedure - NAP tests

CONFIRMATORY TESTING

- Method development & validation
- GMP quantitative tests with validated methods on high risk nitrosamine(s)

NEW MARKETING AUTHORISATION AND BATCH RELEASE

- GMP screening quantitative tests to demonstrate nitrosamines absence before applying for new MA
- GMP QC tests for analytical batch release

ALERTS MANAGEMENT

- Target method development & validation (rush service)
- GMP quantitative tests on APIs and DPs on the market

Contaminants labs

- > 60 FTEs (Technicians / Experts)
- 16 GC Mass Spectrometry
- 28 LC Mass Spectrometry

Science center & R&D

- 27 FTEs (Technicians / Experts / Project Managers)
- 10 GC Mass Spectrometry
- 12 LC Mass Spectrometry

GMP facility nitrosamines laboratory

- > 8 FTEs (Technicians / Experts / Project Managers)
- 5 LC Mass Spectrometry (MS/MS + HRMS)
- 3 GC Mass Spectrometry (MS + MS/MS + HRMS)

GMP equipment / comput. systems qualification

Nitrosamines testing on APIs and DPs

STANDARD METHODS - multiresidual analysis

1. N-Nitrosodimethylamine (NDMA)
2. N-Nitrosodiethylamine (NDEA)
3. N-Nitrosomethylethylamine (NMEA)
4. N-nitrosoethylisopropylamine (NEIPA)
5. N-methyl-4-aminobutyric acid (NMBA)
6. N-nitrosodiphenylamine (NDPHA)
7. N-nitrosodi-n-propylamine (NDPA)
8. N-nitroso-diisopropylamine (NDIPA)
9. N-nitroso-di-n-butylamine (NDBA)
10. N-nitrosomethyphenylammina (NMPA)
11. N-nitroso-di-ethanolamine (NDELA)
12. N-nitroso-piperidine (NPIP)
13. N-nitroso-pyrrolidine (NPYR)
14. N-nitroso-morpholine (NMOR)
15. 1-Nitroso-4-methyl piperazine (MeNP)

TARGET METHODS

(more than 70 methods for specific NDSRIs or NO-impurities available) *- not exhaustive list*

- 1-Nitroso-4-(2-hydroxyethyl)-piperazine
- 2-Nitroso-octahydrocyclopenta[c]pyrrole
- 4-Nitroso-Hydrochlorothiazide
- Donepezil Nitroso-Impurity A
- Methyl N-methyl-N-nitrosoanthranilate
- Methyl-N-Nitroso-Indoline (Indapamide)
- N-methyl-N-nitrosophenylethylamine (NMPEA)
- N-methyl-N-nitrosophenylethylamine (NMPEA)
- N-Nitroso-2,6-pipecoloxilidide (N-Nitroso-Ropivacaine)
- N-Nitroso-Aryl-Piperazine
- N-Nitroso-Atenolol
- N-nitroso-Azithromycin
- N-Nitroso-Benazepril
- N-Nitroso-Betahistin
- N-Nitroso-Biotin
- N-Nitroso-Brinzolamide (N-BRIN)
- N-Nitroso-CAF (Calcium Folinate)
- N-Nitroso-Cinnarizine Impurity A (NCIN)
- N-Nitroso-Ciprofloxacin (N-CIP)
- N-Nitroso-Clonidine
- N-Nitroso-Desethyllidocaine
- N-nitroso-Desmethylazithromycin
- N-Nitroso-Desmethyl-Tripelennamine
- N-Nitroso-Diclofenac
- N-Nitroso-Dimenhydrinate Impurity F
- N-nitroso-Diphenhydramine
- N-Nitroso-Dorzolamide
- N-Nitroso-Duloxetine
- N-Nitroso-Enalapril
- N-Nitroso-Fluoxetine
- N-Nitroso-Folic Acid
- N-Nitroso-Guanidine (Triamterene)
- N-Nitroso-Impurity A Benzydamine
- N-Nitroso-Lisinopril
- N-Nitroso-L-Proline
- N-Nitroso-Masitinib N1
- N-Nitroso-Metoprolol
- N-Nitroso-Naphazoline
- N-Nitroso-Nebivolol
- N-Nitroso-Nortriptyline
- N-Nitroso-Paroxetine
- N-Nitroso-Perindopril
- N-Nitroso-Phenylephrine
- N-Nitroso-Pramipexole Impurity 57
- N-Nitroso-Propranolol
- N-Nitroso-Pseudoephedrine
- N-Nitroso-Quinapril
- N-Nitroso-Ramipril
- N-Nitroso-Rasagiline
- N-Nitroso-Rivaroxaban Hydroxy
- N-Nitroso-Salbutamol
- N-Nitroso-Sertraline
- N-Nitroso-Sotalol
- N-Nitroso-Tamsulosin
- N-Nitroso-Tetryzoline
- N-Nitroso-Ulifloxacin
- N-Nitroso-Vortioxetine
- N-Nitroso-Zolmitriptan
- Posaconazole Nitroso-Impurity 1
- Posaconazole Nitroso-Impurity 2

DOWNLOAD
THE COMPLETE LIST

SCREENING TARGET by HRMS and/or MS/HRMS (bitrosamines without available reference standards).

NITROSATION ASSAY PROCEDURE - NAP test. Residual qualitative test / trace analysis to identify a specific nitrosamine through the following analytical techniques - LC MS and/or MS/MS and/or HRMS and/or MS/HRMS and/or TOF and/or MS/TOF and/or UV.

> **NAP test according to EFPIA protocol (Drug Substance Workflow for Quality Risk Management of Nitrosamine Risks in Medicines - Version 3.0, 2024)**

Identification of Foreign Particles (FP)

The presence of foreign particles (FP) in sterile pharmaceutical products **can affect** their **efficacy and safety**. FP may **originate from both organic and inorganic sources**, as corroded or damaged equipment parts, cross contamination during the process or from biological sources.

Mérieux NutriSciences has developed **various strategies and complementary approaches for the identification of foreign visible and subvisible particles**, using **sophisticated instrumentations** combined with a pool of experts in different fields permit to our expert to develop different approaches:

- Isolation of the foreign particle(s) in clean room (if needed)
- Application of non-destructive **complementary** analytical techniques for the chemical/ morphological characterization
- Exhaustive report elaboration

Morphological characterization

Microscopic examination for visible and sub-visible particles.
The technique allows a first evaluation of sample and the information acquisition order to decide eventual further microbiologic analyses. In some cases, it allows the identification FP.

Elemental characterization

SEM/EDS. The association between SEM (Scanning Electron Microscope) and EDS (Energy Dispersive Spectrometry) allows to carry out microanalyses on small organic and inorganic particles with non-destructive analysis.

TEM/EDS. TEM (Transmission Electron Microscope - maximum potential magnification of 1 nanometer) and EDS (Energy Dispersive Spectrometry) allows to extend the investigation to nanoparticles and relative aggregates/agglomerates.

Spectral identification

FT-IR microscopy allows to carry out spot FT-IR analysis on small particles above 0,1mm and is suitable for both organic and inorganic materials.

µ-FT-IR/Chemical Imaging technology is the golden standard to detect and identify microparticles and microplastics of dimension between 10µm and 1mm and is substitutive or complementary to FT-IR microscopy.

Extractables & leachables studies

Extractables and Leachables studies provide a **full-integrated testing strategy together with toxicological assessment and risk analysis**, in 6 main steps:

1. Profiling of extractables: generation of the extract
2. Characterization of **extractables**:
   a. **Screening research** of VOC, SVOC and NVOC using different techniques (e.g. TOC, HS-GC/MS, GC-MS, GC-HRMS, HPLC UV/ DAD, LC-MS/MS, LC-HRMS)
   b. **Targeted analysis of elemental impurities and anions** using different techniques (e.g. AAS, ICP-MS, IC)
   c. **Targeted analysis for specific compounds of toxicological concern**, using dedicated methods that focus on monomers, additives and extractables typical of the material considered (more than 150 targeted methods available)
   d. **Extractable nanoparticles** and **microplastics** identification
3. Primary and secondary **leachables profile**
4. **Unknown** extractables/leachables tentative identification by HRMS techniques (if needed)
5. Toxicological evaluation and risk assessment
6. Development and validation of targeted methods suitable for the quantification of critical leachables

Analytical techniques

- HPLC-ELSD, HPLC-MS/MS, HPLC UV/DAD, IC
- LC-MS/MS, LC-HRMS Q/Orbitrap
- HS-GC, HS-GC/MS, GC/FID, GC-MS, GC-HRMS Q/Orbitrap
- ICP-OES, ICP-MS, AAS
- MALDI-TOF
- TOC
- SEM/EDS, TEM/EDS

Glass delamination

Testing strategy according to USP <660> *"Containers –Glass" and USP <1660> "Evaluation of the inner surface durability of glass containers":*

1. Determination of visible and subvisible glass particles
2. Determination of extracted elements
3. Characterization of glass inner surface by SEM/EDS

OUR ACCREDITATIONS

Our experience on validation studies for drug products, and our high laboratory standards - in compliance with GMP, GLP, and ISO 17025 - allow us to perform extractables and leachables studies that have recognized value by international regulatory authorities such as the FDA:

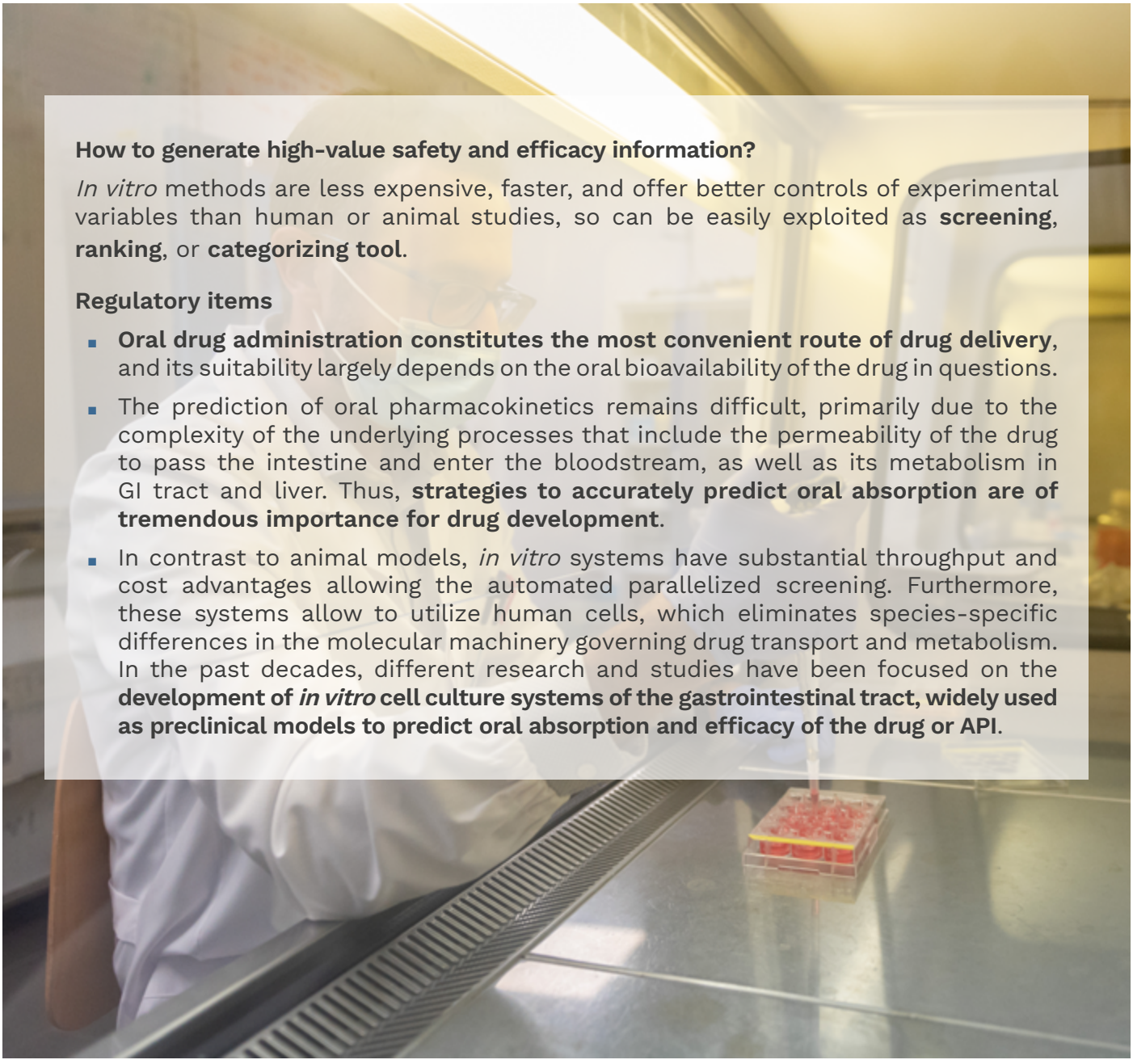
- Mérieux NutriSciences E&L laboratories employ methods compliant with **ISO 17025:2005 standard**, and **certified by Accredia**, the Italian accreditation body;
- accreditation and validation of **migration test methods on specific FCM compounds** (depending on compound).

ABSORPTION STUDIES

In vitro testing *and models* support all pharmaceuticals manufacturing process, from the idea to the commercialization of a product. Thanks to different in vitro applications, it is possible to mimic the effects of drugs through **biological models and absorption studies, performing several screening tests** as:

- identifying the best active ingredient for a chosen purpose
- optimizing the formula to improve its biological activity and properties
- preliminary evaluation of bioaccessibility/bioavailability
- efficacy evaluation

to preliminarily evaluate product, ingredient or formulation before to proceed with the clinical trial.

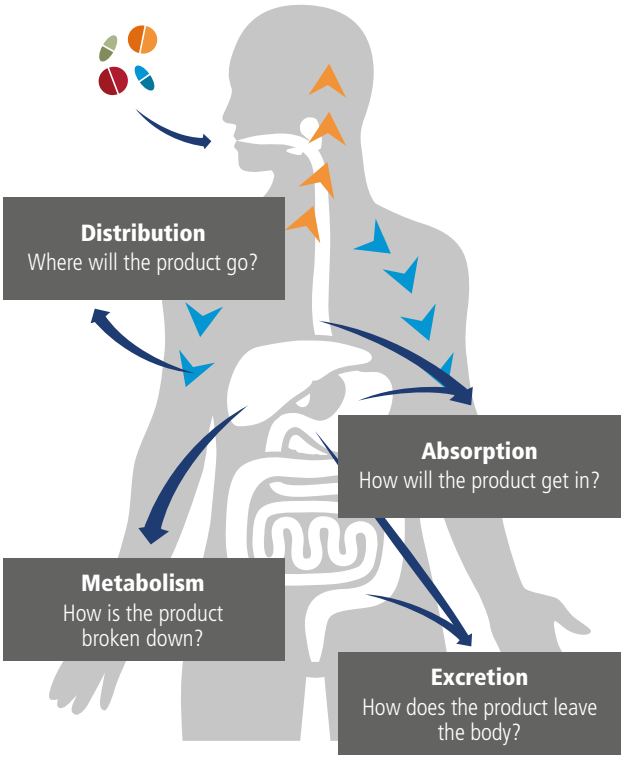


How to generate high-value safety and efficacy information?

In vitro methods are less expensive, faster, and offer better controls of experimental variables than human or animal studies, so can be easily exploited as **screening**, **ranking**, or **categorizing tool**.

Regulatory items

- **Oral drug administration constitutes the most convenient route of drug delivery**, and its suitability largely depends on the oral bioavailability of the drug in questions.
- The prediction of oral pharmacokinetics remains difficult, primarily due to the complexity of the underlying processes that include the permeability of the drug to pass the intestine and enter the bloodstream, as well as its metabolism in GI tract and liver. Thus, **strategies to accurately predict oral absorption are of tremendous importance for drug development**.
- In contrast to animal models, *in vitro* systems have substantial throughput and cost advantages allowing the automated parallelized screening. Furthermore, these systems allow to utilize human cells, which eliminates species-specific differences in the molecular machinery governing drug transport and metabolism. In the past decades, different research and studies have been focused on the **development of *in vitro* cell culture systems of the gastrointestinal tract, widely used as preclinical models to predict oral absorption and efficacy of the drug or API**.

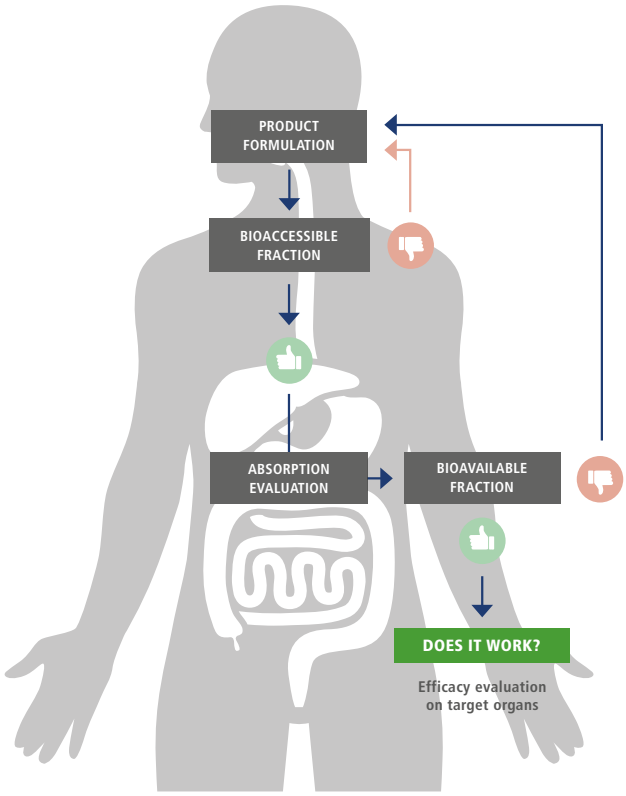


In vitro models for Customized absorption studies

Our experts can develop various and customized in vitro models for different applications able to **mimic the behaviour of drugs through biological models and absorption studies**, performing several screening tests to preliminarily evaluate product, ingredient or formulation before to proceed with the next step evaluation (e.g. clinical trial).

The biological models are composed of **biological fluids** that represent the digestive process, plasma serum, brain tissue, heart and blood, prostate and many others.

The models are implementable and adaptable according to the type of fluid or study to be carried out, and according to the customer's needs.



Our *in vitro* models available

- Oral - Sublingual Model
- Gastro-Intestinal Model
- Mucosal Model
- Hepatic Model
- Prostate Model
- Cardiovascular Model

and other ad hoc models can be developed

R&D AND VALIDATION ACTIVITIES

Quality is always an **imperative prerequisite** when we consider any product and it becomes prime when it relates to life saving products like pharmaceuticals. **The concept of Validation is the overall expression for a sequence of activities in order to demonstrate and document that a specific product can be reliably manufactured by the designed processes (so it is closely related to the substance quality)**.

Thanks to highly qualified experts and state-of-the-art instruments, Mérieux NutriSciences offers services as:

- Method development or optimization
- Method validation (including inter-laboratory validation)
- Forced degradation studies: acidic, basic, oxidative, heat, light exposure stress tests performed to identify potential degradants of the API and verify the stability indicating properties of the analytical procedure(s)

STABILITY & STORAGE

Formal stability studies (long term, accelerated and intermediate) are undertaken on primary and/or commitment batches according to a prescribed stability protocol to establish or confirm the re-test period of an API or the shelf life of a finished product.

ICH-compliant, climate controlled **storage facilities**, including:

- 58 m^3 walk-in room (n. 2)
- 44 m^3 walk-in rooms (n. 2, one equipped for low humidity conditions)
- 22 m^3 walk-in rooms (n. 7)
- 1,5 m^3 cabinets (n. 5, one equipped for photostability testing)
- Various dimensioned cabinets for customized storage conditions and a complete range of ICH climatic conditions

The following **stability conditions** are available for pharmaceutical stability storage:

- 25°C ± 2°C / 60% RH ± 5% RH
- 30°C ± 2°C / 65% RH ± 5% RH
- 30°C ± 2°C / 75% RH ± 5% RH
- 40°C ± 2°C / 75% RH ± 5% RH
- 40°C ± 2°C / <25% RH
- 2 - 8°C
- -15°C (-20°C±5°C)
- -70°C (-75°C±10°C)
- Photostability (according to ICH Q1B, option 1 & 2)
- Transport Stability (freeze and thaw, cycle test)
- In-Use Stability
- Customized conditions available

All conditions are continually monitored and recorded with back-up systems ensuring a totally secure and controlled environment. Access, alarms and changes are under audit trail and electronic signature according to the **Annex 11 of the EU GMP and the Part 11 of 21 CFR**.

Freeze-thaw cycle: assess the stability and integrity of pharmaceuticals under varying thermal conditions. It helps ensure that the products maintain their effectiveness, safety, and quality even after exposure to adverse storage or transportation environments.

CLEANING & DISINFECTANTS VALIDATION

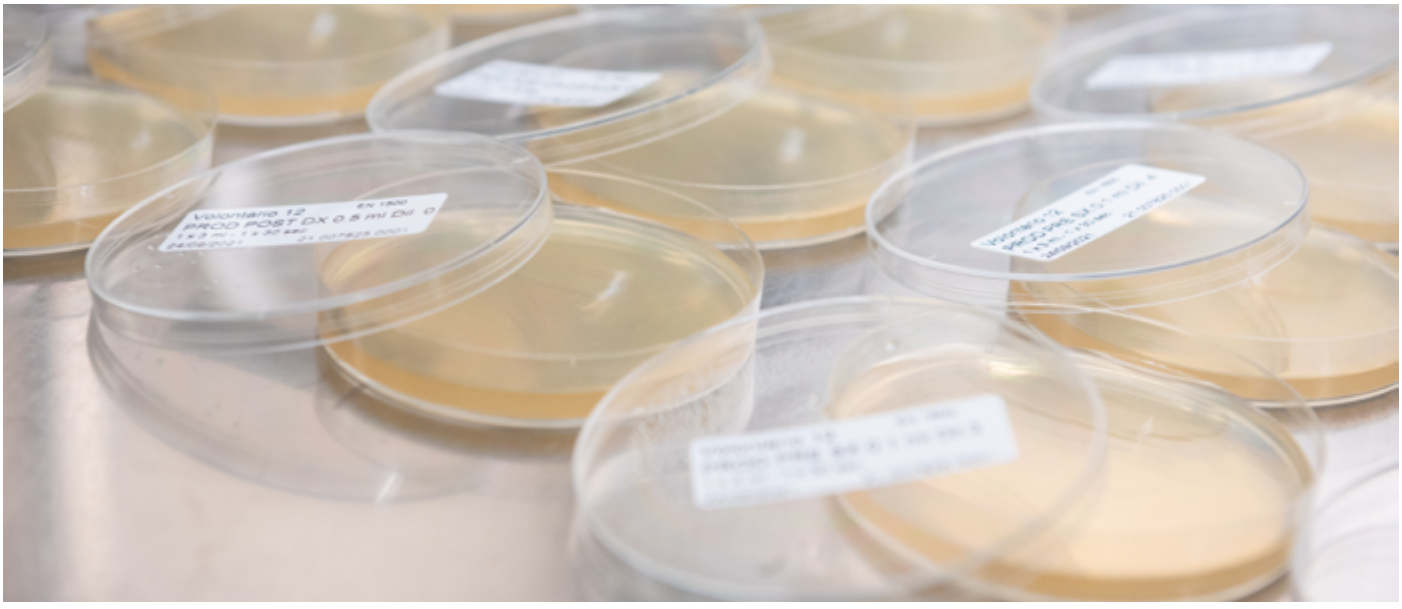
Cleaning validation

- Determine chemical residues or biological contamination
- Selection of appropriate detection methods
- Development of specific methods for the detection/quantification of contaminants
- Analytical cleaning method validation

Disinfectants validation (effectiveness against target organisms)

Efficacy tests on disinfectants used in the medical, veterinary, industrial or domestic area according to national and international standards (**EN 13704, EN 13697** and **USP<1072>**) are performed against following organisms (*not exhaustive list*):

- **Bacteria** (Gram-negative and Gram-positive) (e.g.: *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Enterococcus hirae, Salmonella typhimurium, Listeria monocytogenes, Enterococcus faecium, Legionella pneumophila, Proteus vulgaris,* MRSA, MRSE, VRE, *Enterobacter cloacae*)
- **Yeasts and Molds** (e.g.: *Candida albicans, Saccharomyces cerevisiae Aspergillus brasiliensis*)
- **Spores** (e.g.: *spores of Bacillus subtilis, spores of Bacillus cereus*)
- **Mycobacteria** (e.g.: *Mycobacterium tuberculosis and Mycobacterium terrae*)
- **Bacteriophages** (e.g.: Bacteriophage P001 and P008)
- **Viruses** (e.g.: *Poliovirus type 1, Adenovirus type 5, Murine Norovirus, Murine Parvovirus, Vacciniavirus, Aujeszky's, Bovine Viral Diarrhea, Porcine and Bovine Enterovirus, Hepatitis A virus, Human Respiratory Syncytial Virus, Human coronavirus, Bovine Parainfl uenza, Cardiovirus,* PRRSV, *Pseudorabies*)
- **Isolated strains**



ENVIRONMENTAL SERVICES

Pharmaceutical companies are every day called to demonstrate **operational excellence due to the very serious and important product they realize**: this commitment is also reflected in the **precise control of working environment** and, nowadays more and more important, in the **control and reduction of their impact** on the external environment.
Industrial hygiene is the focus for whom is responsible for workers' risk monitoring, and in pharmaceutical factories, chemical, biological and physical agents should be monitored to **guarantee the safety and the comfort in the working environment**.

- Water monitoring: drinking and process water - waste water
- Waste management programs characterization
- Indoor/Outdoor environment drinking and process water - waste water
- Emissions
- Environmental monitoring

OTHER SERVICES

OUR SERVICES ON MEDICAL DEVICES

Our services to support customers in the **development of the testing plan** to determine which studies are necessary to ensure that the device is safe and effective, meeting the essential requirements for affixing the **CE mark on the product**.

Analytical strategies

- **Regulatory support & Risk assessment**
- **Quality controls & Stability**
- **Biological Safety assessment**
- **Efficacy evaluation**
- **Process validation**
- **Human factor services**

OUR SERVICES ON BIOCIDAL PRODUCT

The Regulation on biocidal products (BPR, Regulation (EU) 528/2012) requires all products to be authorised by a competent authority before they are placed on the market. Authorities can only grant authorisation if the evaluation they carried out shows that **the use of the product is safe** for human and animal health, and the environment. The product must also be **proven to be effective** for its intended uses.

Analytical strategies

- **Effectiveness against target organisms**
- **Physico-Chemical Tests**
- **Stability**
- **Toxicological studies**
- **Compatibility Tests**
- **Consultancy and regulatory support**

ACKNOWLEDGEMENTS & AUTHORIZATIONS

- QC laboratory authorization for human medicinal products (AIFA)
- QC laboratory authorization for medicinal products for veterinary use
- FDA establishment inspection report
- GLP certificate
- GMP certificate for human medicinal products (AIFA)
- GMP certificate - health ministry (vet medicinal products)
- ISO 9001:2015 certification
- Authorization for use of internationally controlled substances
- License for drug precursors
- Approved organisation carring out R&D activities for the recognition of the french Credit d'Impôt Recherche (CIR)
- Accredia accreditation for efficacy studies on biocide products and viruses detection
- Authorization to analytical controls on presidi medico chirurgici (PMC)
- EcoVadis sustainability rating (2024)

One-stop shop pharma facility

Mérieux NutriSciences

A STRONG PRESENCE IN EUROPE AND WORLDWIDE

MÉRIEUX NUTRISCIENCES OFFERS ITS SCIENTIFIC EXCELLENCE IN PHARMACEUTICAL, FOOD, CHEMICAL, BIOCIDE AND COSMETIC PRODUCTS TESTING AND CONSULTING TO ENSURE SUPPORT, OPTIMAL REACTIVITY AND FLEXIBILITY TO ITS CUSTOMERS ALL OVER THE WORLD.

Mérieux NutriSciences

Better Food. Better Health. Better World.

Mérieux NutriSciences
Via Fratta 25, 31023 Resana (TV), Italy
Ph. +39 0423 7177
E-mail: gxp.italy@mxns.com
www.merieuxnutrisciences.com/eu

Follow us - Mérieux NutriSciences Italia

BR0716_5_ENG / Photos: Shutterstock. Printed in Italy
Copyright © 2023 Mérieux NutriSciences Corp. All Rights ReservedALL Rights Reserved