

neutron
pharma



Since 1985 Neutron provides Analytical Services on food and feed products, supplements, materials in contact with food, cosmetics and pharmaceutical products.

In 2019, Neutron was acquired by the Cotecna Group, one of the world's leading providers of testing, inspection and certification services.

Neutron Group can rely on over 550 members of employees to the main areas of Analytical Testing in 10.000 m² of Laboratories.

Neutron Pharma is the GMP business unit of Neutron and, following the main International Standards, provides chemical and physical tests and supplies high-level technical support to many

Pharma companies in the field of GMP.



50

Years of History

+550

Employees

10.000

M² Laboratories/1 Site

+250.000

Samples /Year

+5.000

Accredited Tests

VISION

NEUTRON VISION IS BASED ON TWO WORDS :

"Safety improvement".

Legislation will be a driver for food safety improvement. As a consequence, the demand for analytical services will increase, both for brand protection and for sense of responsibility. We manage two different scenarios: a demand for crises management and specific projects, and a demand for routine controls.

MISSION

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NEOTRON PHARMA CERTIFICATIONS, ACCREDITATIONS AND QUALITY SYSTEM

Neutron Pharma offers a complete chemical analysis service for safety and quality of the entire Pharmaceutical sector: API, Drugs, Excipient, Raw Materials and Packaging.

Thanks to the combination of know-how and technology, Neutron Pharma guarantees the highest level of quality and reliability of the analytical data, as well as immediate assistance to the customer on any alert in the pharma sector, following the main International Standard:

GMP Authorization of Neutron Testing Facility for chemical and physical quality control test

Certificate of registration **FDA (Food and Drugs Administration)** facilities inspected

Accreditation in compliance with **ISO/IEC 17025** standard by **ACCREDIA**

Ministry of Health authorization for **drugs** and **psycotropic substances**

Ministry of Health authorization for **veterinary drugs**

Neutron has been a reference chemical laboratory for the most important Pharma industries for many years.

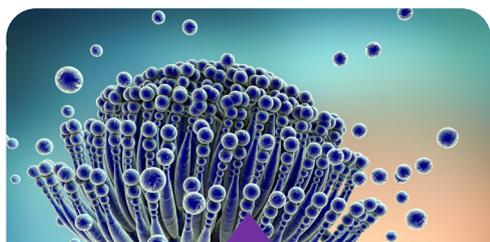
Thanks to our QA team, the quality of the Pharma division is managed and implemented at comprehensively, always guaranteeing the customer maximum transparency and reliability of the analytical data.

PHARMA ANALYTICAL PORTFOLIO



CONTAMINANTS

Currently the Pharma laboratory approach is based on customer needs, through screening and/or validation activities, paying particular attention to timing and related costs.



AFLA/OCHRA TOXINS

Determination of afla and ochra toxins in raw material as excipients and herbals in accordance with what is described in the general chapter Ph. Eur 01/2008:20818 "Determination of aflatoxin B1 in herbal drugs"; Ph. Eur 01/2010:20822 Determination of ochratoxin A in herbal drugs" of the European Pharmacopoeia



NITROSAMINES

Determination of nitrosamine residues, in APIs, excipients and finished products, in accordance with what is reported in the official EMA documents, setting of new nitrosamines and API-excipients interaction studies.



PESTICIDES

Determination of pesticides in raw material as excipients and herbals in accordance with what is described in the general chapter 01/2019: 20813 of the European Pharmacopoeia and USP



ELEMENTAL IMPURITIES

Determination of Elemental Impurities, in ICP-MS / ICP-OES / AAS in accordance with what is reported in tables 1, 2a, 2b and 3 of ICHQ3D



PYRROLIZIDINE ALKALOIDS

Determination by HPLC-MSMS of 28 Pyrrolizidine Alkaloids in herbals extracts and finished products.



ASSAY & IMPURITIES

Control of active ingredients and related substances according to a developed and validated method by Neutron or shared by the customer



PHARMACOPOEIA METHODS

Neutron Pharma provides a wide range of analytical control according to the main Pharmacopoeia test such as EP, USP, JP, BP, CHP. Lab's approach is to evaluate tests and monographs requested with maximum transparency



STABILITY STUDIES

Neutron Pharma is able to perform stability studies and relative storage thanks to the presence of different chambers for climatic zones I, II, IV according to ICH Q1 A (R2) and according to ICH Q1B option 1 guidelines



STRESS TEST STUDY

With specific protocols aligned to customer and according to ICH Q1B option 1 guidelines



RESIDUAL SOLVENTS

Screening and validation activities for the control of raw materials and finished products as per general chapter 467 of the USP



PARTICLE SIZE DISTRIBUTION

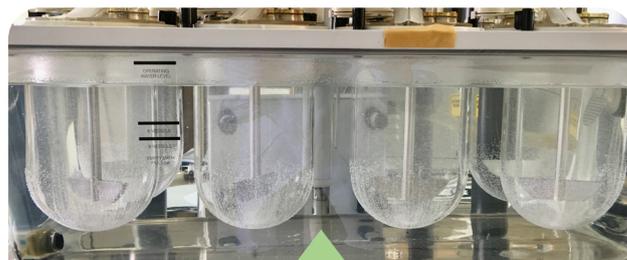
Analysis of particle size distribution by Laser Diffraction according to a developed and validated method by Neutron or shared by the customer.



MICROBIOLOGY

Validation and Development of micro methods and analysis of following parameters:

TAMC, TYMC, TAMC and TYMC, Bile Tolerant gram-negative bacteria, coliform bacteria, Pseudomona Aeruginosa, Salmonella spp, Stafilococcus Areous, E. Coli, Bacterial endotoxins EP 2.16.14 Method A and B.



DISSOLUTION TEST

Neutron Pharma disposes of two apparatuses to perform tests in compliance with the European Pharmacopoeia.



EXTRACTABLE & LEACHABLES

Neutron Pharma disposes of all the Analytical instruments for Extractables/Leachables Testing for products



BIOPHARMACEUTICAL TESTING

Neutron Pharma laboratory tackles the increasing demand for analysis in the Biopharma sector with an innovative approach. By leveraging cutting-edge technologies for macromolecule analysis, Neutron Pharma stands out for its ability to provide precise and reliable analysis services.

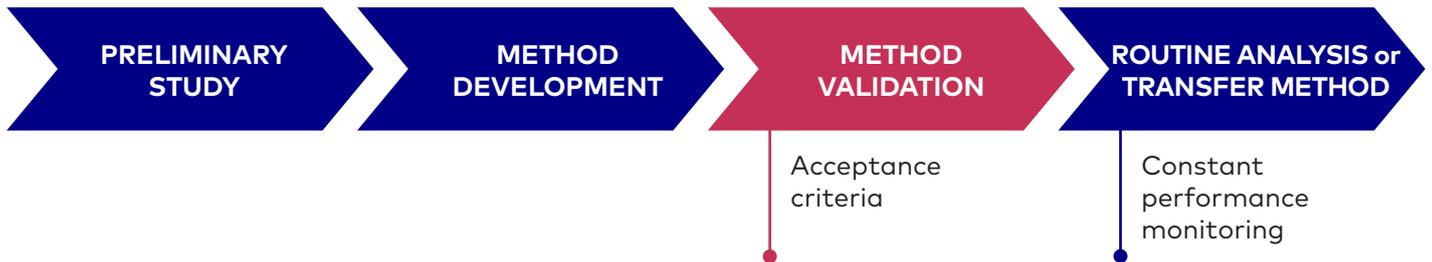


R&D SERVICE

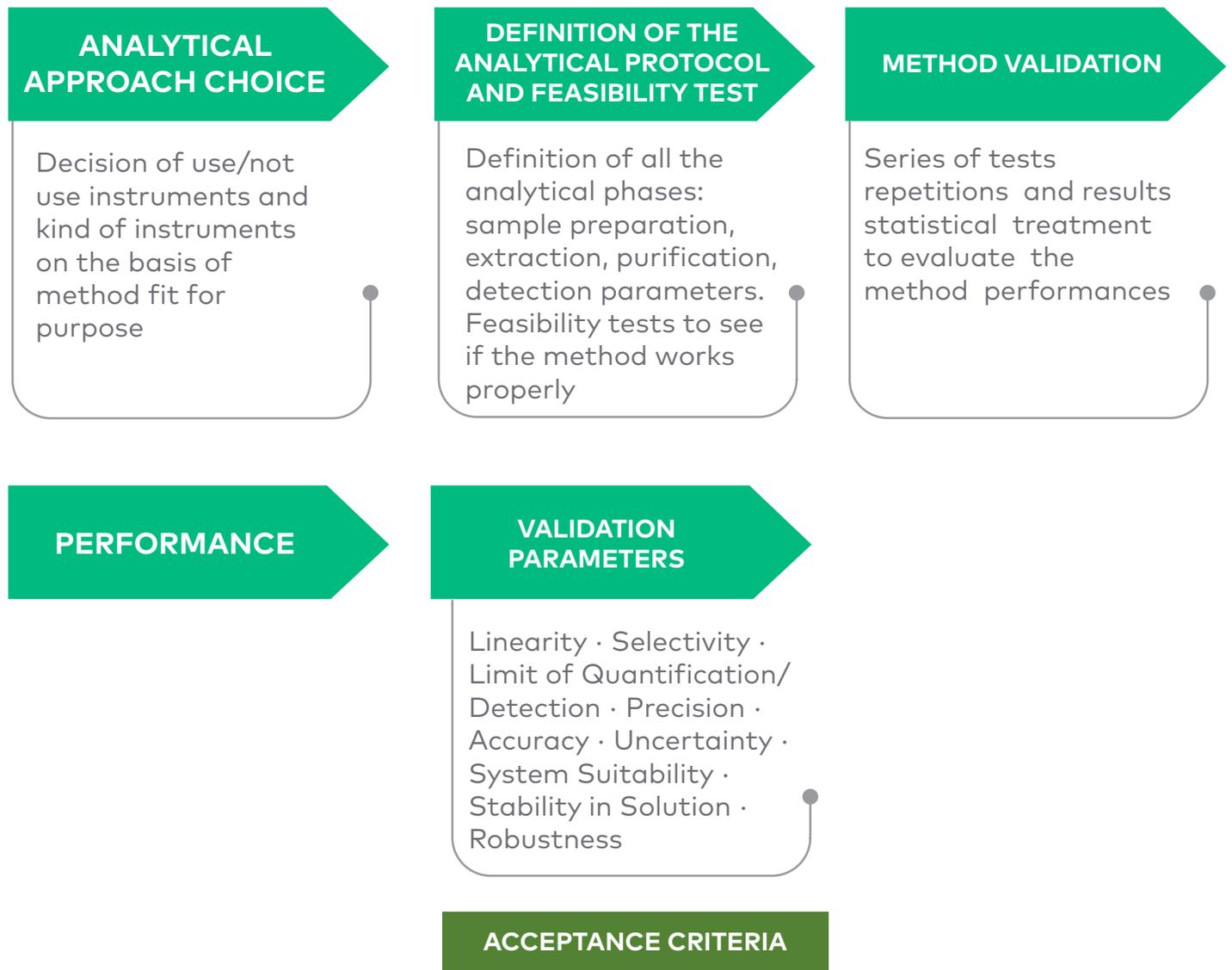
Open collaboration with R&D services or preliminary studies or SET UP for analytical method developments.

ANALYTICAL METHOD VALIDATION

Analytical method development and validation workflow



Before introduction in routine use analytical methods are validated.



LAB EQUIPMENTS

Regular investments and continuous analytical research and innovation allow Neutron Pharma to be a reference point for pharmaceutical companies at an international level.

WET CHEMISTRY SERVICES

Neutron Pharma has the main analytical equipment necessary for carrying out tests in accordance with the main pharmacopoeias.

- Dissolutor
- Disaggregator
- Hardness tester
- Spectrofotometer
- K.F
- Densimeter
- Karl Fischer Coulometric
- Viscometer
- Particle size Distribution
- Melting point
- Drop point
- Tap density

MICRO ANALYTICAL SERVICES

- HPLC and UPLC area → detectors as DAD, refractive index, IR, Fluorimeter, Light scattering, MSMS and QTOF.
- To complete the HPLC division we find a tool dedicated to post-column derivatization.
- GC area → FID, ECD, HS-MS, MSMS
- IC → Ion Chromatography Conductivity Detector
- Q-TOF

METALS SERVICES

The laboratory has ICP-OES, ICP-MS and AAS which together with the presence of a mineralizer, dedicated to the preparation of the samples, allow Neutron pharma to be reactive to the different customer requests.



INFO /CONTACTS

neotron
Part of the Cotecna Group

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