



# Company Profile

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neutron  
**pharma**

# Corporate Organisation



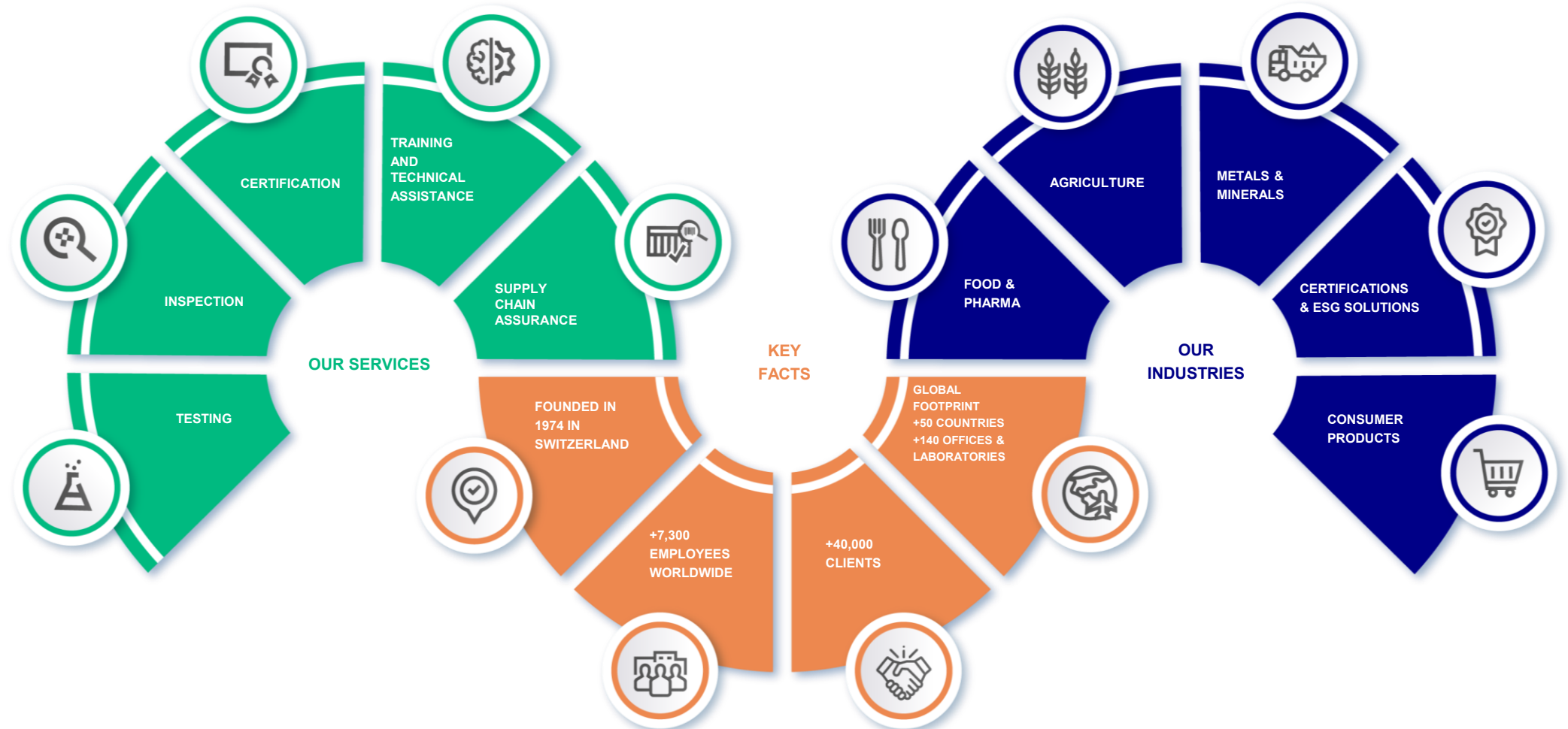
**Pharma Business Unit**

**Activities: Analysis for Pharma GMP**

**Main Certifications AIFA, FDA, Ministry of Health**

# Cotecna Group

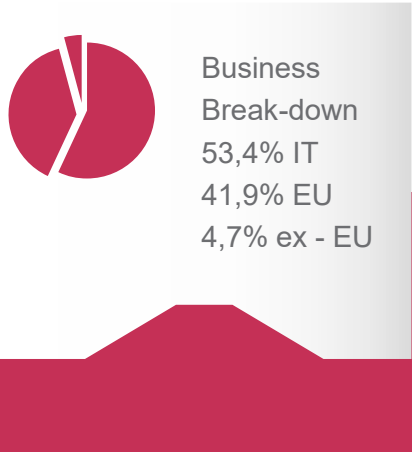
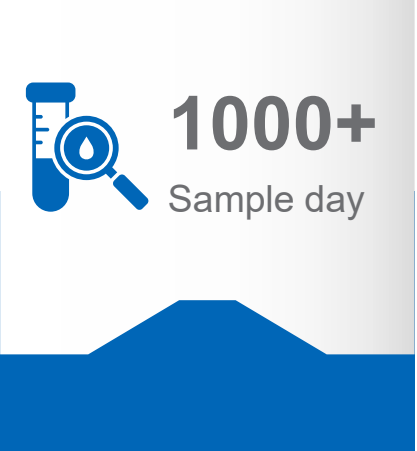
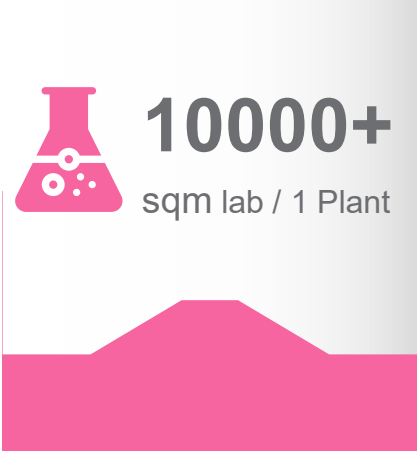
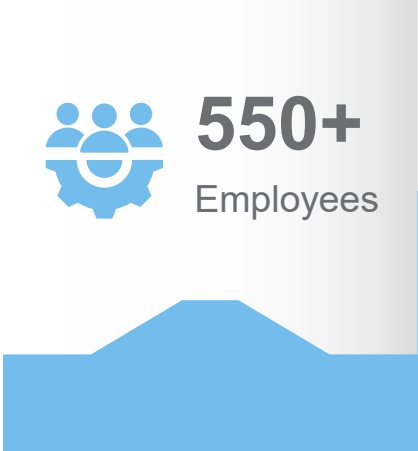
**Cotecna** is a leading provider of testing, inspection and certification services. We offer solutions to make supply chains **safer** and **more efficient** for our clients. Our network of professionals and certified laboratories provides expertise across **five** key sectors: agriculture, food safety, metals and minerals, system certification & ESG solutions and consumer products.





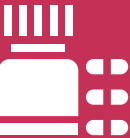


# History



# Neutron numbers



# Fields of testing activity

	BABY FOOD		FOOD SUPPLEMENTS
FOOD & FEED		FOOD INGREDIENTS	
	COSMETICS	neutron pharma	SENSORY CONSUMER ANALYSIS
FOOD CONTACT MATERIALS		PHARMA GMP LAB INSPECTED	Sen&CA sensory and consumer analysis

# Pharmaceutical main authorizations

**AIFA - Italian  
Medicine Agency**

European GMP Certificate  
for Human Medicines



**Italian Ministry of  
Health**

European GMP Certificate  
for Veterinary Medicines

Usage and detention of  
Psychothropic Substances



*Ministero della Salute*

**US Food and Drug  
Administration**

US GMP Certificate for  
Human Medicines



# Analytical proposal

## Analytical activities

- Chemical/physical tests
- Test according to EP, USP, JP
- Impurities/contaminants
- Test according to registration
- Particle size distribution

## Analytical method development and validation

- HS/GC-MS
- GC-FID/ECD
- UPLC-MS
- HPLC-DAD/IR/RID/ELSD
- ICP-MS/OES

## Stability storage services & stability studies



# ICHQ 3D

## Elemental Impurities Analytical Proposal

**Determination of Elemental Impurities,  
in accordance with what is reported in tables 1,  
2a, 2b and 3 of ICHQ3D**

- Screening
  - Method Validation
- Pharmacopoeia analytical approach

**ICP-MS**

**ICP-OES**

**AAS**

# Nitrosamines

**Neutron supports customers for screening activities, validation on API, Drugs or excipients for elemental impurities and nitrosamine residues.**

- **SCREENING** (limited/ semi-quantitative)
- **METHOD VALIDATION** (quantitative)

GC-MS

HPLC-MS

HPLC- QTof

# Nitrosamines

## What's about new Nitroso APIs focus?

**As reported in the latest revision *EMA/409815/2020 Rev.21 of 19 July 2024*, the regulatory authority has updated the list of Nitrosamines to be monitored by also introducing Nitroso APIs and the relative limit for this molecule.**

- Supplying of Nitros STD
- SET UP of Nitros STD and method (R&D)
  - Screening and Method Validation

[Discover our Nitrosamines Analytical Proposal](#)



Documento  
Adobe Acrobat

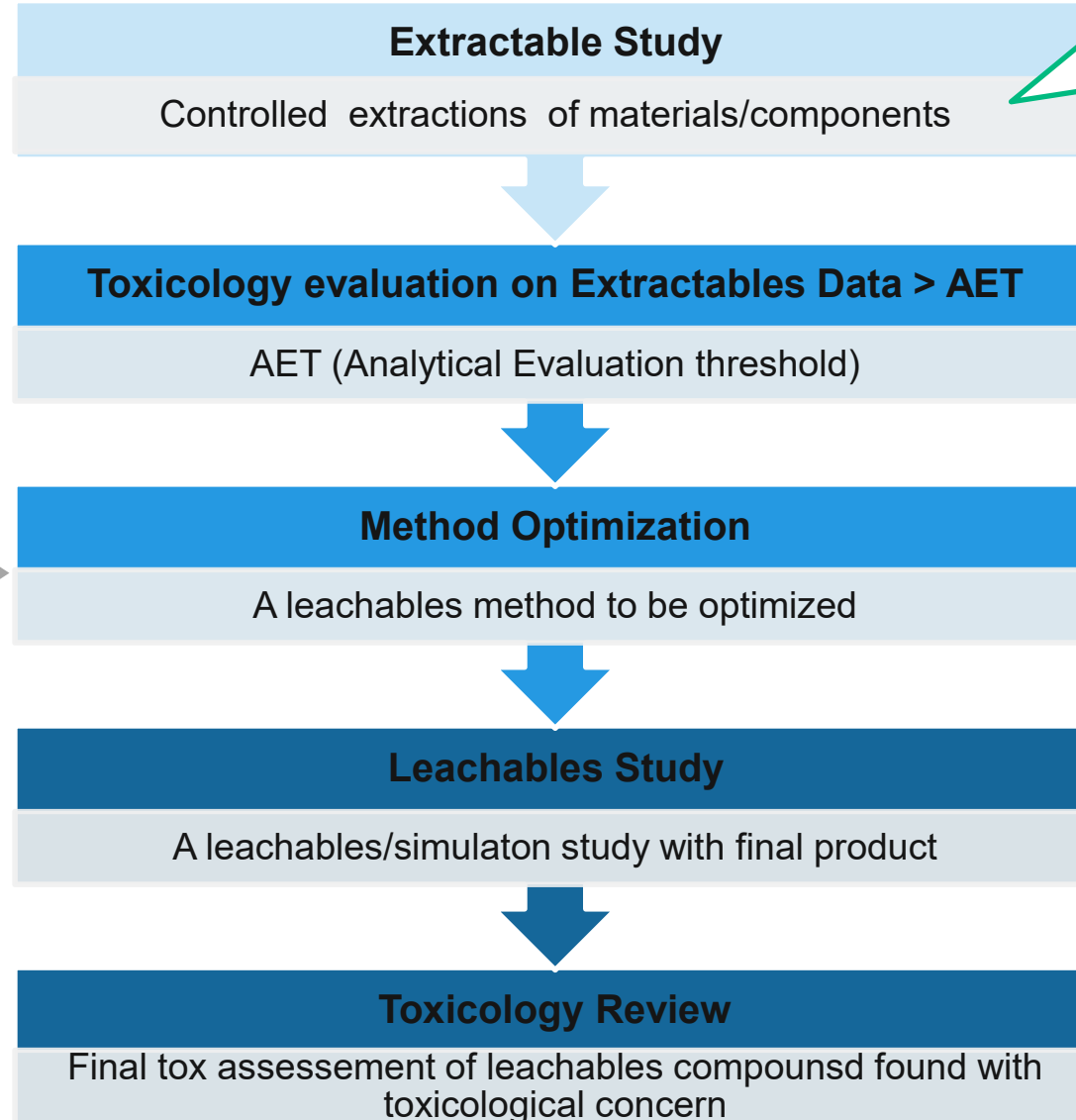
# Extractables and Leachables

Patient safety and Product integrity

ICH,  
ISO 10993-18,  
USP 1663/1664,  
USP 665/1665,  
PQRI,  
BPOG

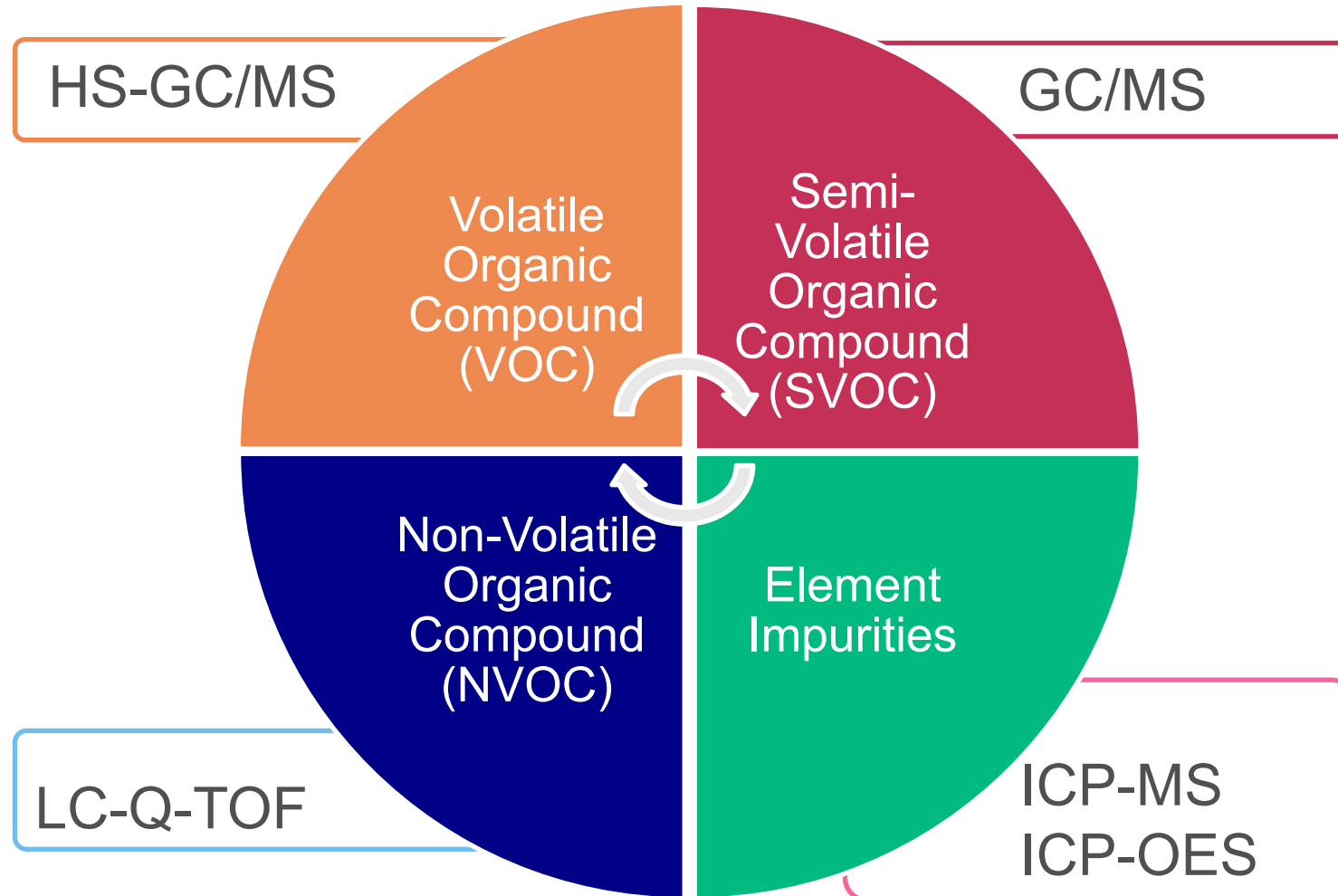
**Packaging materials** are never 100% inert and they can exchange substances through various reaction mechanisms.

**The interaction of pharmaceutical products with packaging** is an important topic in the plan of pharma product development.



# E&L Neutron Approach

Analytical instruments for E&L Testing for products



# Contaminants on Herbals

## Controls of contaminants on excipients or herbal drug products according to GMP standards

- Pesticides residues according to Ph.Eur 2.8.13
- Elemental impurities according to ICH Q3D
- Pyrrolizidine Alkaloids (28 molecules) in House method
- Aflatoxins (B1,B2,G1,G2) in house method
- Ocratoxins in house method

# Hemp & THC/CBD Finished products

## Tests of THC $\Delta$ 8/ $\Delta$ 9 and Cannabinoids on finished pharmaceutical grade products, botanical extracts, CBD oil.

Analytical service offered:

- **DAC monography** for Cannabidiol
- **Contaminants** (EI, Pesticides, Mycotoxins)
- **Cannabinoids**
- **Method validation** for Assay and Impurities on FP

The laboratory is able to support the customer from an analytical point of view, requesting the appropriate ministerial authorizations for the handling of substances, throughout the supply chain from the raw material to the finished product.



# Pharmaceutical method validation

**ACCORDING TO  
ICH Q2 (R1)**

- RAW MATERIALS
- API
- DRUG PRODUCTS



**PRELIMINARY  
STUDY**

**METHOD  
DEVELOPMENT**

**METHOD  
VALIDATION**

**VALIDATION  
REPORT**

**ANALYTICAL  
TRANSFER**



# Stability Studies

## Accelerated or Long-term stability studies

7 Chambers for climatic zones I, II, IV according to ICH Q1 A (R2):

<b>40°C ± 2°C</b>	<b>75% ± 5% U.R.</b>
<b>30°C ± 2°C</b>	<b>65% ± 5% U.R.</b>
<b>25°C ± 2°C</b>	<b>60% ± 5% U.R.</b>
<b>30°C ± 2°C</b>	<b>75% ± 5% U.R.</b>

1 Chamber for light stress test

# Neotron Pharma main equipments

## Wet chemistry

- DISSOLUTION Equipment
- DISAGGREGATION Equipment
  - POLARIMETER
  - FRIABILITY TESTER
  - HARDNESS TESTER
    - K.F.
  - AUTHOMATIC TITRATOR
- SPECTROFOTOMETER UV,  
Vis, IR
  - DENSIMETER
  - VISCOMETER
- PARTICLE SIZE DISTRIBUTION

## Metals

- ICP-MS
- MICROWAVE  
MINERALIZATOR
- ICP-OES
- ATOMIC ABSORPTION

## Microanalytical

- UPLC DAD
- UPLC Refraction Index
- HPLC IR, Fluorimeter, DAD
- HPLC Light Scattering
  - GC-FID
  - GC-ECD
- UPLC-MS-MS
  - GC-MS MS
  - HS/ GC-MS
- UPLC –TOF
  - IC



**THANK YOU**

[www.neotron.it](http://www.neotron.it)