



Company Profile

neutron
pharma

Corporate Organisation



Pharma Business Unit
Activities: Analysis for Pharma GMP
Main Certifications AIFA, FDA, Ministry of Health

Cotecna Group



ACQUISITIONS



History



Neutron numbers



Fields of testing activity



FOOD & FEED



BABY FOOD



FOOD
INGREDIENTS



FOOD
SUPPLEMENTS



FOOD
CONTACT MATERIALS



COSMETICS



neutron
pharma

PHARMA GMP LAB
FDA INSPECTED



Sen&CA
sensory and consumer analysis

SENSORY &
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/LSD
- ICP-MS/OES
- IC

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. 17 of 28 July 2023*, 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

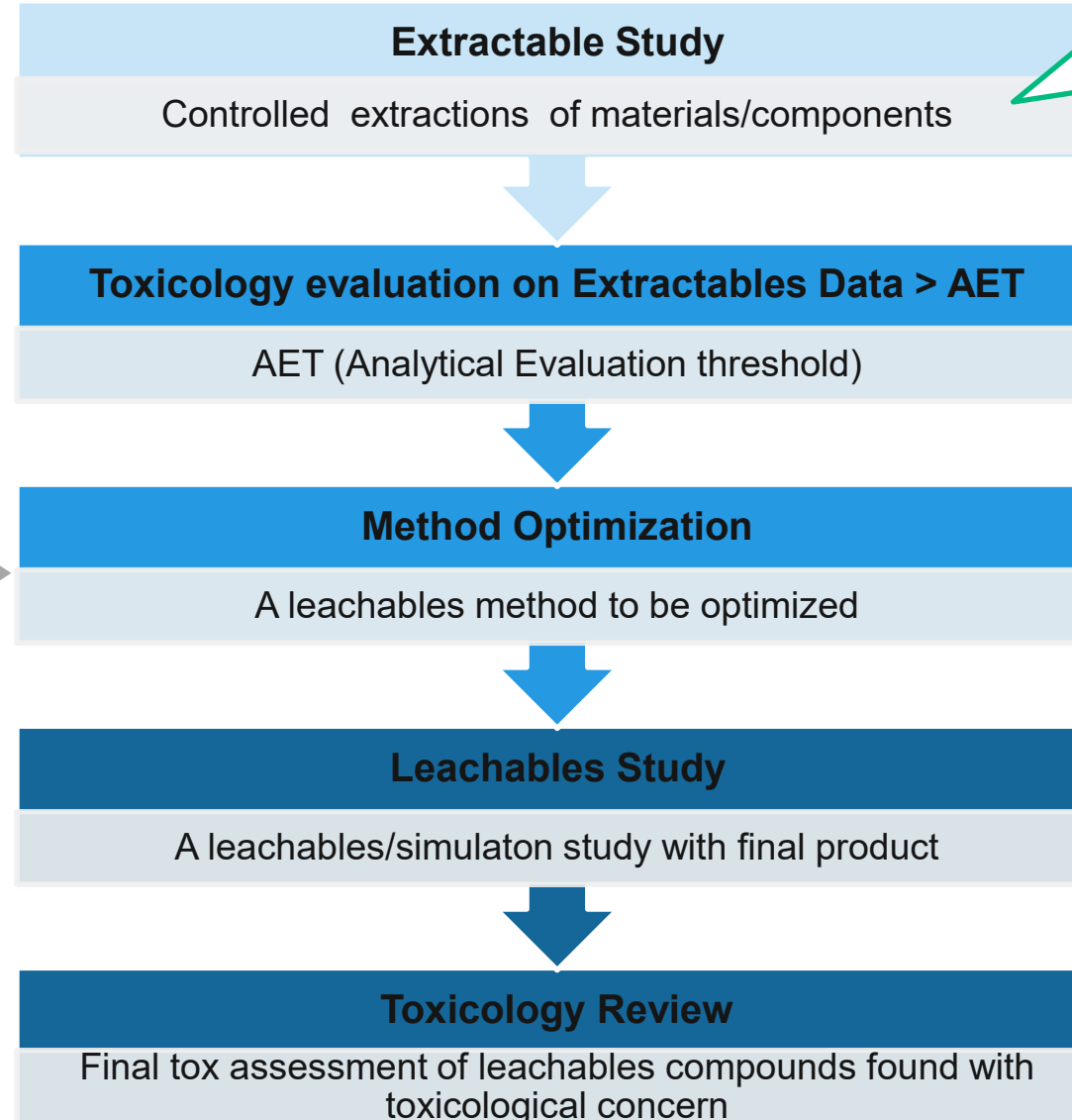
Extractables and Leachables

Patient safety and Product integrity

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

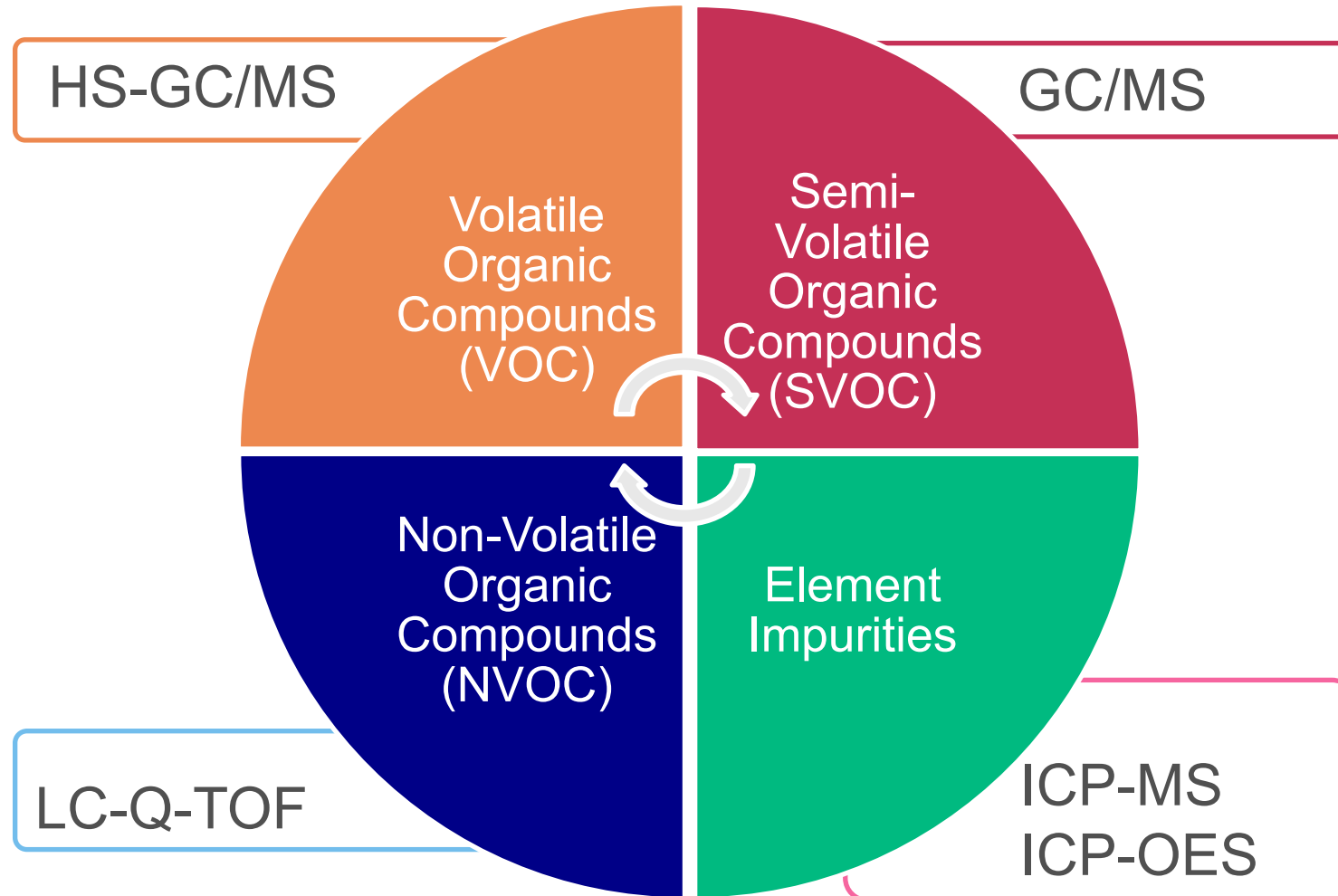
Packaging materials are never 100% inert and they can exchange substances through various reaction mechanisms.

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
- Ochratoxins in house method

Hemp & THC/CBD Finished products

Tests of THC Δ 8/ Δ 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 supports 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):

40°C ± 2°C	75% ± 5% U.R.
30°C ± 2°C	65% ± 5% U.R.
25°C ± 2°C	60% ± 5% U.R.
30°C ± 2°C	75% ± 5% U.R.

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
- HPLC – Post column derivatization
 - GC-FID
 - GC-ECD
- UPLC-MS-MS
 - GC-MS MS
 - HS/ GC-MS
- UPLC –TOF
 - IC
- LC-Q-TOF

The background of the image is a close-up, shallow depth-of-field shot of numerous blister packs containing various pills and capsules. The pills are in shades of blue, yellow, pink, and white. The capsules are primarily white with blue or pink bands. The overall tone is soft and clinical. There are blue geometric shapes in the top right and bottom left corners.

THANK YOU

www.neotron.it