



COTECNA PHARMA

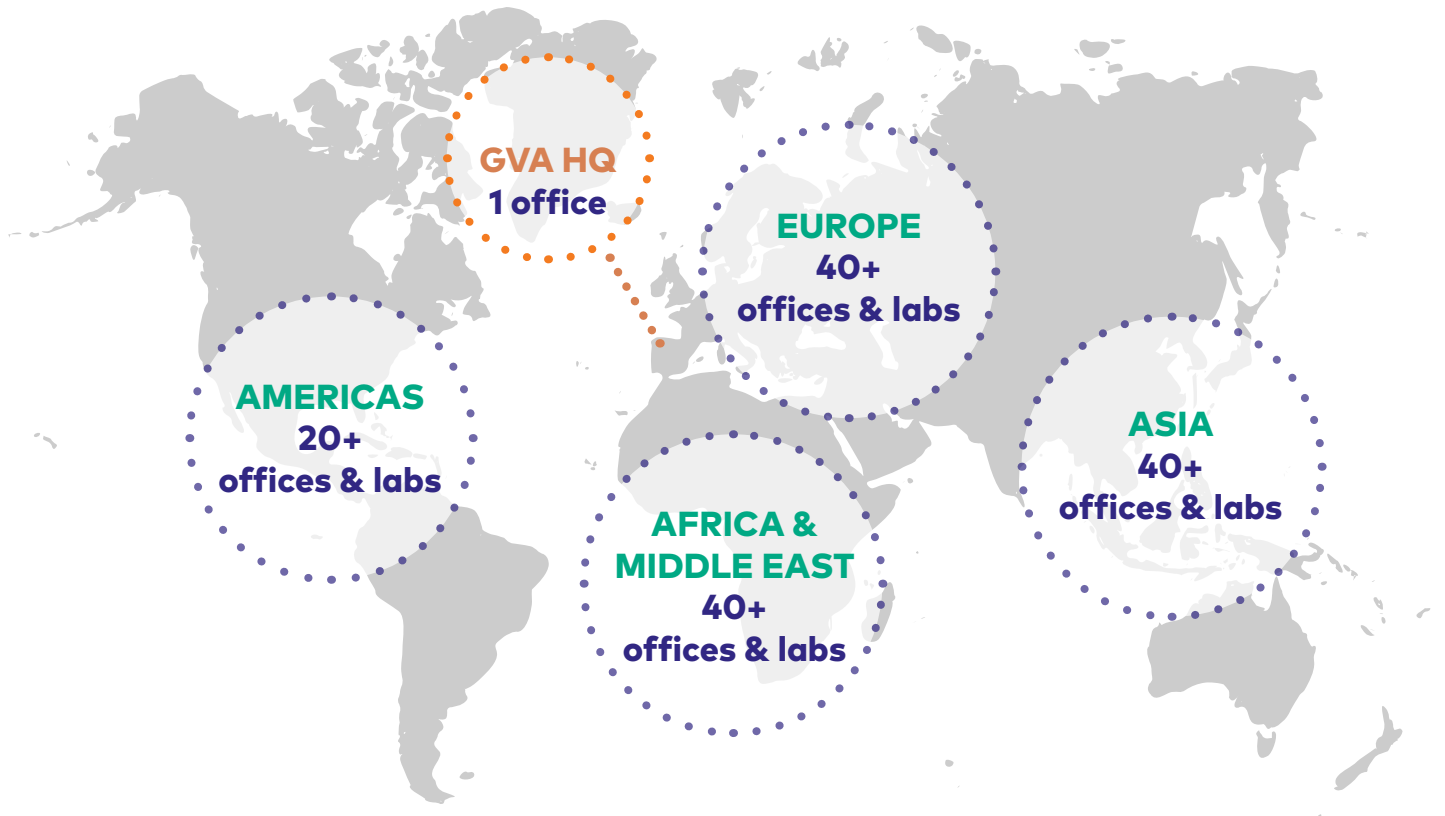
Discover the full services intended to ensure the Quality of your Pharmaceutical products using state-of-art equipment and techniques.

Cotecna is a global provider of testing, inspection & certification services.

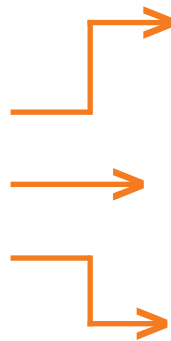
OUR INDUSTRIES

OUR SERVICES





**DREAM
DARE
DELIVER**



We aim to be your **essential partner** for TIC services. We differentiate through technical expertise, innovation, proximity and reactivity.

We behave as **challengers**. We take risk to build our company and offer you solutions tailored to your needs.

Our credibility lies with our ability to respond to **our customer promise** and execute our development plan.



Pharma Services

Pharma testing is a specialized form of laboratory analysis focused on determining the accuracy, strength, and weaknesses of pharmaceutical products. Pharma testing aims to determine the potency, efficacy, and proper dosage and use of medical products, thus ensuring the health and safety of users.

Pharma Service Portfolio & Scope

Cotecna's Pharma Testing capabilities include the testing of different product categories such as



Raw Materials



Bulk Drugs



Personal care products



Active Pharmaceutical Ingredients (APIs)



Herbal Products



Home care products



Finished Products



Primary Packaging Materials



Dyes and Dye intermediates



Medical Devices



Ayush products



Excipients



Cosmetics



Analytical Service Portfolio

Cotecna labs are proficient in testing pharma products for **contaminants, nitrosamines, pesticides, elemental impurities, pyrrolizidine alkaloids, pharmacopoeia methods, assay & impurities, stress test studies, residual solvents, and stability studies.**

The Cotecna Pharma analytical portfolio includes:

- > Analytical Activities (Chemical/Physical/Microbiological Tests)
- > Protocol study
- > Cleaning validation
- > Annual product review
- > API titration according to specification limit
- > Stability study (According to ICH guidelines ICH Q1)
- > Analytical Support for Process Validation
- > Investigation and support on Root Causes Analysis
- > API suppliers auditing
- > Stress test study
- > Method validation (According to ICH Q2 (R1))
- > Analytical Support on Primary Packaging Material choice
- > Full Service for ongoing stability studies (Zone I, II, IV)
- > Identification of impurities
- > Residual test study according to USP





Cotecna Pharma Laboratories

The Cotecna Group includes over 140 offices and laboratories across more than 50 countries worldwide. Laboratories under the Cotecna Group utilize best-in-class equipment to deliver detailed analytical results to our clients. Cotecna has three dedicated pharma laboratories in its network, based in Europe and India:

neotron
Part of the Cotecna Group

Neotron offers an "under one roof" service model in its state-of-the-art laboratory in Modena, Italy. Neotron Pharma is a specialized GMP division dedicated to the Analytical Service for the Pharmaceutical sector on API, Drugs, Excipient and Raw Materials.

SHIVA
Part of the Cotecna Group

Shiva specializes in detailed analytical solutions through its state-of-the-art laboratory and exceptional team. Shiva's advanced pharmaceutical product testing laboratory in Bangalore, India, delivers cGMP compliant and USFDA approved analytical services for clients in the industry.

GEO CHEM
INDIA

Part of the Cotecna Group

Geo-Chem Laboratories (Rajkot) Pvt. Ltd. specializes in detailed analytical solutions through its state-of-the-art laboratory and exceptional team. Geo-Chem's pharmaceutical product testing laboratory in Mumbai, India (Maharashtra) delivers FDA approved analytical services for clients in the industry.



Pharma Approvals/Accreditations

Through its Neutron, Shiva and Geo-Chem subsidiaries, Cotecna has the following Pharma Accreditations

Neutron

- > ISO/IEC 17025: 2017
- > GMP certificate
- > Agenzia Italiana del Farmaco (AIFA) approved
- > FDA U.S Food & Drug Administration – facilities inspected
- > Ministry of Health – Veterinary drugs
- > Ministry of Health – Drugs and psychotropic substances

Shiva

- > ISO/IEC 17025: 2017
- > Facility audited by USFDA in 2007 and 2016, FEI 3006192929, DUNS N° 91-844-1911
- > Approved by Karnataka Drug Control Department
- > AYUSH

Geo-Chem

- > ISO/IEC 17025: 2017
- > Certificate of Approval for Testing of Drugs & Cosmetics by Food & Drug Administration, Maharashtra State
- > Certificate of Approval for Testing of AYUSH by Food & Drug Administration, Maharashtra State



Pharma Laboratory Technologies & Capabilities

In particular our laboratories are equipped with:

Neutron

- > Dissolutor
- > Disaggregator
- > Hardness tester
- > Spectrofotometer
- > K.F, Densimeter
- > Viscometer
- > Mastersizer
- > HPLC and UPLC detectors (DAD, refractive index, IR, Fluorimeter, Light scattering, MSMS, Detector TOF)
- > Ion Chromatography (Dionex)
- > GC area detectors (FID, ECD, HS-MS, MSMS)
- > ICP-OES
- > ICP-MS
- > AAS

Shiva

- > LC-MSMS Triple Quad
- > GC-MSMS Triple Quad Purge & Trap
- > ICP MS
- > ICP OES
- > AAS
- > GC-Head Space
- > GC-Dual FID Autosampler/Manual
- > UV-VIS Spectrophotometer
- > ATR-FTIR
- > Dissolutor
- > HPLC with UV-VIS
- > ELSD
- > RI
- > DAD
- > FLD
- > VWD
- > XRF
- > BET



Geo-Chem

- > HPLC (Waters 6 Nos. and Agilent 4 Nos. with UV Vis, PDA, RI Detector)
- > ICP OES (Perkin Elmer)
- > GC (4 units, two with Head Space facility and two FID)
- > HPTLC (Camag)
- > FTIR with ATR facility (Shimadzu)
- > UV / VIS Spectroscopy (Shimadzu)
- > Dissolution Tester (Electro Lab 3 Nos, Lab India 1 Nos Lab India with Autosampler 1 No.)
- > Brookfield Viscometer (Brook field) (RV, LV, with Helipath)
- > Potentiometric titrations,
- > Fluoride ,
- > Disintegration,
- > Karl Fisher (K.F)
- > Laminar Air Flow,
- > Biosafety Cabinet
- > Autoclave
- > Air sampler
- > Incubators
- > Zone Reader
- > Liquid Particle Analyser (Beckman)
- > Stability Chambers (Four of 1000 lts & Two walk-in Chambers with 9000 ltr. and Two walk-in Chambers with 10000 ltr.)

Inspection and testing services includes:

- > Assay
- > Impurities
- > Residual Solvents
- > Heavy Metals
- > Identification
- > General physical Parameters
- > Microbial limit test
- > Microbiological Assay
- > Pathogens
- > BET
- > PET
- > Sterility
- > Cleaning validation
- > Finger Printing pattern of Herbals
- > Method validation
- > Method Transfer
- > Method verification
- > Stability Studies
- > Area monitoring
- > Cosmetics and personal care analysis as BIS specifications
- > Ayush and herbal as per pharmacopoeias
- > Drugs & pharmaceutical products as per pharmacopoeias

Request an Analysis

To learn more about our Pharma Testing services, or to request a quote for your business please don't hesitate to contact us.

HEAD OFFICE

COTECNA INSPECTION SA
Avenue Peschier 41
CH - 1206 Genève
P.O. Box 6155, 1211 Geneva
+41 22 8496900
cotecna.geneva@cotecna.com

NEOTRON

Stradello Aggazzotti
104 41126 Modena MO, Italy
+39 059 461711
pharma_customer@neutron.it
www.neutron.it

SHIVA

No.24D (P) & 34D, KIADB Industrial
Area, Hoskote,
Bangalore - 562 114, India
+91-80-2801 5333
info@shivaanalytics.com
www.shivaanalytics.com

GEO-CHEM LABORATORIES (RAJKOT) PVT. LTD.,

1t Floor, Pragati Building, Kanjurmarg
(East)
Mumbai 400 042, Maharashtra, India
+ 91 22 66232323
pharma.lab@geochem.net.in
www.geochem.net.in

COTECNA

Trust for a moving world

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