# PHARMACEUTICAL IMPURITY REFERENCE STANDARDS

RESEARCH | MANUFACTURER | DISTRIBUTOR

EUROPE | INDIA | UK | USA

# PRODUCTS


- Impurity Standards
- Working Standards
- Isotope Labelled Compounds
- In-house Reference Standards
- British Pharmacopoeia Standards
- United States Pharmacopoeia Standards
- European Pharmacopoeia (Ph. Eur.) Standards

## QUALIFICATION OF IMPURITY STANDARDS

USP or EP monographs are used to determine RRF and RRT of impurity.

This unique and specific analysis helps to avoid differences in purity at the end user because Veeprho and the end-user use the same monograph.

MASS, HNMR, IR, TGA, and HPLC data are provided by default with each of Veeprho's Impurity Reference Standards.

## QUALIFICATION OF WORKING STANDARDS

Qualification of Working Standards are performed as per the client's SOP or Veeprho's SOP.

This qualification is done against USP RS or EDQM CRS.

These working standards are traceable.

This is a very specific and customised service for our client.

## OVERNIGHT SHIPPING IN US AND EU

# SERVICES

We offer services on Computer Assisted Control Strategy for Genotoxic & Nitrosamine impurities, in Line with Requirement of ICH M7 & FDA guidance.

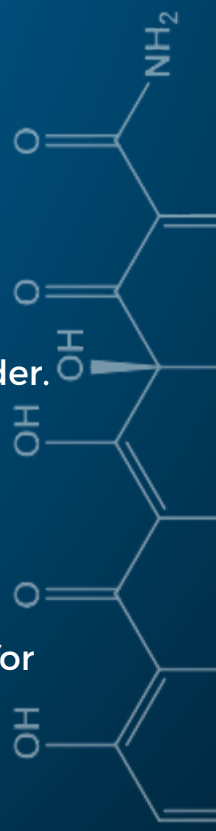
## GENOTOXIC ASSESSMENT OF IMPURITY

According to M7 guidelines, there are 5 classes. Chemical structure is required to do a genotoxic assessment to determine its class.

The Final Assessment Report includes,

- Summary and interpretation by our expert.
- Scientific rationale
- Computational toxicology
- Supporting evidence to aid in the submission to regulators

An assessment report can be submitted on the same day of the Purchase order.




## API/RM MANUFACTURING PROCESS ASSESSMENT (PURGE FACTOR)

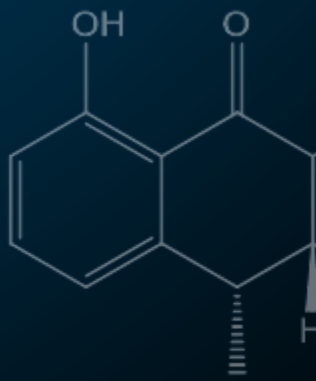
Systematic evaluation of every step by using scientifically designed software for calculating purge factors of potentially mutagenic impurities.

The report includes the purge calculation, scientific rationale, and supporting evidence to aid in the submission to regulators.

Demonstrating that the process is adequately controlled and is capable of consistently reducing nitrosamine impurities through appropriate and robust fate and purge studies.

Summary and interpretation by our expert.

We need: ROS (Route-Of-Synthesis) and creation conditions




## TESTING SERVICES (COST EFFECTIVE)

- 1HNMR
- 13CNMR
- QNMR
- 15N HMBC
- Solid State NMR
- MASS
- TGA
- GC-MS
- FT-IR
- LC-MSMS
- CHNS (Elemental)

# GLOBAL OFFICES

## EUROPE OFFICE

**VEEPRHO PHARMACEUTICALS S.R.O**
Radiova 1122/1, 102 27, Praha 10-Hostivař,
Czech Republic, European Union.

## INDIA OFFICE

**VEEPRHO LABORATORIES PRIVATE LIMITED**
F-504, Tower II, Nexus Seawoods, Seawoods (West),
Navi Mumbai – 400 706, Maharashtra, India.

## US OFFICE

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## UK OFFICE

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