Impurity Qualification Studies

Ensuring Safety. Supporting Compliance. Enabling Regulatory Confidence.

Overview

Impurities are an inherent part of pharmaceutical development, arising during synthesis, formulation, or storage. When present above the defined thresholds, these impurities must be scientifically evaluated to establish their safety and ensure regulatory compliance.

Impurity qualification studies play a critical role in generating the toxicological data required to support impurity limits in drug substances and drug products, in alignment with global regulatory expectations.

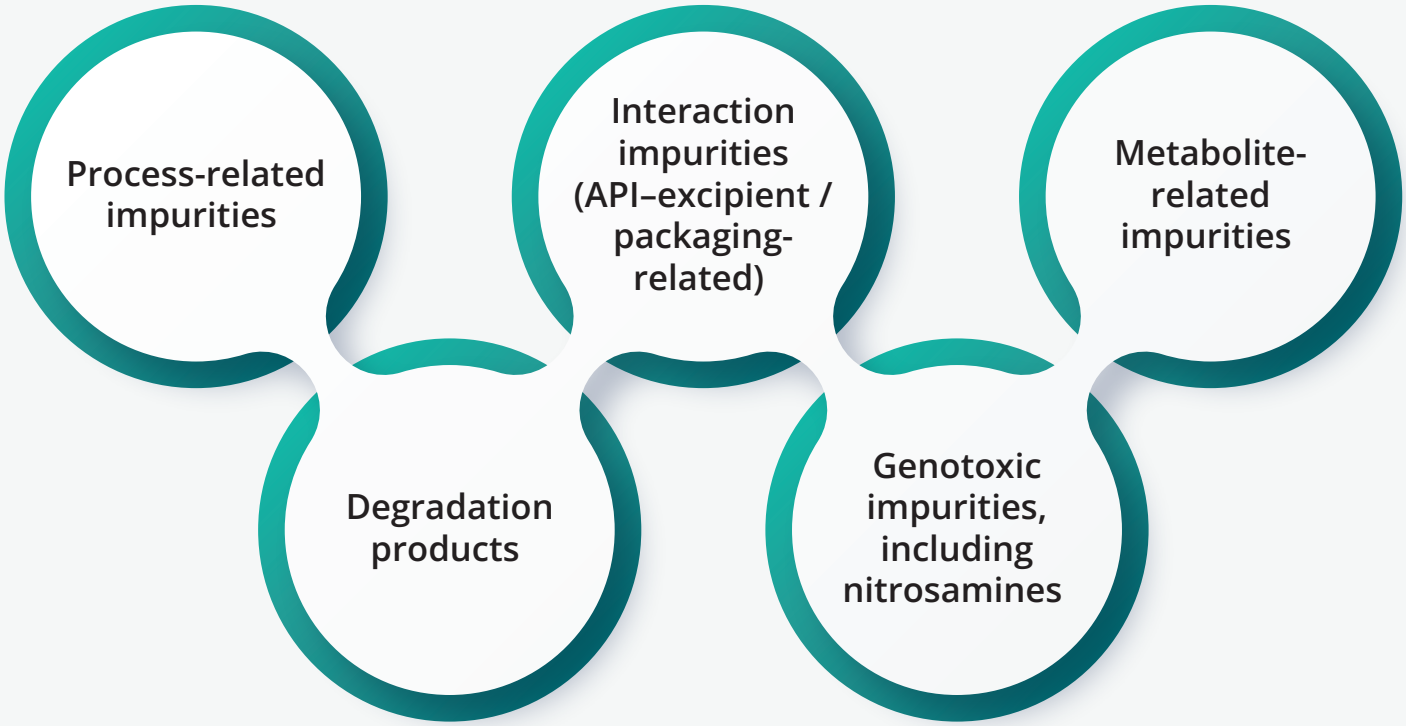
Regulatory Framework

Impurity qualification programs at Veeda Lifesciences are designed in accordance with globally accepted guidelines, including:

- ICH Q3A (R2) – Impurities in Drug Substances
- ICH Q3B (R2) – Impurities in Drug Products
- ICH M7 (R2) – Assessment of Mutagenic Impurities
- ICH S2 (R1) – Genotoxicity Testing
- OECD Guidelines for Genotoxicity Studies

Scope of Services

Veeda Lifesciences supports impurity qualification across a broad range of impurity types:



Our Approach

Impurity qualification studies are executed through a structured and integrated workflow:

Key Capabilities Include

- Ames test and Enhanced Ames test (OECD TG 471)
- In vitro mammalian cell gene mutation assay (OECD 490)
- In vivo micronucleus study (OECD TG 474)
- Repeated-dose toxicity studies (14, 28, 90 days)
- Comparative study design (with and without impurities)

Study Design Considerations

- Dose selection aligned with clinical exposure levels
- Evaluation at multiple impurity concentrations
- Human-relevant route of administration
- Target species/strain selection
- Comprehensive clinical pathology and histopathology
- Toxicokinetic assessment where required

Key Deliverables

- Determination of NOAEL (No Observed Adverse Effect Level)
- Identification of target organ toxicity
- Regulatory-ready GLP study reports
- Qualification of proposed impurity limits

Why Veeda Lifesciences

Veeda Lifesciences offers a scientifically integrated and execution-focused approach to impurity qualification:

Integrated Capabilities
Seamless coordination between analytical, genetox and toxicology functions

Regulatory-Aligned Study Design
Programs designed to meet global regulatory expectations

Expertise in Complex Impurities
Experience in handling genotoxic impurities, including nitrosamines

Customized Study Strategies
Tailored approaches based on impurity profile, exposure, and development stage

Timely Execution
Focus on delivering high-quality, regulatory-ready data within defined timelines

Global Regulatory Acceptance
Enabling successful submissions across major regulatory agencies

Rich Experience in Impurity Qualification Studies
Delivering 325+ impurity qualification studies, including 25+ nitrosamines, enabling successful submissions across major regulatory agencies.

Strategic Value

Partnering with Veeda Lifesciences enables:

- Reduced regulatory risk
- Efficient impurity qualification strategies
- Accelerated development timelines

Connect With Us

To learn more about our impurity qualification capabilities

India: +91 79677 73000
Europe: +30 210 699 7247

info@veedalifesciences.com

www.veedalifesciences.com

Excellence In Everything