

Pharmaceutical ERA Dossier: Regulatory Assessment and GLP Data Generation

Phase I



Phase II
Tier A



Aquatic
toxicity



Environmental Risk Assessment

Efate
properties



Phys-Chem
properties



Sediment
toxicity

Environmental Risk Assessment (ERA) for Pharmaceuticals

Full In-House Regulatory strategy and Laboratory execution.

Staphyt provides an integrated, end-to-end ERA roadmap, from ED and PBT/vPVB screening assessments to Phase I and II A and B of the environmental risk assessment (ERA), triggering GLP data generation in Tier II A (and B) securing the Active Pharmaceutical Ingredient (API) meets all EMA requirements.

PHASE I: Regulatory Assessment & Strategy

Staphyt Regulatory experts in ERA to assess the **Phase I**:

- **Data Intelligence:** Comprehensive data collection and literature searches.
- **Risk Modeling:** Calculations of the predicted environmental concentration in surface water (PEC_surfacewater).
- **Compliance Verification:** Formatting the final report strictly according to EMA guidelines.

If the calculated PEC_surfacewater exceeds regulatory thresholds, or for specific classes like antimicrobials, the assessment triggers **Phase II Tier A**.

PHASE II TIER A:

If **Phase II Tier A** is triggered, Staphyt GLP Lab can generate the missing data to conduct the ERA.

PHYSICO-CHEMICAL PROPERTIES

Characterization of the API

- OECD 105 Water Solubility
- OECD 107/123 Octanol/Water Partitioning
- OECD 112 Dissociation in water
- OECD 101 UV-VIS Absorption Spectra*
- OECD 102 Melting point / melting range*
- OECD 104 Vapour pressure*

** not mandatory*

E-FATE PROPERTIES

Understanding the behaviour and degradation pathway of your compound in the environment.

- OECD 106 Adsorption - Using a Batch Equilibrium Method with 3 soils and 2 sludges*
- OECD 301 Ready Biodegradability test

** non radio-labelled*

AQUATIC TOXICITY

Ecotoxicological assays to determine the toxicity of your compound to aquatic organisms.

- OECD 201 Alga, Growth Inhibition Test
- OECD 211 Daphnia sp., Reproduction Test
- OECD 210 Fish, Early-life Stage Toxicity Test

possible to be carried out in static, semi-static and flow-through test systems

FUNCTIONING OF SEWAGE TREATMENT PLANT (STP)

- OECD 209 Activated Sludge, Respiration Inhibition Test

SEDIMENT TOXICITY

- OECD 218/219 Chironomus, spiked sediment-water toxicity
- OECD 225 Lumbriculus sp., spiked sediment
- OECD 233 Chironomus, sediment-water life-cycle toxicity

SOIL

Where relevant, ecotoxicological assays to determine the toxicity of your compound to terrestrial organisms.

- OECD 216 Nitrogen Transformation Test
- OECD 208 Terrestrial plants, Seedling Emergence and Seedling Growth Test
- OECD 222 Earthworm, Reproduction Test
- OECD 232 Collembola, Reproduction Test

ANALYTICAL DEVELOPMENT AND VALIDATION

Staphyt GLP Lab is fully equipped to develop and validate analytical methods tailored to your specific API across all concerned matrices (water, sediment, and complex test media), according to SANTE/2020/12830 Guideline.



De-risk your Pharma pipeline today.
Contact our Regulatory & Ecotoxicology experts
to initiate your ERA.

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