6 Appendix 1

Study Types and their Critical Phases

General Toxicology

- Body weight
- Clinical Observation
- Dosing
- ECG
- Biological Fluids Sampling
- Necropsy
- Food consumption
- Water consumption
- Ophthalmology
- Impactor/filter sampling (inhalation studies)

Reproductive Toxicology

- Body weight
- Clinical Observations
- Dosing
- Biological Fluids Sampling
- Necropsy
- Food consumption
- Water consumption
- Foetal examination
- Skeletal examination
- Vaginal smears

Genetic Toxicology

In vivo studies

- Dosing
 - Cell harvesting
 - Scoring/assessment

In vitro studies

- Formulation preparation/Dosing
- Cell harvesting
- Scoring/assessment

Safety Pharmacology

In vivo studies

- Body weight
- Dosing
- Biological Fluids Sampling
- Clinical Observation or Study specific observations, as applicable
- Necropsy gastric emptying and intestinal motility studies (UK only)

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