**Regulatory Guidance – Template Numbering**

Fifth and sixth level subheading numbering should be avoided within a document. Thus, the Artos templates are built with subheadings that do not include the module number within the numbering string. For more information on eCTD numbering please see:

• M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use Guidance for Industry: <https://www.fda.gov/files/drugs/published/M4-Organization-of-the-Common-Technical-Document-for-the-Registration-of-Pharmaceuticals-for-Human-Use-Guidance-for-Industry.pdf>

**Regulatory Guidance**

Regulatory Guidance informing Module 2.6.2:

• Guidance for Industry – M4S: The CTD — Safety (August 2001 ICH): <https://www.fda.gov/media/71628/download>

Table of Contents

[1. BRIEF SUMMARY 2](#_Toc22908012)

[2. PRIMARY PHARMACODYNAMICS 3](#_Toc22908013)

[3. SECONDARY PHARMACODYNAMICS 4](#_Toc22908014)

[4. SAFETY PHARMACOLOGY 5](#_Toc22908015)

[4.1. In Vitro Safety Pharmacology 5](#_Toc22908016)

[4.2. In Vivo Safety Pharmacology 5](#_Toc22908017)

[5. PHARMACODYNAMIC DRUG INTERACTIONS 6](#_Toc22908018)

[6. DISCUSSION AND CONCLUSIONS 7](#_Toc22908019)

[7. TABLES AND FIGURES 8](#_Toc22908020)

1. BRIEF SUMMARY

**Regulatory Guidance**

The principal findings from the pharmacology studies should be briefly summarized in approximately two to three pages. This section should begin with a brief description of the content of the pharmacologic data package, pointing out any notable aspects such as the inclusion and/or exclusion of particular data (eg, lack of an animal model).

1. PRIMARY PHARMACODYNAMICS

**Regulatory Guidance**

Studies on primary pharmacodynamics should be summarized and evaluated. Where possible, it would be helpful to relate the pharmacology of the drug to available data (eg, selectivity, safety, potency) on other drugs in the class.

Species should be ordered as follows:

· Mouse

· Rat

· Hamster

· Other rodent

· Rabbit

· Dog

· Nonhuman primate

· Other nonrodent mammal

· Nonmammals

Routes of administration should be ordered as follows:

· The intended route for human use

· Oral

· Intravenous

· Intramuscular

· Intraperitoneal

· Subcutaneous

· Inhalation

· Topical

· Other

1. SECONDARY PHARMACODYNAMICS

**Regulatory Guidance**

Studies on secondary pharmacodynamics should be summarized by organ system, where appropriate, and evaluated in this section.

1. SAFETY PHARMACOLOGY

**Regulatory Guidance**

Safety pharmacology studies should be summarized and evaluated in this section. In some cases, secondary pharmacodynamic studies can contribute to the safety evaluation when they predict or assess potential adverse effects in humans. In such cases, these secondary pharmacodynamic studies should be considered, along with safety pharmacology studies.

* 1. In Vitro Safety Pharmacology
	2. In Vivo Safety Pharmacology
1. PHARMACODYNAMIC DRUG INTERACTIONS

**Regulatory Guidance**

If they have been performed, pharmacodynamic drug interaction studies should be briefly summarized in this section.

1. DISCUSSION AND CONCLUSIONS

**Regulatory Guidance**

In the Discussion and Conclusion sections, information should be integrated across studies and across species.

This section provides an opportunity to discuss the pharmacologic evaluation and to consider the significance of any issues that arise.

1. TABLES AND FIGURES

**Regulatory Guidance**

Text tables and figures can be included at appropriate points throughout the summary within the text. Alternatively, tables and figures can be included at the end of the summary.