



# **Module 2 Overviews – C & NC Common Technical Document CTD Index**

**(Sample Document will provide on request)**



---

## 2.4 Non Clinical Overview

### TABLE OF CONTENTS

<b>2.4.1</b>	<b>OVERVIEW OF THE NON CLINICAL TESTING STRATEGY</b>	<b>2</b>
<b>2.4.2</b>	<b>PHARMACOLOGY</b>	<b>3</b>
2.4.2.1	Primary Pharmacodynamics	3
2.4.2.1.1	Receptor binding	3
2.4.2.1.2	Dose response relationship	4
2.4.2.2	Secondary Pharmacodynamics	4
2.4.2.2.1	Comparative studies	4
2.4.2.2.2	Combination therapies	6
2.4.2.3	Safety Pharmacology	6
2.4.2.4	Pharmacodynamic Drug Interactions	6
<b>2.4.3</b>	<b>PHARMACOKINETICS</b>	<b>7</b>
2.4.3.1	Absorption	7
2.4.3.2	Distribution	9
2.4.3.3	Elimination and Metabolism	10
2.4.3.4	Pharmacokinetic Drug Interactions	11
<b>2.4.4</b>	<b>TOXICOLOGY</b>	<b>12</b>
2.4.4.1	Safety Pharmacology - Single Dose Toxicity	12
2.4.4.2	Repeated Dose Toxicity	13
2.4.4.3	Genotoxicity	15
2.4.4.4	Carcinogenic Potential	16
2.4.4.5	Reproduction Toxicity	17
<b>2.4.5</b>	<b>INTEGRATED OVERVIEW AND CONCLUSIONS</b>	<b>18</b>
<b>2.4.6</b>	<b>LIST OF LITERATURE REFERENCES</b>	<b>19</b>



---

## 2.5 Clinical Overview

### TABLE OF CONTENTS

<b>2.5.1</b>	<b>PRODUCT DEVELOPMENT RATIONALE</b>	<b>2</b>
<b>2.5.2</b>	<b>OVERVIEW OF BIOPHARMACEUTICS</b>	<b>2</b>
2.5.2.1	Bioavailability	2
2.5.2.2	Dosage Form/Strength Proportionality	3
2.5.2.3	Differences Between The To-Be-Marketed Formulation And The Formulation(S) Used In Clinical Trials	3
2.5.2.4	Influence Of Food On Exposure	3
<b>2.5.3</b>	<b>OVERVIEW OF CLINICAL PHARMACOLOGY</b>	<b>4</b>
2.5.3.1	Pharmacokinetics of Ranitidine hydrochloride	4
2.5.3.2	Pharmacodynamics of Ranitidine hydrochloride	8
<b>2.5.4</b>	<b>OVERVIEW OF EFFICACY</b>	<b>9</b>
2.5.4.1	Duodenal Ulcer	9
2.5.4.2	Pathologic GI Hypersecretory Conditions	11
2.5.4.3	Gastric Ulcer	12
2.5.4.4	Gastroesophageal Reflux	12
2.5.4.5	Erosive Esophagitis	13
2.5.4.6	Increasing Gastric pH in Neonates Undergoing Extracorporeal Membrane Oxygenation (ECMO)	14
2.5.4.7	Other Uses	14
<b>2.5.5</b>	<b>OVERVIEW OF SAFETY</b>	<b>14</b>
2.5.5.1	Toxicity	14
2.5.5.2	Tolerability	14
2.5.5.3	Drug interactions	19
<b>2.5.6</b>	<b>BENEFITS AND RISKS CONCLUSIONS</b>	<b>22</b>
2.5.6.1	Therapeutic indications	22
2.5.6.2	Posology and method of administration	22
2.5.6.3	Contraindications	24
2.5.6.4	Special warnings and precautions for use	24
2.5.6.5	Interaction with other medicinal products and other forms of interaction	25
2.5.6.6	Pregnancy and lactation	25
2.5.6.7	Effects on ability to drive and use machines	25
2.5.6.8	Undesirable effects	25
2.5.6.9	Overdose	27
<b>2.5.7</b>	<b>LITERATURE REFERENCES</b>	<b>27</b>