



ASEAN Common Technical Dossier for Pharmaceutical Registration

ACTD Clinical Check List for Product Classification

ACTD Clinical Check List for Product Classification
(ASEAN Common Technical Dossier for Pharmaceutical Registration)

Part IV : Clinical Document	NCE	BIOTECH	MaV			MiV	GP
			RT	ST/P	IND		
Section A. Table of Contents	✓	✓	✓	✓	✓	-	-
Section B. Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions	✓	✓	✓	✓	✓	-	-
Section C. Clinical Summary 1.Summary of Biopharmaceutic Studies and Associated Analytical Method 1.1 Background and Overview 1.2 Summary of Results of Individual Studies 1.3 Comparison and Analyses of Results Across Studies Appendix 1	✓	✓	✓	✓	✓	-	-

Part IV : Clinical Document	NCE	BIOTECH	MaV			MiV	GP
			RT	ST/P	IND		
<p>Section C. Clinical Summary (Cont.)</p> <p>2.Summary of Clinical Pharmacology Studies</p> <p>2.1 Background and Overview</p> <p>2.2 Summary of Results of Individual Studies</p> <p>2.3 Comparison and Analyses of Results Across Studies</p> <p>2.4 Special Studies</p> <p>Appendix 2</p> <p>3.Summary of Clinical Efficacy</p> <p>3.1 Background and Overview of Clinical Efficacy</p> <p>3.2 Summary of Results of Individual Studies</p> <p>3.3 Comparison and Analyses of Results Across Studies</p> <p>3.4 Analysis of Clinical Information Relevant to Dosing Recommendations</p> <p>3.5 Persistence of Efficacy and/or Tolerance Effects</p> <p>Appendix 3</p>							

Part IV : Clinical Document	NCE	BIOTECH	MaV			MiV	GP
			RT	ST/P	IND		
Section C. Clinical Summary (Cont.)							
4.Summary of Clinical Safety 4.1 Exposure to the Drug 4.2 Adverse Events 4.3 Clinical Laboratory Evaluations 4.4 Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5 Safety in Special Groups and Situations 4.6 Post-marketing Data Appendix 4 5.Synopses of Individual Studies							
Section D. Tabular Listing of All Clinical Studies	✓	✓	✓	✓	✓	-	-

Part IV: Clinical Document	NCE	BIOTECH	MaV			MiV	GP
			RT	ST/P	IND		
Section E. Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.1 BA Study Reports 1.2 Comparative BA or BE Study Reports 1.3 <i>In vitro-In vivo</i> Correlation Study Reports 1.4 Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials 2.1 Plasma Protein Binding Study Reports 2.2 Reports of Hepatic Metabolism and Drug Interaction Studies 2.3 Reports of Studies Using Other Human Biomaterials	✓	✓	✓	✓	✓	-	-

Part IV : Clinical Document	NCE	BIOTECH	MaV			MiV	GP
			RT	ST/P	IND		
<p>Section E. Clinical Study Reports (if applicable)</p> <p>3. Reports of Human Pharmacokinetic (PK) Studies</p> <p>3.1 Healthy Subject PK and Initial Tolerability Study Reports</p> <p>3.2 Patient PK and Initial Tolerability Study Reports</p> <p>3.3 Population PK Study Reports</p> <p>4. Reports of Human Pharmacodynamic (PD) Studies</p> <p>4.1 Healthy Subject PD and PK/PD Study Reports</p> <p>4.2 Patient PD and PK/PD Study Reports</p>							

Part IV : Clinical Document	NCE	BIOTECH	MaV			MiV	GP
			RT	ST/P	IND		
<p>Section E. Clinical Study Reports (if applicable)</p> <p>5. Reports of Efficacy and Safety Studies</p> <p>5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication</p> <p>5.2 Study Reports of Uncontrolled Clinical Studies</p> <p>5.3 Reports of Analyses of Data from More Than One Study, Including Any Formal Integrated Analyses, Meta-analyses, and Bridging Analyses</p> <p>5.4 Other Clinical Study Reports</p> <p>6. Reports of Post-Marketing Experience</p> <p>7. Case Report Forms and Individual Patient Listing</p>							
Section F. List of Key Literature References	✓	✓	✓	✓	✓	■	■