INVESTIGATIONAL PRODUCT QUALITY OVERALL SUMMARY

*This template should be filled in and submitted in **Microsoft word format** with New times roman style font size 12 black ink). Details on this summary should as inserted as prescribed in the CTD module 3.)*	
Title of Study	
Protocol Identification Number/code	
Protocol Version Number (where applicable)	
Date of Protocol	
Rwanda FDA Application Number	
Name of Investigational Product or Intervention	
Therapeutic Classification	
Dosage Form(s) and Strength(s)	
Route(s) of Administration	
Clinical trial Design *(extract from the protocol)*	
Name of Comparator Product (where applicable)	
Name and address(es) of the Applicant	
Name and address(es) of the Sponsor	
Name and address(es) of the Principal Investigator (PI)	
Name and address(es) of the Study Monitor	
Name and address(es) of Study Site(s)	
Name and address of the manufacturer of investigational product	
Name and address of the manufacturer of comparator product (if applicable)	
Phase of Trial	
Proprietary (Brand) Name of FPP	
Non-proprietary or Common Name of Drug Substance (Medicinal Ingredient)	
Company Name	
Dosage Form(s)	
Strength(s)	
Country from which the Clinical Supplies were Obtained for the Lot to be Used in this Clinical Trial (as well as the market status in that country)	

2.3. S ACTIVE PHARMACEUTICAL INGREDIENT (NAME, MANUFACTURER)

2.3. S.1 General Information (name, manufacturer)

2.3. S.1.1 Nomenclature (name, manufacturer)

(a) Recommended International Non-proprietary name (INN):

(b) Compendial name, if relevant:

(c) Chemical name(s):

(d) Company or laboratory code:

(e) Other non-proprietary name(s) (e.g., national name, USAN, BAN):

(f) Chemical Abstracts Service (CAS) registry number:

Note: For Phase I Trials only (a) and (b) is required

2.3. S.1.2 Structure (name, manufacturer)

(a) Structural formula, including relative and absolute stereochemistry:

(b) Molecular formula:

(c) Molecular mass:

2.3. S.1.3 General Properties (name, manufacturer)

(a) Physical description (e.g., appearance, colour, physical state):

(b) Physical form (e.g., preferred polymorphic form, solvate, hydrate):

(c) Solubilities (e.g., aqueous/non aqueous solubility profile, tabular format, reporting in mg/mL):

(d) pH and pKa values:

(e) Other relevant information:

2.3. S.2 Manufacture (name, manufacturer)

2.3. S.2.1 Manufacturer(s) (name, manufacturer)

(a) Name, address, and responsibility of each manufacturer, including Contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial:

(b) List of referenced Drug Master Files (DMFs) and DMF Numbers (copies of DMF letters of access should be located in Module 1):

2.3. S.2.2 Description of Manufacturing Process and Process Controls (name, Manufacturer)

(a) Flow diagram of the synthetic process(es):

Note: For Phase II & III include also the following should be submitted: -

(b) Detailed narrative description of the manufacturing process(es):

2.3.S.2.3 Control of Materials (name, manufacturer)

(a) For Active Pharmaceutical Ingredient manufactured with reagents obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents:

Note: For Phase II & III include also the following should be submitted:

(b) Information on starting materials

2.3. S.2.4 Controls of Critical Steps and Intermediates (name, manufacturer)

(a) Summary of the controls performed at critical steps of the manufacturing

(b) Process and on intermediates:

2.3. S.3 Characterization (name, manufacturer)

2.3. S.3.1 Elucidation of Structure and other Characteristics (name, manufacturer)

(a) List of studies performed (e.g., IR, UV, NMR, MS, elemental analysis) and Summary of the interpretation of evidence of structure:

(b) Discussion on the potential for isomerism and identification of Stereochemistry (e.g., geometric isomerism, number of chiral centres and configurations):

(c) Summary of studies performed to identify potential polymorphic forms (including solvates):

(d) Summary of studies performed to identify the particle size distribution of the Active Pharmaceutical Ingredient:

(e) Other characteristics:

2.3. S.3.2 Impurities (name, manufacturer)

a. Identification of potential and actual impurities arising from the synthesis, manufacture and/or degradation:

b. List of drug-related impurities (e.g., starting materials, by-products, intermediates, chiral impurities, degradation products, metabolites), including chemical name, structure and origin:

Drug-related Impurity (chemical name or descriptor)	Structure	Origin

(c) List of process-related impurities (e.g., residual solvents, reagents, catalysts), including compound name and step used in synthesis:

(d) Actual levels of impurities (e.g., drug-related and process-related) found in Batches used in nonclinical and clinical studies:

Impurity (drug-related and process-related)	Acceptance Criteria	Results (include batch number and use) (e.g., clinical)		

2.3. S.4 Control of the Active Pharmaceutical Ingredient (name, manufacturer)

2.3. S.4.1 Specification (name, manufacturer)

(a) Specification for the Active Pharmaceutical Ingredient:

Test	Acceptance Criteria	Analytical Procedure (Type and Source)

2.3. S.4.2 Analytical Procedures (name, manufacturer)

(a) Summary of the analytical procedures (e.g., suitability, key method parameters, conditions):

2.3. S.4.3 Validation of Analytical Procedures (name, manufacturer)

(a) Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results):

2.3. S.4.4 Batch Analyses (name, manufacturer)

(a) Description of the batches to be used in this clinical trial (or representative batches):

Batch Number	Batch Size	Date of Manufacture and Site of Production	Use (e.g., clinical)

(b) Summary of results for the batches to be used in this clinical trial or Representative batches (should include tests, types of analytical procedures (type and source), and actual results):

2.3. S.4.5 Justification of Specification (name, manufacturer)

(a) Justification of the Active Pharmaceutical Ingredient specification (e.g., manufacturing

experience, stability, historical batch analysis results, safety considerations):
For Phase one trial only Batch analysis report is required.

2.3. S.6 Container Closure System (name, manufacturer)

(a) Description of the container closure system(s) for the storage and shipment of the Active Pharmaceutical Ingredient:

2.3. S.7 Stability (name, manufacturer)

2.3. S.7.1 Stability Summary and Conclusions (name, manufacturer)
(a) Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained):

(b) Proposed storage conditions and re-test period (or shelf life, as appropriate):

2.3. S.7.2 Stability Protocol and Stability Commitment (name, manufacturer)
(a) If full long term stability data is not available at the time of filing, provide a summary of the stability protocol and a commitment for the continued monitoring of the Active Pharmaceutical Ingredient stability according to the protocol:

2.3. S.7.3 Stability Data (name, manufacturer)

(a) The actual stability results (i.e., raw data) may be found in:

(b) Summary of analytical procedures and validation information for those Procedures not previously summarized in 2.3.S.4 (e.g., analytical procedures used only for stability studies):

2.3. P FINISHED PHARMACEUTICAL PRODUCT (NAME, DOSAGE FORM)

2.3.P.1 Description and Composition of the FPP (name, dosage form)

(a) Description of the dosage form:
(b) Composition of the dosage form:

(i) Composition, i.e., list of all components of the dosage form, and their amounts on a per unit basis (including overages, if any):

Component and Quality Standard (and Grade, if applicable)	Function	Strength (label claim)			
		Quantity per unit	%	Quantity per unit	%

(i) Composition of all *components that are mixtures* (e.g., colourants, coatings, capsule shells, imprinting inks):-

a) Description of reconstitution diluent(s), if applicable:

b) Type of container closure system used for accompanying reconstitution diluent, if applicable:

c) Qualitative list of the components of the placebo samples to be used in this Clinical trial, if different from the components listed in 2.3. P.1(b):

2.3. P.2 Pharmaceutical Development (name, dosage form)

(a) Discussion on the development of the dosage form, the formulation, Manufacturing process, etc.:

(b) For sterile, reconstituted products, summary of compatibility studies with Diluents/containers:

2.3. P.3 Manufacture (name, dosage form)

2.3. P.3.1 Manufacturer(s) (name, dosage form)

(a) Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial:

(b) List of referenced Drug Master Files (DMFs) and DMF Numbers (copies of DMF letters of access should be located in Module 1):

(c) Attestation that the dosage form was manufactured under Good Manufacturing Practices (GMP) conditions:

2.3. P.3.2 Batch Formula (name, dosage form)

(a) List of all components of the dosage form to be used in the manufacturing process, and their amounts on a per batch basis (including overages, if any):

Strength (label claim)	
Batch Size(s) (number of dosage units)	
Component and Quality Standard (and Grade, if applicable)	Quantity per batch
Total	

2.3. P.3.3 Description of Manufacturing Process and Process Controls (name, dosage form)

(a) Flow diagram of the manufacturing process:

(b) Detailed narrative description of the manufacturing process, including Equipment type and working capacity, process parameters ***(for Phase II & III trials***)

(b) For sterile products, details and conditions of sterilization and lyophilization:

2.3. P.3.4 Controls of Critical Steps and Intermediates (name, dosage form)

(a) Summary of controls performed at the critical steps of the manufacturing Process and on isolated intermediates (***for Phase II & III trials***)

2.3. P.4 Control of Excipients (name, dosage form)

2.3. P.4.1 Specifications (name, dosage form)

Specifications for non-compendial excipients and for compendial excipients Which include supplementary tests not listed in the monograph(s) may be found in:

(a) List of referenced Drug Master Files (DMFs) and DMF Numbers (copies of DMF letters of access should be located in Module 1):

2.3. P.4.5 Excipients of Human or Animal Origin (name, dosage form)

(a) List of excipients that are of human or animal origin (including country of origin):

(b) Summary of the information (e.g., sources, specifications, description of the Testing performed, viral safety data) regarding adventitious agents for excipients of human or animal origin:

For excipients obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents:

2.3. P.4.6 Novel Excipients (name, dosage form)

(a) Summary of the details on the manufacture, characterization, and controls, With cross references to supporting safety data (nonclinical and/or clinical) on novel excipients (i.e., those used for the first time in a FPP or by a new route of administration):

2.3. P.5 Control of FPP (name, dosage form)

2.3. P.5.1 Specification(s) (name, dosage form)

(a) Specification(s) for the FPP:

Test	Acceptance Criteria	Analytical Procedure (Type and Source)

2.3. P.5.2 Analytical Procedures (name, dosage form)

(a) Summary of the analytical procedures (e.g., key method parameters, conditions, suitability):

2.3. P.5.3 Validation of Analytical Procedures (name, dosage form)

(a) Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results):

2.3. P.5.4 Batch Analyses (name, dosage form)

(a) Description of the batches to be used in this clinical trial (or representative batches):

Strength and Batch Number	Batch Size	Date of Manufacture and Site of Production	Input Drug Substance Batch	Use (e.g., clinical)

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(b) Summary of results for the batches to be used in this clinical trial or Representative batches (should include tests, types of analytical procedures (type and source), and actual results):

Note: For Phase one trial only Batch analysis report is required.

2.3. P.5.5 Characterization of Impurities (name, dosage form)

(a) Information on the characterization of impurities, not previously provided in 2.3. S.3.2 (e.g., summary of actual and potential degradation products):

2.3. P.5.6 Justification of Specification(s) (name, dosage form)

(a) Justification of the Active Pharmaceutical Ingredient specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations):

2.3.P.7 Container Closure System (name, dosage form)

(a) Description of the container closure systems, including unit count or fill size, container size or volume:

(b) Materials of construction of each primary packaging component:

(c) For sterile products, details of washing, sterilization and depyrogenation

d) Procedures for container closures:

2.3. P.8 Stability (name, dosage form)

2.3. P.8.1 Stability Summary and Conclusions (name, dosage form)

(a) Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained):

(i) Description of stability study details:

Storage Conditions (oC, % RH, light)	Strength and Batch Number	Batch Size and Date of Manufacture	Container Closure System	Completed (and Proposed) Test Intervals

(ii) Summary and discussion of stability study results:

(b) Proposed storage conditions and shelf life (and in-use storage conditions and in-use period, if applicable):

2.3. P.8.2 Post-approval Stability Protocol and Stability Commitment (name, dosage form)

(a) If full long term stability data is not available at the time of filing, provide a summary of the stability protocol and a commitment that the stability of the clinical trial samples or representative batches will be monitored throughout the duration of the clinical trial or proposed shelf life:

2.3. P.8.3 Stability Data (name, dosage form)

(a) The actual stability results (i.e., raw data) may be found in:

(b) Summary of analytical procedures and validation information for those Procedures not previously summarized in 2.3.P.5 (e.g., analytical procedures used only for stability studies):

5. Additional Requirements for Clinical trials for medical devices

An application to authorize a clinical trial involving a medical devices or diagnostics shall be made in accordance with provisions provided in section 2 of these guidelines. In addition, the following documentation will be required;

a) Device Description, design and materials including User manual, catalogue of IFU of the device.
b) Marketing history
c) Risk assessment and standard list
d) Toxicology and biological safety
e) Sterilization validation
f) Electrical safety
g) Safety and usefulness of medicinal substance
h) Safety and appropriateness of use of tissues of animal origin
i) Signed and approved protocol with data compiled as prescribed in ANNEX-II and current ISO standards.
j) Certificate of ISO/ Quality audit (ISO 13485) for manufacturer of the device if applicable.