ANNEX III: ARRANGEMENT OF DOCUMENT REQUIRED FOR REGISTRATION OF CCP IN EASY ASSESSMENT FORMAT

The document is subdivided in two main sections and must contains all information necessary for registration of CCP and must be arranged as the following to make the document to be assessed in easy way.

Section 1: Administrative information and product information requirement

Section 2: Technical data requirements

Section 2.1 Raw materials

Section 2.2: Finished product technical data requirements

Note: All sections and subsections of this document must be presented on the CD as directed in the guideline (1.5 g) and if, due to the form of the product, there are information which cannot be completed, NA must be indicated on that part.

a) The application and supporting document should be submitted in CD-ROM or External driver addressed to Rwanda FDA. Also online submission is acceptable.

b) The application form should be typed in English. Any document which is in any language other than English must be accompanied by a certified or notarised English translation.

c) Application Form and section 2.2 should be in both PDF and word format

d) The PDF documents should be selectable and searchable

e) All pages of the application should be numbered in the style: ***page x of y***.

Therefore, the applicant shall prepare and present the product dossier information in the following format.

SECTION 1: ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION REQUIREMENT

1.1 Table of contents

1.1.1 Cover letter

1.1.2 Application form

1.1.10 Proof of payment of non-refundable registration application fee

1.1.3 Manufacturing license or Operation license

1.1.4 Contract Manufacturing Agreement

1.1.6 Valid GMP Certificate or other applicable internationally recognised Management System certification. Otherwise, the applicant has to apply for GMP inspection to Rwanda FDA.

1.1.7 Appointment letter supported by the power of attorney of the Local technical representative (LTR) for the foreign product. For local manufacturer, they must specify a qualified person in charge of the CCP safety monitoring and post marketing surveillance.

1.1.8 Product samples

1.1.9 Commitment letters

1.1.10 Product license or approval in other countries

1.1.8.1 Registration status

1.1.8.2 Statement on rejection or withdrawn application

1.1.11 Annex

SECTION 2: TECHNICAL DATA REQUIREMENTS

2.1 RAW MATERIALS

2.1.1 Table of content

2.1.2 Name and address of manufacturer for each Chemical ingredients

2.1.2.1 General information

2.1.2.1.1 Nomenclature

2.1.2.1.2 Address of manufacturer

2.1.3 Supporting document of source of each ingredient

2.1.4 Material Safety Data Sheets (MSDS) for each ingredient

2.1.5 Annex

2.2: FINISHED PRODUCT TECHNICAL DATA REQUIREMENTS

2.2.1 Table of content

2.2.2 Description of the FP and intended use

2.2.2.1 Description of the FP

2.2.2.2 Intended use

2.2.3 Composition of the FP

2.2.4 Manufacturing process

2.2.5 Certificate of Analysis for the FP

2.2.6 Packaging and labelling information

2.2.6.1 Packaging

2.2.6.2 Labelling

2.2.6.2.1 Product information content

2.2.6.2.2 Hazard and safety information

2.2.7 Stability data

2.2.7.1 Study design (protocol)

2.2.7.2 Test conditions (humidity and temperature), testing interval and Duration:

2.2.7.3 Type of container used

2.2.7.4 Parameters to be tested

2.2.7.5 Test results

2.2.8 Material Safety Data Sheets of finished product

2.2.9 Annex