RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

Doc N°: DAR/FOM/013

A – PRODUCT ADMINISTRATIVE INFORMATION

Date of receipt by Rwanda FDA		
Application Reference Number	**(after screening)**	
Date of Application		
Date of 1st assessment		
Date of 2nd assessment		
Type Application	☐ Full assessment ☐ Abridged	
Payment reference Number , date and bank name		
Name and complete address of the Applicant		
Name of appointed Local Technical Representative		
Product proprietary name (brand name0		
Product non-proprietary name (INN)		
Product dosage form		
Product Route of administration		
Description of appearance of pharmaceutical dosage form		
Therapeutic group /ATC CODE		
Therapeutic indications		
Distribution category		
Proposed shelf life (in Months)		
Proposed Primary and secondary packaging		
Proposed product Pack size		
Proposed Storage Conditions and special precautions		
FIRST ASSESSOR	**Names**	**Signature**
SECOND ASSESSOR	**Names**	**Signature**
Name (s) and complete address (es) of the manufacturer (s) of the finished pharmaceutical product (s), including the final product release if different from the manufacturer **[FPP].**		
GMP status of the manufacturing facility, and production lines audited by Rwanda FDA	GMP Status: ☐ **Compliant** ☐ **Non-Compliant** ☐ **Not yet Audited** Production lines approved:	
The applicant has applied for GMP Inspection to Rwanda FDA	☐ **YES** ☐ **NO**	
GMP status of the manufacturing facility, and production lines audited by other authorities (SRA, WHO, EAC, Country of origin, other)	GMP Status: ☐ **Compliant** ☐ **Non-Compliant** Production lines approved:	
Name and address (es) of the manufacturer(s) of the active pharmaceutical ingredient(s) [**API**].		
Name and address of the Contract research Organisation (s) where the clinical studies proving efficacy and safety of the product were conducted		
List of the countries in which the applicant has evidence of registration of the product if any		
SUMMARY OF QUALITY ASSESSMENT OF LABELLING AND SAMPLES		
Summary of product characteristics	☐ Provided ☐ Not provided	

Labelling (outer and inner labels)	☐ Provided ☐ Not provided
Package leaflet (patient information leaflet)	☐ Provided ☐ Not provided
Samples (e.g. FPP, device)	☐ Provided ☐ Not provided
SAFETY AND EFFICACY DATA	
Insert the summary of safety and efficacy information	
Active ingredient Specifications	☐ Provided ☐ Not provided
Finished Pharmaceutical product Specifications	☐ Provided ☐ Not provided
Products Mock-Ups	☐ Provided ☐ Not provided
Latest Version of Quality overall Summary (QIS) in MS word	☐ Provided ☐ Not provided
General remarks to next assessors:	*Insert comment*
Recommendations for inspection	*Insert comment*
OVERALL OUTCOME OF THE ASSESSMENT ☐ **ACCEPTED** ☐ **ADDITIONAL DATA REQUESTED** ☐ **REJECTED**	
OVERALL ASSESSMENT SUMMARY	

Copy and Paste the QOS in MS WORD and continue the assessment of Dossier information as per SOP for product assessment

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TEMPLATE FOR DOSSIER SCREENING

	Date of application		
	Application reference number (assigned number)		
	Product Proprietary name (BRAND NAME)		
	Product Non-Proprietary name (INN)		
	Names of Assessor		
	Date of Screening		

A.	**ADMINISTRATIVE SCREENING**		
	Administrative requirements	**Tick as appropriate**	**Comment(s)**
1.	Dated and Signed Application cover letter	☐ **Yes** ☐ **No**	
2.	Dated and Signed Application Form for registration	☐ **Yes** ☐ **No**	
3.	**Proof of Payment of prescribed fees**	☐ **Yes** ☐ **No**	
4.	Name of appointed Local Technical Representative	☐ **Yes** ☐ **No**	
5.	Has the applicant provided the PD in electronic form?	☐ **Yes** ☐ **No**	
6.	**Has the applicant provided the PD in CTD format and openable electronic files?**	☐ **Yes** ☐ **No**	
7.	**Has the applicant provided a properly filled Quality Overall Summary (QOS) in Microsoft Office (MS) Word and easily accessible?**	☐ **Yes** ☐ **No**	
8.	Has the applicant provided a properly filled Quality Information Summary (QIS) in Microsoft Office (MS) Word and easily accessible?	☐ **Yes** ☐ **No**	
9.	Is minimum of two (2) samples submitted with application?	☐ **Yes** ☐ **No**	
10.	Are Certificates of Analysis (COAs) of submitted samples provided	☐ **Yes** ☐ **No**	
11.	Has the applicant applied for GMP Inspection to Rwanda FDA	☐ **Yes** ☐ **No**	
12.	If the abridged procedure/CRP is Claimed has the applicant specified the reference SRA and included SRA assessment reports?	☐ **Yes** ☐ **No**	
B	**TECHNICAL SCREENING**		
	B1.Critical Product Quality Information on API	***Tick as appropriate***	**Comment(s)**
1.	Has the applicant provided information on Procedures used to submit the API information i.e. APIMF, CEP, WHOAPI with letter of access?	☐ **Yes** ☐ **No** ☐ **N/A**	
2.	Has the applicant provided the section **3.2.S1.1 - 3.2.S1.3** regarding the general information and physical chemical properties?	☐ **Yes** ☐ **No** ☐ **N/A**	

3.	Has the applicant provided the section **3.2.S.2** regarding the API manufacture and Manufacturer of the API?	☐ **Yes** ☐ **No** ☐ **N/A**	
4.	Has the applicant provided the section **3.2.S.3** regarding the API characterization	☐ **Yes** ☐ **No** ☐ **N/A**	
5.	Has the applicant provided the section **3.2.S.4** regarding the API Control/Specifications	☐ **Yes** ☐ **No** ☐ **N/A**	
6.	Has the applicant provided the section **3.2.S.5** regarding the API references materials	☐ **Yes** ☐ **No** ☐ **N/A**	
7.	Has the applicant provided the section **3.2.S.6** regarding the container closure system	☐ **Yes** ☐ **No** ☐ **N/A**	
8.	Has the application provided in the section **3.2.S.7** regarding the Stability studies and stability data	☐ **Yes** ☐ **No** ☐ **N/A**	
	B.2 Critical Product Quality Information on FPP	***Tick as appropriate***	**Comment(s)**
1.	Has the applicant submitted the **Summary of product characteristics**	☐ **Yes** ☐ **No** ☐ **N/A**	
2.	Has the applicant submitted the **Labelling** (outer and inner labels)	☐ **Yes** ☐ **No** ☐ **N/A**	
3.	Has the applicant submitted the Package leaflet (patient information leaflet)	☐ **Yes** ☐ **No** ☐ **N/A**	
4.	Has the applicant provided the section **3.2.P.1.1** regarding the description and composition of the FPP?	☐ **Yes** ☐ **No** ☐ **N/A**	
5.	Has the applicant provided the section **3.2.P.2** regarding the pharmaceutical development FPP?	☐ **Yes** ☐ **No** ☐ **N/A**	
6.	Has the applicant provided the section **3.2.P.3** regarding the manufacture and manufacturer FPP?	☐ **Yes** ☐ **No** ☐ **N/A**	
7.	Has the applicant provided the section **3.2.P.4** regarding the control of excipients?	☐ **Yes** ☐ **No** ☐ **N/A**	
8.	Has the applicant provided the section **3.2.P.5** regarding the control of FPP?	☐ **Yes** ☐ **No** ☐ **N/A**	
9.	Has the applicant provided the section **3.2.P.7** regarding the container closure system, proposed shelf life and storage conditions of the FPP?	☐ **Yes** ☐ **No** ☐ **N/A**	
10.	Has the applicant provided the section **3.2.P.8.3** regarding the accelerated and long-term stability data of the FPP?	☐ **Yes** ☐ **No** ☐ **N/A**	
11.	Has the applicant provided the section **3.2.R1** regarding the executed and master products documents?	☐ **Yes** ☐ **No** ☐ **N/A**	
	B.2 Critical Product Safety and Efficacy Information of FPP	***Tick as appropriate***	**Comments**
1.	Has the applicant provided the **Module IV** containing the non-Clinical information on FPP?	☐ **Yes** ☐ **No** ☐ **N/A**	
2.	Has the applicant provided the **Module V** containing the Clinical studies information on FPP?	☐ **Yes** ☐ **No** ☐ **N/A**	
3.	If a **BIOEQUIVALENCE STUDY** is required, has the applicant submitted the Bioequivalence Trial Information (BTIF) as a Word document?	☐ **Yes** ☐ **No** ☐ **N/A**	
4.	Has the applicant provided a list of all **BIOEQUIVALENCE STUDIES**, including pilot studies, conducted with the proposed product?	☐ **Yes** ☐ **No** ☐ **N/A**	
5.	If a **BIOWAIVER** is requested, has the applicant submitted the appropriate biowaiver application form as a Word document?	☐ **Yes** ☐ **No** ☐ **N/A**	
C.	**ADDITIONAL DATA REQUESTED**		

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	(formulate questions with reference to missing information in the table above and list them. These questions are copied and pasted in the acknowledgement letter to be sent to the applicants)
D	**COMMENTS ON DEFICIENCIES**
	(If an comments to above shall be typed here)
E	**OVERALL OUTCOME OF THE SCREENING ASSESSMENT (***If the applicant has submitted the* ***Proof of payment****, openable electronic Dossier (PD) in* ***CTD format*** *and* ***properly filled Quality Overall Summary (QOS)*** *in Microsoft Office word, then the application is* **ACCEPTED**. *If the* ***proof of payment*** is missing then the application is **REJECTED.**
	☐ **ACCEPTED** ☐ **ADDITIONAL REQUESTED** ☐ **REJECTED**

Report Approvals	**Names**	**Signature**	**Signature**
1 **Screened by:**			
2 **Approved by:**			