JUMUIYA YA AFRIKA MASHARIKI	**EAC SCREENING CHECKLIST FOR –APIMF SUBMISSION**

(EAC/TF-MED/MER/FD/APIMF/N3R1)

PART A – ADMINISTRATIVE INFORMATION

EAC-APIMF Reference number	***Applicant name***	***Submission date***
Screening date	***Recommendation***	***Number of files: file + CD***
Name of the active ingredient; (*INN name), including form (salt, hydrate, polymorph)*		
Applicant's part reference/version number and date of the APIMF (*Open part****)***		
Restricted part reference/ version number and date of the APIMF (*Restricted part****)***		
Primary Packaging Container		
Secondary Packaging Container		
Retest period / Shelf life		
Proposed storage conditions		
Full name of applicant and official address		
Full name and physical address of the manufacturing site/ facility of API *i.e. including unit and block numbers, where applicable*		
List all the activities done at the declared manufacturing site/facility of API *i.e. manufacturing, packaging, testing*		
Full name and physical address of the manufacturing sites/ facilities of intermediates (*where applicable) i.e. including unit and block numbers*		
Full name and physical address of the Contract Research and Laboratories involved with testing of the API (*where applicable) i.e. including unit and block numbers*		

PART B

	Information required *(Please put a tick √ as applicable. If requirement not fully met, please comment below)*	***Yes***	***No***
1.	Is the API currently invited as per current Expression of Interest?		
Comment			
2.	Does the application form include a statement indicating that the information and data submitted is "true, complete and correct"?		
Comment			
3.	Has the applicant paid applicable EAC application fees for assessment of APIMF and submitted evidence of payment?		
Comment			
4.	Has the applicant submitted a valid Manufacturing Licence and valid GMP certificate for the API manufacturing facility/site issued by country of manufacture?		
Comment			
5.	A declaration been provided by the applicant/ API manufacturer that they will inform the EAC of any changes to the preparation, control and stability of the API?		
Comment			
6.	Are the APIMF submitted with completed data in section **3.2.S.1.General Information** in acceptable way, including references to page number of the APIMF? *Check submission of key information in the following sections, tick √ as applicable and provide comment;* *3.2.S.1.1. Nomenclature* (Yes / No) *3.2.S.1.2. Structure* (Yes / No) *3.2.S.1.3 General properties* (Yes / No)		
Comment			
7.	Are the APIMF submitted with completed data in section **3.2.S.2 Manufacture** in acceptable way, including references to page number of the APIMF? *Check submission of key information in the following sections, tick √ as applicable and provide comment;*		

	3.2.S.2.1 manufacturer *(Name, Physical address - country, state, city, road, plot number, unit, block/workshop)* (Yes / No) *3.2.S.2.2. Description of the manufacturing process and process controls* (a) Reaction scheme showing chemical reactions and reagents (Yes / No) (b) A detailed narrative of the synthetic process (Yes / No) (c) Materials reprocessing and reworking (Yes / No) *3.2.S.2.3 Control of Materials* (a) List of the starting materials (Yes / No) (b) Source of the starting material (Yes / No) (c) Specifications of the starting material (Yes / No) (c) Specifications of other materials (Yes / No) *3.2.S.2.4 Critical steps, parameters and controls* (Yes / No) *3.2.S.2.5 Process validation and / or evaluation* (Yes / No) *3.2.S.2.6 Manufacturing process development* (Yes / No)		
Comment			
8.	Are the APIMF submitted with completed data in section **3.2.S.3 Characterization** in acceptable way, including references to page number of the APIMF? *Check submission of key information in the following sections, tick √ as applicable and provide comment;* *3.2.S.3.1 Elucidation of Structure and other Characteristics* (Yes / No) *3.2.S.3.2 Impurities* (Yes / No)		
Comment			
9.	Are the APIMF submitted with completed data in section **3.2.S.4 Control of the API** in acceptable way, including references to page number of the APIMF? *Check submission of key information in the following sections, tick √ as applicable and provide comment;* *3.2.S.4.1. Specifications of the API* (Yes / No) *3.2.S.4.2Analytical procedures* (Yes / No)		

	3.2.S.4.3 Validation data of analytical procedures (Yes / No) *3.2.S.4.4 Batch analyses* (Yes / No)		
Comment			
10.	Are the APIMF submitted with completed data in section **3.2.S.5 Reference Standards or Materials** in acceptable way, including references to page number of the APIMF?		
Comment			
11.	Are the APIMF submitted with completed data in section **3.2.S.6 Container Closure System** in acceptable way, including references to page number of the APIMF?		
Comment			
12.	Are the APIMF submitted with completed data in section **3.2.S.7 Stability** in acceptable way, including references to page number of the APIMF? *Check submission of key information in the following sections, tick √ as applicable and provide comment;* 3.2.S.7.1 Stability Summary and Conclusions Is the stability data of at least 6 months (both accelerated and long term) submitted API ? (Yes / No) 3.2.S.7.2 Post-approval Stability Protocol and Stability Commitment (Yes / No) 3.2.S.7.3 Stability data. (Yes / No)		
Comment			

Conclusion of the screening *Please indicate if the submission fulfils all screening requirements. Comment on the acceptability of the submission*

Comments on deficiencies *with reference to the table above and specific APIMF sections*
Additional data requested *(in a wording to be communicated to the applicant)*

SCREENING LETTER TEMPLATES

(A) ACCEPTANCE OF THE APIMF

Ref. No.: **Date:……**

Applicant name and address

RE: NOTICE OF ACCEPTANCE OF THE APIMF FOR ASSESSMENT OF *(Insert the API name)*

This is in reference to your submitted EAC APIMF *(insert name of the API).*

We are glad to inform you that screening of the submission on APIMF of above mentioned API has been completed and the information has been considered acceptable for assessment.

The assessment of APIMF shall be carried out in line with the EAC procedure. The outcome of the assessment will be communicated to you within 120 calendar days from the date of this letter. Please note that the manufacturing facility will have to be *verified for compliance* to current good manufacturing practices.

We thank you for your cooperation and continued support to the EAC APIMF procedure.

Name of signatory
Designation

(B) ADDITIONAL DATA REQUESTED

Ref. No.: **Date:……**

Applicant name and address

RE: REQUEST FOR ADDITIONAL DATA ON THE APIMF OF *(Insert name of the API)*

This is in reference to your submitted EAC APIMF *(Insert name of the API).*

We wish to inform you that screening of the APIMF of above mentioned API has been completed. Please note that the information submitted did not fulfil all the submission requirements for EAC APIMF procedure.

In order for the submission to be accepted for evaluation, please update the respective part of the APIMF by addressing the following issues:

(i) .....

(ii) .....

(iii) .....

Your response should be provided within 3 months from the date of this letter. As part of the response an updated APIMF should be submitted. In addition, you are requested to create a table to highlight all the changes made against the above comments and section/volume/page number of the APIMF where the required information has been incorporated.

We thank you for your cooperation and continued support to the EAC APIMF procedure.

(EAC/TF-MED/MER/FD/APIMF/N3R1)

Name of signatory
Designation