APPLICANT'S SELF-SCREENING CHECKLIST BEFORE SUBMISSION OF APPLICATION FOR MARKETING AUTHORIZATION OF HUMAN MEDICINAL PRODUCT

DOSSIER/PRODUCT DETAILS
Proprietary / Product Name;
……

INN, strength, dosage form;
……

Full name of applicant and official address;
……

CHECKLIST NOTE

- This checklist is provided to guide applicant to prepare submission of product dossier and does not mean that is only information/data for complete submission. For more detailed requirements, refer to the relevant Medicines Registration Guidelines available at www.tmda.go.tz/publications/42
- The acceptance of the application after screening does not preclude requests by TMDA for additional documents or changes to the information/documents during assessment.
- A screening checklist should be completed by the applicant. The Authority will assess the application for completeness upon submission before it is accepted for assessment by TMDA. Incomplete application will not be accepted and the applicant requested to submit a complete application.
- A completed copy of the application checklist in MS word format should be included in the dossier submission.
- Please Tick ✓ (yes) or X (No) or write as applicable.

S/No.	Application Form and Administrative	Submitted?		Remarks
		Yes	No	
1.	A complete list of all documents provided in the product dossier as per CDT format?			
2.	Is duly signed and dated application form provided?			
3.	Is a cover letter provided?			

4.	Is a sample provided at least two products as packaged for commercial pack?			
5.	Is an image or picture of unpack product that indicate a visual description of the appearance of the product in line with FPP specifications uploaded in png, jpeg or jpg format? E.g., the physical appearance of product should show the colour, symbol, markings, logo, imprints etc.			
6.	Has the applicant submitted product information and labelling, including product labels (primary and secondary artwork), SmPC, package insert and where applicable Patient Information Leaflet?			
7.	Has the applicant submitted a valid manufacturing license or valid Good Manufacturing Practice certificate for the FPP and API issued by competent authority or local authority?			
8.	Has the applicant submitted registration certificates from Stringent Regulatory Authority(ies) or other regulatory authority? (If applicable)			
9.	Has the applicant submitted complete Quality Overall Summary – Product Dossier (QOS-PD) and Quality Information Summary (QIS) as Word documents using the most recent version?			
	Quality/ Body of Data of API	**Submitted?**		**Remarks**
		YES	**NO**	
10.	If PQ-API or CEP is used to present API data, are the respective Confirmation of API Prequalification, Letters of Access or EDQM CEP provided?			
11.	If the full dossier route is used to present API data for an API, has a complete module 3.2.S been provided?			
12.	Has the applicant submitted information under section 3.2.S.1 (General Information)? and where applicable including the dose/solubility volume data			

13.	Has the applicant submitted information under 3.2.S.2 (Manufacture) including a valid GMP certificate?			
14.	Has the applicant submitted information under section 3.2.S.2.3; Control of Materials including appropriate specifications, analytical procedures and certificates of analysis for all raw materials?			
15.	Has the applicant submitted information under section 3.2.S.2.4; Controls of Critical Steps and Intermediates?			
16.	Has the applicant submitted information under section 3.2.S.2.5; Process Validation and/or Evaluation? This section must be submitted for sterile APIs and New Chemical Entities			
17.	Are the APIMF submitted with completed data in section 3.2.S.3 Characterization in acceptable way, including elucidation of structure and other characteristics and impurities?			
18.	Has a risk for the potential presence of nitrosamines been identified? If yes, a copy of the Risk Assessment report along with confirmatory test results should be provided. If no, a formal confirmation should be provided. Status should also be indicated in 2.3.S.3.2 and 2.3.P.5.5 of QOS-PD.			
19.	Are the APIMF submitted with completed data in section 3.2.S.4 Control of the API in acceptable way, including API specification from both API and FPP manufacturers, analytical procedures, validation/verification data of analytical procedures (whenever applicable) and certificates of analysis in controlled documents?			
20.	Are the APIMF submitted with completed data in section 3.2.S.5 Reference Standards or Materials in acceptable way, including reference materials from both API and FPP manufacturers?			
21.	Are the APIMF submitted with completed data in section 3.2.S.6 Container Closure System in acceptable way, including acceptable specifications, analytical procedures and			

	certificates of analysis in controlled documents?			
22.	Are the APIMF submitted with completed data in section 3.2.S.7 Stability in acceptable way, including batch size, date of manufacture, site of manufacture and container closure system, testing frequency?			
Finished Pharmaceutical Product (FPP)		**Submitted?**		**Remarks**
		YES	**NO**	
23.	Is the unit composition table presented fully and filled out correctly?			
24.	Is there data presented on pharmaceutical Development as annexure to 3.2.P.2?			
25.	Is there data on FPP batch sizes and composition of pilot and production scale as well as those used in bioequivalence and dissolution studies? Where applicable			
26.	Has the applicant provided a list of <u>all</u> bioequivalence or comparative bioavailability studies, including pilot studies, conducted during pharmaceutical development (development of formulation and/or manufacturing processes) of the product, regardless of the comparator (reference) product employed and regardless of the study outcome? Where applicable			
27.	Does the manufacturer include in Section 2.3.R copies of executed biobatch/biowaiver batch(es) and proposed blank master production record(s) for the largest proposed production batch(es) (3.2.R. under Module 3)? where applicable			
28.	Does the manufacturer include Controls of Critical Steps and Intermediates under section 3.2.P.3.4?			
29.	Is there data or a protocol presented for prospective validation of 3 consecutive production scale batches (of all proposed commercial batch size(s)) (3.2.P.3.5 or as annexures under 3.2.P.3)?			

30.	Does the manufacturer include submission of appropriate specifications and certificates of analysis for each excipient in controlled documents under section 3.2.P.4?			
31.	Has the manufacturer submitted the completed data in section 3.2.P.5; Control of FPP in acceptable way, including acceptable specifications, analytical procedures, validation/verification data of analytical procedures and certificates of analysis in controlled documents?			
32.	Has the manufacturer submitted the completed data in section 3.2.P.6; Reference Standards or Materials in acceptable way, including reference materials from FPP manufacturer?			
33.	Has manufacturer submitted the completed data in section 3.2.P.7; Container Closure System in acceptable way, including acceptable specifications, analytical procedures and certificates of analysis in controlled documents?			
34.	Has the manufacturer submitted the completed data in section 3.2.P.8; Stability in acceptable way, including batch size, date of manufacture, site of manufacture and container closure system, testing frequency?			
	Safety and Efficacy data where applicable	**Submitted?**		**Remarks**
		YES	**NO**	
35.	If a bioequivalence study is required, has the applicant submitted the Bioequivalence Trial Information (BTIF) as a Word document and complete bioequivalence study protocol and report (including all appendices and data)?			
36.	If a biowaiver is required, has the applicant submitted the appropriate biowaiver application form (additional strengths, BCS) as a Word document and complete comparative dissolution study protocol and report (including all appendices and data)?			
37.	Justifications and relevant supporting documents for biowaiver request has been submitted (where applicable)?			

38.	Justifications for selection comparator products/innovators in bioequivalence / BCS studies or pharmaceutical development have been provided?			
39.	Has the applicant submitted documentation regarding the purchase, shipping, and storage of the comparator product used in the bioequivalence study or biowaiver application?			
40.	Has the applicant submitted comparative dissolution profile data on Individual 12 units, mean, range and RSD of dissolution data and f2 where applicable?			
41.	Has the applicant submitted the complete study reports of ALL clinical trials (including the appendices and tables)? where applicable			

Signed by>…… (Authorized personnel)

Date>……