REGISTRATION AND REGULATORY AFFAIRS DIRECTORATE

Dossier Screening Checklist

SECTION A (Administrative)

Applicants Name and Address:

Proprietary Name of Product:

INN Name of Product:

Screening Date:

Information required (please comment below, if requirements not fully met)			
	YES	**NO**	**Page No**
Please confirm that the primary batches described in the dossier were manufactured specifically for this application (i.e. the batches are submission batches)	☐	☐	
Packaging, pack sizes and shelf life for each different packaging format (check table 2.3.P.8.1C, 2.3.P.7 or 3.2.P.8.1, 3.2.P.7)	☐	☐	
Format of submission – confirm Common Technical Document format	☐	☐	
If the product contains more than one API confirm that separate S-parts for each API is provided under Module 3	☐	☐	
Confirm that modules and sections are segregated into folders and subfolders	☐	☐	
Confirm that the Dossier is prepared in line with NAFDAC CTD guidelines/ template	☐	☐	
Confirm if document is Searchable pdf	☐	☐	
Biowaiver applied (yes, no), if YES, specify whether Biopharmaceutics Classification System (BCS) or additional strengths (Module 1.2)	☐	☐	
Submission of API data – ☐Active Pharmaceutical Ingredient (API) Master File, ☐API Prequalification PQ-API), ☐Certification of Suitability (i.e. CEP from European Directorate for the Quality of Medicines)			

☐Full data, specify for each API (Check QOS-PD: 2.3.S (Introduction Table) ☐Not Indicated			
Confirm if information on comparator product used for product development is provided (Module 1.2 (BAF), Module 1.4 (BTIF), Module 5 (5.3), 2.3.P.2, 3.2.P.2	☐	☐	

SECTION B

S/N	Information required (please comment below, if requirements not fully met)	YES	NO	Page No
1.	Does the cover letter include a statement indicating that the information and data submitted is "true, complete and correct"? (Module 1.0) check if the ND in module 1.2.5 satisfies this requirement	☐	☐	
2.	Has the applicant submitted a valid manufacturing license and/or valid Good Manufacturing Practice certificate **for the API and FPP sites**? (Module 1.2) or Pre-production approval letter for local manufacturer?	☐	☐	
3.	Has the product been authorized for marketing in other countries?	☐	☐	
4.	Has evidence been provided for marketing in other NMRA's (**other countries**)	☐	☐	
4.	Has valid documentation been provided to support marketing authorization in other countries?	☐	☐	
5.	Has the applicant submitted valid COPP?	☐	☐	
6	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? For CEP, ensure the valid version on the EDQM website at the time of screening is submitted or request the valid version. (Module 1.2) Confirm if a commitment is provided by the API manufacturer to inform the Agency in the event the CPQ or the CEP is withdrawn	☐	☐	
7.	If full dossier option is used to provide API data, has a declaration been provided from the API manufacturer that: it has provided to the FPP manufacturer all confidential and non-confidential information regarding the preparation, control and stability of the API as per ICH CTD module 3.2.S.; and it will inform the FPP manufacturer of any changes to the preparation, control and stability of the API? (Check module 1.2)	☐	☐	
8.	If full dossier option is used to provide API data for an API site, has a complete module 3.2.S been provided	☐	☐	

9.	If API submission is supported by DMF/APIMF or CEP or CPQ, confirm if Module 3 has the structured S-part (Drug substance part; 3.2.S) of the ICH CTD product dossier not a wholesale adoption of the API manufacturer's opened part of the DMF.	☐	☐	
10.	Has the applicant submitted Quality Overall Summary – Product Dossier (QOS-PD) and Quality Information Summary (QIS) as Word documents?	☐	☐	
11.	Has all the provisions in the QOS-PD and QIS been filled or properly referred	☐	☐	
12.	If a bioequivalence study is required (no biowaiver application), has the applicant submitted the Bioequivalence Trial Information (BTIF) as a Word document? (Module 1.4)	☐	☐	
13.	If a biowaiver is requested, has the applicant submitted the appropriate biowaiver application form (additional strengths, BCS, or zinc sulphate) as a Word document? (Module 1.2)	☐	☐	
14.	Is the unit composition table presented fully and filled out correctly, e.g. completed with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection, and are excipient standards indicated (e.g. United States Pharmacopeia (USP), British Pharmacopoiea, in house)? (2.3.P.1 and 3.2.P.1)	☐	☐	
15.	At the time of submission, is the stability data provided for at least 6 months at the accelerated condition and 12 months at the long-term condition and for at least two pilot scale batches of the FPP (three pilot scale batches of the API)? (3.2.S.7.3 and 3.2.P.8.3)	☐	☐	
16.	Do the stability batches (submitted under the sections stated above) correspond to the primary batches described in the dossier	☐	☐	
17.	Is there data or a protocol presented for prospective validation of 3 consecutive production scale batches (of the largest proposed production size) (3.2.P.3.5 or as annexures under 3.2.P.3)	☐	☐	
18.	Does the manufacturer include in Section 2.3.R copies of executed biobatch and proposed blank master production record(s) for proposed production batch(es) (3.2.R. under Module 3)	☐	☐	
19.	Is there data presented on validation of analytical procedures (3.2.P.5.3 or as annexure to 3.2.P.5) and summary in 2.3.R.2 of QOS-PD	☐	☐	
20.	Is there data on FPP batch sizes and composition of pilot and production scale as well as those used in bioequivalence and dissolution studies (e.g. 2.3.P.2.2.1)	☐	☐	

21.	Does the applicant indicate the full physical address of the FPP manufacturing site including Unit and Block numbers, where applicable (2.3.P.3.1)	☐	☐	
22.	Additional requirements for Sterile FPP are met? (see attached)			

If sterile API is purchased (Only for Sterile products)		
Manufacturing process validation data including media fill results from a recent media fill exercise/study for the aseptic process at the API manufacturing site is submitted? (2.3.S.2.5 or 3.2.S.2.5)	☐	☐
Suitability of container closure — compatibility with API, demonstration of seal integrity (e.g. by microbial ingress test, dye ingress test), suitability for transportation to FPP site etc. Provided? (2.3.S.6 and 3.2.S.6)	☐	☐
Rubber stoppers/gasket: Supplier name, type and stopper number; evidence of physicochemical testing as per USP <381> and its physiological safety as per USP < 87>/<88>) or other equivalent requirements. Attestation from the supplier that the closure is free of 2-mercapto benzothiazoles (2-MCBT) and nitrosamines; compatibility with API (e.g. leachable/ extractable). Provided? (2.3.S.3.6 or 3.2.S.6)	☐	☐
Transportation studies — to demonstrate mode of transport chosen is appropriate (e.g. through simulation). Provided?	☐	☐
A copy of blank and executed batch manufacturing record (BMR) including copies of all standard operating procedures (SOPs) pertinent to: sterilization of manufacturing equipment, packaging materials and accessories; aseptic procedures + media fill exercises; in-process controls. Provided? (2.3.S.2 and 3.2.S.2)	☐	☐
Filters: Make/type, article number and/or code, suppliers, filter validation data (e.g. compatibility with the API, leachable/extractable, microbial retention for sterilizing filters etc.). Provided? (2.3.A or 3.2.A)	☐	☐
Description of manufacturing process/flow diagram: Environmental conditions in the manufacturing, filling and packaging areas (temperature, pressure, grades of area class etc.). Provided? (2.3.S.2 or 3.2.S.2)	☐	☐
Evidence of validation of the conditions/parameters used for the sterilization/depyrogenation of the processing equipment and accessories, filters and packaging components. Provided? (2.3.S.2.5	☐	☐
Stability data generated using samples stored in inverted orientation where rubber closures are used. Provided?	☐	☐

For Sterile FPP			
Procedures for receipt and handling of sterile API — SOPs on checks, tests, handling, storage, sampling, dispensing etc., if applicable. Provided?	☐	☐	
Manufacturing process validation data including media fill results from a recent media fill exercise/study for the aseptic processes at the FPP manufacturing site. Provided?	☐	☐	
Suitability of container closure – compatibility with FPP, demonstration of seal integrity (e.g. by microbial ingress test, dye ingress test), protection of product, suitability for transportation of the FPP, suitability for use etc. Provided?	☐	☐	
A copy of the blank and executed BMR and copies of all SOPs pertinent to: sterilization of manufacturing equipment, packaging materials and accessories; aseptic procedures + media fill exercises; in-process controls. Provided?	☐	☐	
Filters: Make/type, article/model number and/or code, suppliers, filter validation data (e.g. compatibility with the formulation ingredients, leachable/extractable, microbial retention for sterilizing filters etc.). Provided?	☐	☐	
Description of manufacturing process/flow diagram: Environmental conditions in the manufacturing, filling and packaging areas (temperature, pressure, grades of area class etc.). Provided?	☐	☐	
Evidence of validation of the conditions/parameters used for the sterilization/depyrogenation of the processing equipment and accessories, filters and packaging components. Provided?	☐	☐	
Stoppers: Supplier name, type and stopper number of the rubber; evidence of physicochemical testing as per USP <381> and its physiological safety as per USP < 87>/<88>) or other equivalent requirements. Attestation from the supplier that the closure is free of 2-mercapto benzothiazoles (2-MCBT) and nitrosamines; compatibility with product (e.g. leachable/ extractable). Provided?	☐	☐	
Any holding periods for intermediates and supporting data submitted?	☐	☐	
Stability data generated using samples stored in inverted orientation where rubber closures are used. Provided?	☐	☐	
Glass vials/ampoules: data to demonstrate that the glass meets the requirements of USP <660> or other equivalent requirements. Provided?	☐	☐	
Diluents/ Solvents			
QOS-PD (FPP part) completed for any diluent/solvent packaged with the product?	☐	☐	
Evidence of validation of the terminal sterilization process for the diluent/solvent provided?	☐	☐	

Compatibility data for any diluents/solvents proposed to be used with the product + stability data to support in-use period of reconstituted solutions. Provided?	☐	☐	
If plastic containers are used, compatibility data with the diluent/solvent. Provided?	☐	☐	

Comments: