SADC MRH PROJECT

BIOSIMILAR MEDICINES: SCREENING CHECKLIST FOR APPLICATIONS FOR REGISTRATION

Administrative information

Trade name of the medicinal product:	
INN (or common name) of the drug substance(s), if applicable:	
Drug substance(s):	
Applicant:	
Proposed Indication(s):	
Pharmaco-therapeutic group (ATC Code):	
Pharmaceutical form(s) and strength(s):	

Where data have been submitted, click in the appropriate check box. Indicate "N/A" (not applicable) in the comments section if data are not applicable.

Module 1

		Comments
1.0 Proof of compliance with current Good Manufacturing Practices (cGMP) 1.10 Drug substance Manufacturing Site 1.12 Finished product Manufacturing Site	☐ ☐	
1.2 International registration status (list of countries and registration details)	☐	
1.3.1 Summary of product characteristics (SmPC) 1.3.2 Labelling (primary and secondary packaging) 1.3.3 Package insert and patient information leaflet	☐ ☐ ☐	
1.4 Quality information summary (QIS)	☐	
1.5 Samples a) Representative drug product sample- 2 units minimum b) Sample batch COA	☐	
1.6 Risk Management Plan	☐	

Module 2

	Comments
Quality overall summary (QOS) in Ms Word	

Module 3

3.2.S Drug Substance

3.2.S.2 Manufacture

S.2.1 Manufacturer(s)	☐	
S.2.2 Description of Manufacturing Process and Process Controls (*Reference ICH Q11 step 4*)	☐	
S.2.3 Control of Materials Expression construct (*Reference ICH Q5B*) Description of the producer strain/cell line (type, origin) Cell bank system: Establishment and testing of the MCB/WCB/ExCB (*Reference ICH Q5D*) Raw Materials and Reagents	 ☐ ☐ ☐ ☐	
S.2.4 Controls of Critical Steps and Intermediates Highlight any specific critical steps (e.g. for virus removal/inactivation).	 ☐	
S.2.5 Process Validation and/or Evaluation Validation of fermentation process Validation of purification process	 ☐ ☐	
S.2.6 Manufacturing Process Development History of development of manufacturing process Description of changes and reasons for changes (justification)	 ☐ ☐	

3.2.S.3 Characterization

S.3.1 Elucidation of Structure and other Characteristics Determination of the composition, physical properties, and primary structure, information on higher-order structure and biological activity.	☐	
S.3.2 Impurities Acceptance criteria for impurities (individual and/or collective) should be based on data obtained from batches used in preclinical and clinical studies and manufacturing consistency batches. Host cell derived Process-related (including host-cell derived) Product-related	☐	

3.2.S.4 Control of drug substance

S.4.1 Specifications	☐	
S.4.2 Analytical Procedures	☐	
S.4.3 Validation of Analytical Procedures	☐	
S.4.4 Batch Analyses	☐	
S.4.5 Justification of Specifications	☐	

3.2.S.5 Reference standards or materials

Reference standards or reference materials used for testing of the drug substance	☐	

3.2.S.6 Container closure system

Container closure system	☐	

3.2.S.7 Stability

S.7.1 Stability Summary and Conclusions	☐	
S.7.2 Post- approval stability Protocol and stability commitment	☐	
S.7.3 Stability Data Stress studies Accelerated Stability Studies & Real-Time Stability Studies *(Refer to ICH Q5C)*	 ☐ ☐	

3.2.P Drug product

3.2.P.1 Description of the Drug Product

P.1 Drug product description	☐	

3.2.P.2 Pharmaceutical development

P.2.1 Components of the Drug product	☐	
P.2.2 Drug Product	☐	
P.2.3 Manufacturing Process Development	☐	
P.2.4 Container Closure System	☐	
P.2.5 Microbiological Attributes	☐	
P.2.6 Compatibility	☐	

3.2.P.3 Manufacture

P.3.1 Manufacturer(s)	☐	
P.3.2 Batch Formula	☐	
P.3.3 Description of Manufacturing Process and Process Controls	☐	
P.3.4 Controls of Critical Steps and Intermediates	☐	
P.3.5 Process Validation and/or Evaluation	☐	

3.2.P.4 Control of excipients

P.4.1 Specifications	☐	
P.4.2 Analytical Procedures	☐	
P.4.3 Validation of Analytical Procedures	☐	
P.4.4 Justification of Specifications	☐	
P.4.5 Excipients of Human or Animal Origin	☐	
P.4.6 Novel Excipients	☐	

3.2.P.5 Control of drug product

P.5.1 Specification(s)	☐	
P.5.2 Analytical Procedures	☐	
P.5.3 Validation of Analytical Procedures	☐	
P.5.4 Batch Analyses	☐	
P.5.5 Characterisation of Impurities	☐	
P.5.6 Justification of Specification(s)	☐	

3.2.P.6 Reference standards or materials

Reference standards or reference materials used for testing of the drug product	☐	

3.2.P.7 Container closure system

Container closure system	☐	

3.2.P.8 Stability

P.8.1 Stability Summary and Conclusion	☐	
P.8.2 Post-approval Stability Protocol and Stability Commitment	☐	
P.8.3 Stability Data		

Photostability Data *(Refer to ICH Q5C) (at least 1 batch)* Accelerated stability data *e.g., 25°C/60%RH (Refer to ICH Q5C)* Long-term stability data *e.g., 5±3°C (Refer to ICH Q5C)* *Note: Bracketing or matrixing approach can be considered as applicable.*	☐ ☐ ☐	
In–use stability data	☐	

3.2.A Appendices

A.1 Facilities and Equipment	☐	
A.2 Adventitious agents safety evaluation	☐	
A.3 Excipients		

3.2.R Regional Information

Master production documents	☐	
Comparability Exercise	☐	

Module 4

Non-Clinical Data

Relevant comparative Non-clinical studies	☐	

Module 5

Clinical Data

Comparative clinical studies: Relevant PK/PD Relevant Efficacy and Safety (*including immunogenicity*)	 ☐ ☐	

Document History

Date	Reason for update	Version & publication
September 2019	First publication released for comment to agencies	Version 1
24 Jan 2020	Several sections inserted	Version 2
	Editorial changes	
03/11/2021	Editorial changes	Version 3
	Incorporation of changes based on Industry comments	