Medicines Control Authority of Zimbabwe

EVALUATIONS AND REGISTRATION DIVISION

EVRF34

APPLICANT'S SCREENING CHECKLIST FOR REGISTRATION OF HUMAN BIOLOGICAL MEDICINES

International Non-proprietary Name (INN) of the drug substance, strength, pharmaceutical form.	
Proprietary Product or Trade name (if relevant)	
Number of binders	
Samples *(At least 2 market packs should have been submitted)*	
Fee	

SECTION	DOCUMENTS	Submitted?		
Module 1	**Administrative and Regional Information**	**Yes**	**No**	**Location and any relevant comments**
	Completed, signed and dated MC8 form			
	Package insert			
	Labels			
	Current GMP status of manufacturing sites			
	GMP certification for each drug substance manufacturing site			
	GMP certification for each drug product manufacturing site (if different from drug substance manufacturing site)			
	Risk Management Plan			
Module 2	**COMMON TECHNICAL DOCUMENT SUMMARIES**			
2.3	**Quality Overall Summary (QOS) (In MS WORD format)**			
Module 3	**QUALITY**			

3.2.S	**DRUG SUBSTANCE**			
3.2.S.1	**General information**			
3.2.S.1.1	**Nomenclature**			
3.2.S.1.2	**Structure** Schematic of amino acid sequence, including indication of any glycosylation sites, etc			
3.2.S.1.3	**General properties** A discussion rather than presentation of specifications			
3.2.S.2	**MANUFACTURE**			
3.2.S.2.1	**Manufacturer and address**			
3.2.S.2.2	**Description of manufacturing process and process controls** Flow diagram of manufacturing/fermentation process Batch and scale definition			
3.2.S.2.3	**Control of Materials**			
	Development Genetics *Origin of the gene, description of the gene construction, rationale behind the gene construct, genetic stability* *Refer to ICH Q5B*			
	Analysis of expression construct *Refer to ICH Q5B*			
	Source, history of establishment and identification of producer strain/ cell line *Refer to ICH Q5D*			
	Cell banking system *Refer to ICH Q5D*			
	Cell bank characterization and testing *Refer to ICH Q5D*			
	Control of material of biologic origin (e.g. monoclonal antibody purification columns, blood/plasma derivatives)			
	Viral safety evaluation *Refer to ICH Q5A. This data may also be located in section 3.2.S.2.5*			

3.2.S.2.4	**Control of critical steps and intermediates**			
3.2.S.2.5	**Process Validation and/or Evaluation**			
3.2.S.2.6	**Manufacturing Process Development** Evolution of the manufacturing process Comparability assessment (non-clinical, clinical, stability lots)			
3.2.S.3	**CHARACTERISATION**			
3.2.S.3.1	**Elucidation of Structure and other Characteristics** • Primary, secondary and tertiary structure • Physicochemical characterization • Biological characterization, etc			
3.2.S.3.2	**Impurities** • Cell-derived impurities • Process-derived impurities • Product-related impurities			
3.2.S.3.2	**Impurities**			
3.2.S.4	**CONTROL OF Drug Substance**			
3.2.S.4.1	**FPP manufacturer's and Drug Substance manufacturer's Specifications for the Drug substance**			
3.2.S.4.2	**FPP manufacturer's and Drug Substance manufacturer's Analytical Procedures for Drug Substance**			
3.2.S.4.3	**FPP manufacturer's and Drug Substance manufacturer's Validation data for Analytical Procedure**			
3.2.S.4.4	**Batch analysis data** *Should include the lot(s) used to manufacture the clinical batch(es)*			
3.2.S.4.5	**Justification of specifications**			
3.2.S.5	**Reference standards** • History of reference materials • Preparation of reference materials • Characterisation of reference materials			
3.2.S.6	**Container closure system**			
	Specifications			
	Test Methods			
3.2.S.7	**Stability**			
3.2.S.7.3	**Forced degradation studies**			
	Accelerated Stability Studies & Real-Time Stability Studies *Refer to ICH Q5B*			
3.2.S/3.2.R	**Comparability Exercise**			

	Candidate biosimilar vs Reference product *Comparison of structures, physicochemical attributes, biological activity, etc.* *Must include at least 10 lots of the reference and at least 6 lots of the candidate biosimilar*			
3.2.P	**FINISHED PHARMACEUTICAL PRODUCT (FPP)**			
3.2.P.1	**Description and Composition of the FPP**			
	Section 77A Undesirable Ingredients present in formulation			
3.2.P.2	**Pharmaceutical Development**			
3.2.P.2.3	**Manufacturing Process Development** Filter-product compatibility studies Filter microbial retention studies			
3.2.P.2.5	**Microbial Attributes** In-use stability data for multi-dose products			
3.2.P.2.6	**Compatibility** Compatibility of the drug product with reconstitution diluent(s)			
3.2.P.3	**Manufacture**			
3.2.P.3.1	**Manufacturer(s) name(s) and physical address(es)**			
3.2.P.3.2	**Batch Formula**			
3.2.P.3.3	**Description of manufacturing process and process controls**			
3.2.P.3.4	**Control of critical steps and intermediates**			
3.2.P.3.5	**Process validation**			
	Media fill studies			
	Manufacturing process validation			
	Validation of sterilization of vials, rubber bungs, syringes, etc			
3.2.P.4	**Control of Excipients**			
3.2.P.4.1	**Specifications**			
3.2.P.4.2	**Analytical Procedures** Only required if specifications are non-compendial			
3.2.P.4.5	**Excipients of Human or Animal Origin** BSE / TSE free certification			
3.2.P.4.6	**Novel excipients**			

	Provide information provided as per full API Section			
3.2.P.5	**Control of FPP**			
3.2.P.5.1	**Specification(s) of Finished Pharmaceutical Product (FPP)**			
3.2.P.5.2	**Analytical Procedures**			
3.2.P.5.3	**Validation of Analytical Procedures**			
3.2.P.5.4	**Batch analyses data for at least two batches**			
3.2.P.5.5	**Characterisation of Impurities**			
3.2.P.6	**Reference Standards**			
3.2.P.7	**Container- Closure System**			
	Test Methods			
	Specifications			
3.2.P.8	**Stability**			
3.2.P.8.3	**Photostability Data**			
	Accelerated stability data *e.g., 25°C/60%RH*			
	Long-term stability data *e.g., 5±3°C*			
3.2.R	**REGIONAL INFORMATION**			
3.2.R.1.1	**Executed production document(s)** For applications accompanied by clinical data, the executed BMR should be for the batch(es) used in the clinical study			
3.2.R.1.2	**Master production documents**			
Module 4	**NON-CLINICAL DATA**			
	Please refer to specific relevant SRA guidance where available for required non-clinical data e.g., **erythropoietin:** EMA Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins			
Module 5	**CLINICAL DATA**			
	Please refer to specific relevant SRA guidance where available for required clinical data e.g.,			

	soluble insulin: EMA Guidance on similar medicinal products containing human soluble insulin **erythropoietin:** EMA Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins			