HPT/PER/GUD/014

Rev. No.: 02

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF SIMILAR BIOTHERAPEUTIC PRODUCTS

JULY, 2026

Citation of this document

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Recommended citation: *Republic of Kenya, Ministry of Health, Pharmacy and Poisons Board. Guidelines on Submission of Documentation for Registration of Similar Biotherapeutic Products, Rev.:02, 2026*

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HPT/PER/GUD/014	Guidelines on Submission of Documentation for Similar Biotherapeutic Products	Revision No.: 02	Effective Date: 28/07/2026 Review Date: 28/ 07/2031

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ABBREVIATIONS AND ACRONYMS

BMRs	-	Batch Manufacturing Records
CMC	-	Chemistry, Manufacturing and Controls
CA	-	Clinical Assessor
DNA	-	Deoxyribonucleic Acid
EAC	-	East African Community
EMA	-	European Medicines Agency
EU	-	European Union
GCP	-	Good Clinical Practice
GLP	-	Good Laboratory Practice
GMP	-	Good Manufacturing Practice
ICH	-	International Council for Harmonization
INN	-	International Non-proprietary Names
MOA	-	Mechanism of Action
NCE	-	New Chemical Entity
NMRA	-	National Medicines Regulatory Authority
Ph. Eur	-	European Pharmacopeia
PK/PD	-	Pharmacokinetic/Pharmacodynamic
PBRER	-	Periodic Benefit-Risk Evaluation Report
RBP	-	Reference Biotherapeutic Product
RMP	-	Risk Management Plan
SBP	-	Similar Biotherapeutic Product
WHO	-	World Health Organization

GLOSSARY

In these Guidelines, unless the context otherwise states:

Antibody	means a spectrum of proteins of the immunoglobulin family that is produced, in the human (or animal) body, in response to an antigen (e.g., a virus or bacterium, or a foreign protein unknown to the body's immune system). Antibodies are able to combine with and neutralize the antigen, as well as to stimulate the immune system for defense reactions.
Antigen"	means a substance that causes the immune system to produce antibodies against it.
Applicant	means the product owner or license holder. Representatives of license holders may not hold themselves as applicants unless they own the product.
Drug substance	means an antigenic substance (or compounds thereof) that can induce specific responses in human against infectious agents, its antigens and toxins..
Batch/Lot	means a defined quantity of starting material, packaging material or product processed in one process or series of processes so that it can be expected to be homogenous.
biotherapeutic product".	A biological medicinal product with the indications of treating human diseases
Bioequivalence"	means that two proprietary preparations of a drug, when administered in the same dose and by the same route, will have the same bioavailability, duration of action and efficacy.
Biotechnology"	means a set of tools that employ living organism (or part of organism) to make or modify products, to improve plants and animals, or to develop microorganisms for specific uses Or a collection of

	technologies that use living cells and/or biological molecules to solve problems or make useful products.
Chemically synthesized polypeptide	means any alpha amino acid polymer that is (a) made entirely by chemical synthesis, and (b) is less than 100 amino acids in size.
CMC (Chemistry, Manufacturing and Controls)"	means the section of a submission dealing with the substance properties, manufacturing and quality control, intended for evaluating the provided information in the context of the current standards in chemical science and technology, and the current regulations.
Comparability Exercise	means the activities including study design, conduct of studies, and evaluation of data, that are designed to investigate whether the products are comparable (head to head comparison).
Conformance to specification	means that the drug substance and drug product, when tested according to the listed analytical procedures, will meet the acceptance criteria.
Equivalent	means equal or virtually identical in the parameter of interest. Small non-relevant differences may exist. Equivalent efficacy of two medicinal products means they have similar (no better or no worse) efficacy and any observed differences are of no clinical relevance.
Head-to-head comparison	means the direct comparison of the properties of the similar biologic with the reference biologic in the same study.
International council for Harmonisation	ICH is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater

	harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. For more information, see http://www.ich.org/.
Immunogenic	means any substance that is recognized as foreign by the immune system in a (particular) higher organism and induces an immune response which may include the formation of antibodies and developing immunity, hypersensitivity to the antigen, and tolerance.
Immunogenicity	means the ability of a substance to trigger an immune response or reaction (e.g., development of specific antibodies, T cell response, allergic or anaphylactic reaction).
Impurity	means any component present in the drug substance or drug product that is not the desired product, a product-related substance, or excipients including buffer components. It may be either process- or product-related.
Innovator Product	means a means a new chemical entity which has received a patent on its chemical formulation or manufacturing process, obtains chemical formulation or manufacturing process, obtains approval from a regulatory authority after extensive testing and is sold under a brand name.
In-process control or Process control	means checks performed during production to monitor and, if appropriate, to adjust the process and/or to ensure that the intermediate or API conforms to its specifications.
Interchangeability	is the medical practice of changing one medicine for another that is expected to achieve the same clinical

	effect in a given clinical setting and in any patient on the initiative, or with the agreement of the prescriber. For interchangeable products, one or the other can be used (prescribed) but these products cannot be substituted with one another during a treatment period. Hence, interchangeability does not imply substitutability.
"Non-clinical (Pre-clinical)"	means during pre- clinical drug development, a sponsor evaluates the drug's toxic and pharmacologic effects through in vitro and in vivo laboratory animal testing. Generally, genotoxicity screening is performed, as well as investigations on drug absorption and metabolism, the toxicity of the drug's metabolites, and the speed with which the drug and its metabolites are excreted from the body.
Pharmacovigilance	means, the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. The decision to approve a drug is based on a satisfactory balance of benefits and risks within the conditions specified in the product labeling. This decision is based on the information available at the time of approval. The knowledge related to the safety profile of the product can change over time through expanded use in terms of patient populations and the number of patients exposed. In particular, during the early post-marketing period the product might be used in settings different from clinical trials and a much larger population might be exposed in a relatively short timeframe. Detailed evaluation of the information generated through pharmacovigilance activities is important for all products to ensure their safe use

Protein	means any alpha amino acid polymer with a specific defined sequence that is greater than 40 amino acid in size.
Reference Biotherapeutic Product	A reference biotherapeutic product is used as the comparator for head-to-head comparability studies with the similar biotherapeutic product in order to show similarity in terms of quality, safety and efficacy. Only an originator product that was licensed on the basis of a full registration dossier can serve as a RBP. It does not refer to measurement standards such as international, pharmacopoeial, or national standards or reference standards.
Similar Biotherapeutic Product	means a new biotherapeutic product claimed to be similar" to an already approved reference biotherapeutic product, which is marketed by an independent applicant, subject to all applicable data protection periods and/or intellectual property rights in the innovator product. The requirements for the registration of similar biotherapeutic product are based on the demonstration of similarity (i.e. no clinically meaningful difference between the similar biotherapeutic product and the reference biotherapeutic product) in terms of quality, safety and efficacy to an already registered, reference biological product.
Similar	means absence of a relevant difference in the parameter of interest
Similarity	means if a company chooses to develop a new biological product claimed to be „similar" to a reference product, comparative studies are needed to generate evidence substantiating the similar nature, in terms of quality, safety and efficacy, of the new

	similar biological product and the chosen reference product.
Specification	means a list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a drug substance, drug product or materials at other stages of its manufacture should conform to be considered acceptable for its intended use.
Substitution	Practice of dispensing one medicine instead of another equivalent and interchangeable medicine at the pharmacy level without consulting the prescriber Switching Decision by the treating physician to exchange one medicine for another medicine with the same therapeutic intent in patients who are undergoing treatment
Validation	The process of demonstrating that the system (or process) under consideration meets in all respects the specification of that system or process. Also, the process of evaluating a system or component during or at the end of the development process to determine whether it satisfies specified requirements.
Variation	means a change in the indication(s), dosage recommendation(s), drug classification and/or patient group(s) for a previously registered drug being marketed under the same name in Tanzania. A variation also includes, but is not limited to, a change in the product name, site of manufacture and/or source of ingredients.
Well-characterized biologic	A well-characterized biologic is a chemical entity whose identity, purity, impurities, potency and quantity can be determined and controlled. Most of these products are recombinant DNA-derived

	proteins or monoclonal antibodies. For DNA-derived proteins, determining identity requires establishing the primary and secondary structures, including amino acid sequence, disulfide linkages (if possible), and post-translational modifications such as glycosylation (the attachment of carbohydrate side chains to the protein). Monoclonal antibodies can be identified with rigorous physicochemical and immunochemical assays. Purity and impurities must be quantifiable, with impurities being identified if possible; the biological activity and the quantity must be measurable.
Well-established biotherapeutic product:	A biotherapeutic product that has been marketed for a suitable period with a proven quality, efficacy and safety.

1.0 INTRODUCTION

Biotherapeutic products have significantly improved the management of many diseases through targeted therapies with enhanced clinical outcomes. However, their complex development and manufacturing processes often result in high costs, limiting patient access. The expiry of patents for innovator biotherapeutic products has enabled the development of similar biotherapeutic products (biosimilars), which can improve access to affordable biological medicines.

Unlike generic chemical medicines, biosimilars cannot be considered identical copies of their reference products. Biotherapeutic products are large, complex molecules produced in living systems, and their quality characteristics are influenced by the manufacturing process. Consequently, biosimilars require a comprehensive comparability exercise to demonstrate high similarity to the reference product in terms of quality, safety and efficacy.

Recognising these scientific considerations, the European Medicines Agency (EMA), the World Health Organization (WHO), and other regulatory authorities have established dedicated regulatory frameworks for the evaluation of biosimilars based on the principles of comparability.

The Pharmacy and Poisons Board (PPB) requires that all medicinal products intended for marketing in Kenya meet acceptable standards of quality, safety and efficacy and are manufactured in compliance with current Good Manufacturing Practices (GMP). These Guidelines provide applicants with the requirements and procedures for the registration of similar biotherapeutic products (biosimilars) in Kenya.

1.1 Legal Framework

The Pharmacy and Poisons Board (PPB), under Cap 244, Section 3(A)**,** is empowered to formulate guidelines for the regulation of medical products, including their manufacture, import, export, distribution, sale, and use. Additionally, Section 3(C) grants the Board the authority to grant or withdraw

marketing authorization for medical products, subject to appropriate conditions, and to revise these conditions as necessary.

The Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022**,** under Section 5(1)**,** authorizes the Board to register a health product or technology once it is satisfied with its safety, efficacy, quality, performance, and economic value.

In accordance with these regulations, the Pharmacy and Poisons Board will ensure that vaccine dossiers submitted for market authorization meet all the relevant requirements as outlined in the technical guidelines. This includes adherence to the applicable policies, laws, legal frameworks, guidelines, manuals, and procedures in force in Kenya.

1.2 Scope

This Guideline is made to provide guidance to applicants on the procedure for registering a Similar Biotherapeutic Product in Kenya. The guideline applies to well-established and well-characterized biotherapeutic products such as recombinant DNA-derived therapeutic proteins. Vaccines and plasma derived products and their recombinant analogues are excluded from the scope of these guidelines.

This document is intended to provide guidance on issues to consider when demonstrating that a proposed biological product is similar to, a reference biotherapeutic product already registered, well established for purposes of submitting a marketing application.For the purpose of this document, a Similar Biotherapeutic Product (a short designation for highly similar biological medicinal product) is considered as a new biological medicinal product developed to be similar in terms of quality, safety and efficacy to an already registered, well established, medicinal product.

NB: This guideline should be read in conjunction with the Guideline for the Registration of Biotherapeutic products.

SBP submission must follow the format described in guidelines for human biotherapeutic products.

1.3 Language

All applications and supporting data submitted to the Pharmacy and Poisons Board should be presented in English (UK). Original documents not in English should be accompanied by an English translation.

1.4 Evaluation pathways

Biotherapeutic product applications for new registrations and variations in Kenya will follow one of four evaluation / review pathways:

a) Full review
b) Abridged review
c) Verified review
d) Recognition

Review pathways (b), (c) and (d) represent reliance-based evaluations.

For further Guidance on reliance refer to Guidelines on *Reliance Mechanisms for Marketing Authorization of Health Products and Technologies in Kenya*

1.5 Fees

The fees payable is published in the Government Gazette and are also available on the Pharmacy and Poisons Board website.

To ensure evaluation of the relevant submission(s) a copy of proof of payment both invoice and receipts must be attached with the relevant submission documents.

Processing of applications shall be as per Part VII the Compendium Of Guidelines On Medicines Evaluation And Registration In Kenya .

1.6 Samples

All applications for registration must include at least three 6(s) of a unit pack. Where the submission of samples is not feasible, the dossier screening officer shall request the applicant to submit a letter of exemption to the Board accompanied by coloured secondary and primary packaging artworks and

assessors shall extract the details of manufacturing and expiry dates from the executed Batch Manufacturing Records (BMR) or certificate of analysis.

1.7 Timelines for Evaluation of Applications for Marketing Authorization

Applications shall be evaluated on a First in First out (FIFO) basis and the timeline for review and approval shall be as per the published time for each application pathway in the Pharmacy and Poisons Board Service Delivery Charter.

2.0 THE CONCEPT OF SIMILAR BIOTHERAPEUTIC PRODUCTS

The concept of a Similar Biotherapeutic Product (SBP) applies to biological drug submission in which the manufacture would be based on demonstrated similarity to a Reference Biotherapeutic Product (RBP).

The rationale for creating the new regulatory framework to evaluate SBP is that biotherapeutic products claimed to be highly similar to a reference product do not usually meet all the conditions to be considered as a generic product. The term generic medicine is used for chemically derived products which are identical and therapeutically equivalent to the innovator product. For such generics, demonstration of bioequivalence with the innovator product is usually appropriate to infer therapeutic equivalence. However, this procedure cannot be used for SBP. The large and complex molecular structure of biologics makes them difficult to adequately characterize in the laboratory.

Based on the current analytical techniques, two biotherapeutic products produced by different manufacturing processes cannot be shown to be identical, but similar at best. For these reasons, the standard generic approach is scientifically not applicable to development of SBP products and additional non-clinical and clinical data are usually required.

Based on the comparability approach and when supported by state-of-the-art analytical systems, the comparability exercise at the quality level may allow a reduction of the non-clinical and clinical data requirements compared to a full dossier. This in turn, depends on the clinical experience with the substance class and will be a case-by-case approach.

The aim of the SBP approach is to demonstrate close similarity of the 'similar biotherapeutic product' in terms of quality, safety and efficacy to one chosen reference Biotherapeutic product, subsequently referring to the respective dossier.

References:

WHO TRS 977, Annex 2, i.e. WHO biosimilar guidelines

2.0. GENERAL INFORMATION

2.1 General Requirements

For general requirements of application for registration of SBPs reference should be made to the Pharmacy and Poisons Board guidelines on documentation for registration of biotherapeutic products.

There are some additional requirements, specific to SBP's, which are described in module 3,4 and 5.

2.2 Consideration for the Choice of RBP

The aim of the SBP approach is to demonstrate close similarity of the SBP product in terms of quality, safety and efficacy to a RBP

The following should be considered in selecting RBP;

i. The RBP should have been marketed for a suitable duration and have a volume of marketed use such that the demonstration of similarity to it brings into relevance a substantial body of acceptable data regarding the safety and efficacy.
ii. The manufacturer must demonstrate that the chosen RBP is suitable to support the application for marketing authorization of SBP.
iii. The RBP should have been licensed on the basis of full quality, safety, and efficacy data. An SBP should therefore *not* be chosen as an RBP.
iv. The same RBP should be used throughout the development of the SBP (i.e. throughout the comparative quality, nonclinical, and clinical studies).
v. The active ingredient of the RBP and the SBP must be shown to be similar.
vi. The dosage form and route of administration of the SBP should be the same as that of the RBP.
vii. The following factors should be considered in the choice of an RBP that is marketed in another jurisdiction:
viii. The RBP should be licensed and widely marketed in another jurisdiction that has a well-established regulatory framework and principles, as well as considerable experience of evaluation of biotherapeutic products and post-marketing surveillance activities.

ix. The acceptance of an RBP for evaluation of an SBP does not imply that the pharmacy and Poisons Board has approved the RBP for use.

2.3 Product Specific Requirements

It should be recognized that there may be subtle differences between SBPs from different manufacturers or compared with reference products, which may not be fully apparent until greater experience in their use have been established. Therefore, in order to support pharmacovigilance monitoring, the specific SBPs given to patient should be clearly labeled and identified (by the brand name) by the prescriber.

Application submitted for the registration of SBPs should contain, among other things, data demonstrating that the SBP is similar to a RBP which should be derived from: -

a) Analytical assessment (physicochemical and functional studies) demonstrating the biological product is highly similar to the reference product regardless of minor differences in clinically inactive components.
b) Animal studies, including the assessment of toxicity.
c) A clinical study or studies, including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics, that are sufficient to demonstrate safety, purity, and potency in one or more appropriate indications of use for which the reference product is registered and intended to be used and for which registration is sought for the biological product.
d) Risk management/pharmacovigilance plans

2.4 Other Requirements

2.4.1 Manufacturer's declaration

A document should be presented certifying that the information provided corresponds to all the studies performed, regardless of their results. This should include all the pertinent information regarding all toxicological and/or clinical tests or trials of the biological product that are incomplete or have been abandoned and/or completed tests related to indications not covered by the application.

The applicants intending to develop SBPs should meet with regulators in their country of origin to present their product development plans and establish a schedule of milestones that will serve as standards for future discussions with the respective regulators.

2.4.2 Expert Report

Experts must provide detailed reports of the documents and particulars, which constitute sections 3, 4 and 5.

The requirement for these signed Expert Reports may be met by providing

i. The Quality Overall Summary, Non-clinical Overview/Summary and
ii. Clinical Overview/Summary
iii. A declaration signed by the experts(annex 2)
iv. Brief information on the educational background, training and occupational experience of the experts

Experts should additionally indicate in their declarations the extent, if any of their professional or other involvement with the applicant/dossier owner and confirm that the report has been prepared by them or if not, any assistance provided and by whom. Reports should be based on an independent assessment of the dossier and references must be provided for any additional claims not supported by the dossier.

2.5 Scientific Guidelines Applicable to all Similar Biotherapeutic Product

For product specific guidance, applicants are encouraged to refer to the product specific guidelines available at the following websites:

References:

a) EMA: http://www.ema.europa.eu
b) International council of Harmonisation (**ICH**) Guidelines: http://www.ich.org/
c) WHO TRS 977, Annex 2, i.e. WHO Similar biotherapeutic guideline

The submission must follow CTD format detailed in Pharmacy and Poisons Board guideline for the Registration of Biotherapeutic products. The requirements specific to SBP dossiers are as detailed in the Modules below.

MODULE 1: ADMINISTRATIVE AND PRODUCT INFORMATION

Module 1 should contain all administrative information as stipulated in the pharmacy and Poisons Board Guideline for the Registration of Biotherapeutic products. The application form (Annex 1) is the same that for Biotherapeutic products, but should be indicated by the applicant as SBP.

Information on SmPC should be consistent with the RBPs SmPC, any difference in the proposed SmPC vis-à-vis the RBPs SmPC, should be appropriately discussed and justified

Labelling of SBP should be individualized and should clearly indicate which clinical safety and efficacy data have been obtained with the SBP. (Data itself should not be included in the label, but studies need to be described). Furthermore, it should clearly be stated that the product is a biosimilar.

Naming of Products shall be as per Part VIII of the Compendium Of Guidelines On Medicines Evaluation And Registration In Kenya

MODULE 2: OVERVIEW AND SUMMARIES

The purpose of this module is to summarize the quality (chemical, pharmaceutical, and biological), nonclinical and clinical information presented in modules 3, 4, and 5 in the market authorization application. The submission for this section will be as stipulated in the pharmacy and Poisons Board Guideline for the Registration of Biotherapeutic products.

MODULE 3: QUALITY

The information requested under this section should be supplied in format stipulated in the pharmacy and Poisons Board Guideline for the Registration of Biotherapeutic products

The quality part of a SBP, like all other biological products should comply with established scientific and regulatory standards. SBP manufacturer should provide full information on Chemistry, manufacturing and control.

IN ADDITION TO SUBMISSION OF THE QUALITY PART

The applicant of the SBP is required to submit extensive data focused on the similarity, including comprehensive comparative (head – to- head) physicochemical, molecular and biological characterization (these may include bioassays, biological assays, binding assays, and enzyme kinetics) of the SBP and the RBP.

Information on the development studies conducted to establish the dosage form, the formulation, manufacturing process, stability study and container closure system including integrity to prevent microbial contamination and usage instructions should be documented.

A summary of the analytical results (these may be in a form of a report) on three consecutive batches of finished product must be provided to support the application for registration. These batches may be pilot or production batches. If they are pilot batches, they must be representative of production batches

3.1 Qualitative and Quantitative Particulars

Qualitative and Quantitative Particulars of SBP shall be presented in a tabular form as indicated in the pharmacy and Poisons Board Guideline for the Registration of Biotherapeutic products.

A list of all components of the SBP and diluents (if applicable) should be given. The quantities per dose should be stated. A clear description of the active ingredient including the name(s) of the active ingredientshould be provided.

The reason(s) for inclusion of each excipient and a justification for overages should also be stated.
Where applicable; special characteristics of excipients should be indicated. The type of water (e.g purified, demineralised), where relevant, should be indicated.

3.2 Manufacturing process

The manufacturing process for SBP should be highly consistent and robust. The process should be developed and optimized taking into account state-of-the-art technology in relation to the manufacturing processes and consequences on product characteristics.
For the establishment and characterization of the cell banks, EAC Guideline for the Registration of Biotherapeutic products.
, ICH guidelines Q5A, Q5B and Q5D should be referred to.
Complete description of the manufacturing process from the development and characterization of cell banks, stability of clone cell culture/fermentation, harvest, excipients, formulation, purification, primary packaging interactions etc should be submitted.
When demonstrating similarity between a SBP and an RBP, the following factors should be critically considered: -

1) Differences between the chosen expression system of the proposed SBP and that of the RBP should be carefully considered and appropriately documented.
2) Characterization of the expression construct, including its genetic stability, should be demonstrated in accordance with principles recommended in ICH Q5B.
3) Characterization tests, process controls, and specifications that will emerge from information gained during process development must be specific for the proposed SBP and the manufacturing process. The use of Quality-by-Design approaches is recommended to assure consistent manufacturing of high-quality product.

4) The full drug master file (DMF), manufacturing process validation protocol and report should be submitted.
5) Product employing clearly different approaches to manufacture from the reference product will not be eligible for registration as an SBP.The applicant shall be required to provide information to fulfill the requirements for registration of new biological products as prescribed in the EAC Guideline for the Registration of Biotherapeutic products

Reference

i. ***ICH Q5A****: Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002801.pdf)*

ii. **ICH Q5B:** *Quality Of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products.*
http://www.gmp-manual.com/showdoc/GMP-MANUAL/GMP-Regulations/E-ICH-Guidelines/E5B-ICH-Q5B-Quality-of-Biotechnological-Products-Analysis-of-the-Expression-Construct-in-Cells-Used-for-Production-of-R-DNA-Derived-Protein-Products

iii. **ICH Q5D:** *Derivation and Characterization of Cell Substrates used for Production of*
Biotechnological/Biological Products
http://www.gmp-manual.com/showdoc/GMP-MANUAL/GMP-Regulations/E-ICH-Guidelines/E5D-ICH-Q5D-Derivation-and-Characterisation-of-Cell-Substrates-used-for-Production-of-BiotechnologicalBiological-Products

3.3 Analytical Comparability studies

The SBP should be highly similar to the RBP and studies shall be done according to the capability of available appropriate analytical assays to assess, for example, the molecular weight of the protein, complexity of the protein (higher order structure and post-translational modification), degree of

heterogeneity, functional properties, impurity profiles and degradation profile denoting stability. Design of the Comparability approach should be supported by scientifically sound methodologies.
Note; the capabilities of the methods used in the analytical assessment as well as their limitations shall be described.

3.4 Analytical procedure/technique/Product characterization

The applicant should submit assessment of the analytical similarity to the RBP in additional to information on Chemistry Manufacturing and Controls (CMC). The purpose of the analytical similarity assessment should be clearly described with consideration for the known quality attributes and performance characteristics of the specific reference product.
Extensive analytical methods should be applied to increase the likelihood of detecting subtle variations in the quality attributes of the product. Methods used in both the characterization studies and comparability studies should be appropriately qualified and validated [as in **ICH Q2** (**R1**)]

Reference standards and international reference materials shall be used for method qualification and validation. Specifications and Certificates of analysis for both reference standards and raw materials from the manufacturer must be provided.
Characterizations of a biological product by appropriate techniques, as described in ICH Q6B and WHO TRS 987 annex 4 should include the determination of physicochemical properties, biological activity, immunochemical properties, purity, impurities, contaminants, and quantity. Product-related impurities, product-related substances, and process-related impurities should be identified, characterized as appropriate, quantified and compared to those of the RBP to the extent feasible and relevant, as part of an assessment of the potential impact on the safety, and potency of the product.
For further guidance on key points to be considered in the characterization exercise,ICH Q6B guidelines shall be referred to.

Reference;

ICH Q2 (R1): Validation of Analytical Procedure: Test and Methodology.
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q2_R1/Step4/Q2_R1__Guideline.pdf

ICH Q6B: *Note for guidance on specifications: Test Procedures and Acceptance Criteria for Biotechnological/ Biological products.*
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002824.pdf

3.5 Container closure system

A description of the container and closure system, and its compatibility with the SBP shall be submitted. Any differences of the RBP and SBP container closure should be justified. Detailed information concerning the supplier(s), address (es), and the results of any relevant information on compatibility, toxicity and biological tests shall be provided for containers of novel origin. Evidence of container and closure integrity shall be provided for the duration of the proposed shelf life. Drawings of the containers and closures should be included.

Specification shall be provided for the components of the container closure system that come into contact with the product. Specification for primary container shall include among other tests, an identification test for material of construction of the container.

3.6 Product stability

The stability studies should comply with relevant pharmacy and poisons Board Guidelines for application of Registration for Biotherapeutic products, ICH Q5C andQ1A (R2). Studies should be carried out to show that the biodegradation profiles are comparable between SBP and RBP. Generally, stability studies results should be summarized in a tabular format, and they should include the results from real time and accelerated degradation studies and studies under various stress conditions (temperature, light, humidity and mechanical agitation).

An appropriate physicochemical and functional comparison of the stability of the proposed SBP with that of the RBP should be monitored to confirm storage conditions selected.

Stability data should be provided for at least three representative consecutive batches stored in the final container. The three consecutive production runs shall (the largest scale validated and proposed for registration for commercial use) The storage temperature should be stated together with the results of tests on the batches. A plan for on-going stability studies should be provided indicating the batch numbers of the batches on test and the time points when testing is planned.

Note: Shelf life before opening the container and shelf-life after first opening the container (if applicable) shall be demonstrated.

Reference;

ICH Q5C - *Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products*
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002803.pdf

Q1A (R2)–*Stability Testing of New Drug Substances and Products*
http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073369.pdf

MODULE 4: NON-CLINICAL STUDY

The establishment of safety and efficacy of an SBP usually requires the generation of some non-clinical data with the SBP. The spectrum of studies required to established safety and efficacy of the SBP may vary considerably and should be defined on a case-by-case basis.

Non-clinical studies should be performed in a facility that is GLP accredited. Certificate of GLP compliance issued by competent authority should be included in the dossier.

These studies should be comparative in nature and should be designed to detect differences in the pharmaco-toxicological response between the SBP and the RBP.

The approach taken will need to be fully justified in the non-clinical overview. Nonclinical studies should be a part of the overall comparability studies. Any deviation from this approach should be appropriately justified.

4.1 Special consideration

The design of an appropriate nonclinical study should consider the product characteristics. Results from the physicochemical and biological characterization studies should be reviewed from the point of view of potential impact on efficacy and safety. In the development of SBP, existing guidelines such as EAC Guideline for the Registration of Biotherapeutic products and ICH S6, should also be taken into account.

Additional nonclinical data may be required to establish the safety and efficacy of SBP depending on the product and on factors related to substance class as stipulated in the Pharmacy and poisons Board Guideline for the Registration of Biotherapeutic products

Factors that may elicit the need for additional nonclinical studies include, but are not restricted to, the following:

a) Quality-related factors:

i. Significant differences in the cell expression system compared with the RBP;

ii. Significant differences in purification methods used;

iii. The presence of a complex mixture of less well-characterized product- and/or process-related impurities e.g.a highly complex immunogenic substance that is difficult to characterize by analytical techniques and that possesses a narrow therapeutic index.

b) Factors related to pharmaco-toxicological properties of the drug substance:

i. Mechanism(s) of drug action are unknown or poorly understood;

ii. The drug substance is associated with significant toxicity and/or has a narrow therapeutic index;

iii. Limited clinical experience with the RBP.

Depending on these factors, the spectrum of studies required to establish the safety and efficacy of the SBP may vary considerably and should be defined on a case-by-case basis.

4.2 Pharmacodynamics

a) In vitro studies:

In order to assess any alterations in reactivity between the SBP and the RBP, data from a number of comparative bioassays (e.g. receptor-binding studies, cell proliferation assays), many of which may already be available from quality-related bioassays, should be provided.

b) In vivo studies:

Animal studies should be designed to maximize the information obtained. They should be comparative in nature (see above), should be performed in a species known to be relevant (i.e. a species in which the RBP has been shown to possess pharmacodynamic and/or toxicological activity), and should employ state-of the-art technology.

Where the model allows, consideration should be given to monitoring a number of end-points such as:

a) Biological/pharmacodynamic activity relevant to the clinical application. These data should usually be available from biological assays described in the quality part of the dossier (Section 3) and reference to these studies can be made in the nonclinical part of the dossier.

b) If feasible, biological activity may be evaluated as part of the nonclinical repeat-dose toxicity study (described below). Invivo evaluation of

biological/pharmacodynamic activity may be unnecessary if in vitro assays are available that have been validated as reliably reflecting the clinically relevant pharmacodynamic activity of the RBP.At least one PD marker is accepted as surrogate marker but must be validated.

4.3 Toxicology

Data on at least repeated dose toxicity conducted in relevant specie should be submitted.

Toxicokinetic measurements shall include the following;

4.3.1 Determination and characterization of antibody responses, including anti-product antibody titres

4.3.2 Cross-reactivity with homologous endogenous proteins, and

4.3.3 Product-neutralizing capacity.

The studies should be of sufficient duration to allow detection of potential differences in toxicity and antibody responses between the SBP and the RBP. A head-to-head repeat dose toxicity study should usually constitute a minimum requirement for non-clinical evaluation of a SBP**.** Comparative repeat-dose toxicity studies should be submitted to demonstrate that no "unexpected"toxicity will occur during clinical use of the SBP. The repeat-dose toxicity study performed on the final formulation should aim at detecting potential toxicity associated both with the drug substance and with product- and process-related impurities.

Although the predictive value of animal models for immunogenicity in humans is considered low, antibody measurements, if applicable, should be included in the repeat-dose toxicity study to aid in the interpretation of the toxicokinetic data and in assessing, as part of the overall comparability exercise, whether important differences in structure or immunogenic impurities exist between the SBP and the RBP (the immunological response may be sensitive to differences not detected by laboratory analytical procedures).

Depending on the route of administration, local tolerance may need to be evaluated. If feasible, this evaluation may be performed as part of the described repeat-dose toxicity study.

On the basis of the demonstration of similarity between the SBP and RBP by the additional comparability exercise performed as part of the quality evaluation, other routine toxicological studies – such as safety pharmacology, reproductive toxicology, genotoxicity and carcinogenicity studies – are not generally requirements for the nonclinical testing of an SBP, however when the results of the repeat-dose toxicity or the local tolerance study and/or by other known toxicological properties of the RBP (e.g. known adverse effects of the RBP on reproductive function) study reveal the need, it should be done.

- Refer to **ICH S6:** Preclinical safety evaluation of biotechnology-derived pharmaceuticals
- WHO TRS 977 Annex *2*

MODULE 5: CLINICAL STUDIES

The requirements for documentation of the clinical data depend on the existing knowledge about the reference product and claimed therapeutic indications.

The submission must include the information demonstrating that there are no clinically meaningful differences between the SBPs and the RBPs in term of Safety, Quality and Efficacy.

Clinical programmes for a SBPs application should be conducted in a facility which is Good Clinical Practice (GCP) compliant and a certificate issued by regulatory Authority from the country of origin and/or competent regulatory Authority should be present in the submission.

The clinical comparability exercise should include pharmacokinetics (PK), Pharmacodynamics (PD) studies followed by Clinical Efficacy and Safety trials.

Further guidances on statistical considerations and extrapolations of indications can be obtained in WHO guidelines on evaluation of Similar biotherapeutic product,2013.

5.1 Pharmacokinetic (PK) studies

Comparative pharmacokinetic studies should be conducted to demonstrate the similarities in pharmacokinetic (PK) parameters between SBPs and the RBPs.

5.1.1 If appropriate from an ethical point of view, healthy volunteers will in most cases represent a sufficiently sensitive and homologous model for such comparative PK studies.

5.1.2 Choice of designs must be justified and should consider factors such as clearance and terminal half-life, linearity of PK parameters, where applicable, the endogenous level and diurnal variations of the product under study, production of neutralizing antibodies, conditions and diseases to be treated.

5.1.3 The acceptance criteria to conclude clinical comparability should be defined prior to the initiation of the study, taking into consideration

known PK parameters and their variations, assay methodologies, safety and efficacy of the RBPs.

5.1.4 Other PK studies such as interaction studies or PK studies in special populations (e.g. children, elderly, and patients with renal or hepatic insufficiency) shall be submitted.

5.2 Pharmacodynamics (PD) studies

Pharmacodynamics (PD) markers should be selected on the basis of their relevance to demonstrate therapeutic efficacy of the product. If direct PD markers are not practical a surrogate marker which is clinically validated may be employed.

The Pharmacodynamic effects of the SBPs and the RBPs should be compared in a population where the possible differences can be best observed.

Design and duration of the studies must be justified. The PD study may be combined with a PK study and the PK/PD relationship should be characterized so as to provide information on relationship between exposure and effects.

The selected dose should in the steep part of the dose-response curve. Studies at more than one dose may be useful.

Reference;

ICH E 10: *Choice of control group and related issues in clinical trials*
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E10/Step4/E10_Guideline.pdf

5.3 Clinical efficacy trials

Comparative clinical trials (head-to-head adequately powered, randomised, parallel group clinical trials, so-called equivalence trials") are required to demonstrate the similarity in the efficacy and the safety profiles between the SBPs and the RBPs. Assay sensitivity must be ensured (refer to **ICH E10**).

Equivalence margins should be pre-specified and adequately justified on clinical grounds. Equivalent rather than non-inferior efficacy should be shown in order for the SBPs to adopt the posology of the RBPs and to open

the possibility of extrapolation to other indications, which may include different dosages.

Clinical studies should be designed to demonstrate comparable safety and efficacy of the SBP to the reference product and therefore need to employ testing strategies that are sensitive enough to detect relevant differences between the products, if present.

5.4 Clinical safety and effectiveness

Similar efficacy will usually have to be demonstrated in adequately powered, randomized and controlled clinical trials(s). Clinical studies should preferably be double-blind or at a minimum observed blind. Furthermore, a sensitive and preferably well-established clinical model is required. Equivalence trials are clearly preferred for comparison of the SBP with the reference product. Non-inferiority designs may be considered if appropriately justified.

Even if the efficacy is shown to be comparable, the similar biological medicinal product may exhibit a difference in the safety profile (in terms of nature, seriousness, or incidence of adverse reactions). Thus, data from a sufficient number of patients and adequate study duration with sufficient statistical power to detect major safety and effectiveness differences are needed.

Data from pre-approval studies are insufficient to identify all these differences in safety. Therefore, applicant should submit a risk management plan/pharmacovigilance plan for the SBPs. The plan must be with the intention to mitigate potential risks associated to the SBPs.Also, the submission should address the strategy to execute the plan.

For products intended for use for more than 6 months, the size of the safety database should typically conform to the recommendations of **ICH E1**.

Reference;

ICH E1: *The extent of population exposure to assess clinical safety for drug intended for long term treatment for non-life-threatening conditions.*

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E1/Step4/E1_Guideline.pdf

5.5 Clinical Immunogenicity

Immunogenicity of SBPs should be investigated prior to Marketing Authorization. Structural and functional studies as well as animal data are generally not adequate to predict immunogenicity in humans. Therefore, at least one clinical study that includes a comparison of the immunogenicity of the proposed SBPs to that of the RBPs in humans has to be submitted. The data should be submitted so as to evaluate potential differences between the proposed SBPs and the RBPs in the incidence and severity of human immune responses.

A written rationale on the strategy for testing immunogenicity should be provided.

EAC recommends that immunogenicity assays be developed and validated with respect to both the proposed SBPs and RBPs product early in development. Validated assays/methods should be used for testing immunogenicity with appropriate specificity and sensitivity.

Special attention should be given to the possibility that the immune response seriously affects the endogenous protein and its unique biological function and thus leads to adverse reactions.

The proposed SBPs and RBPs should be evaluated in the same clinical trial of sufficient duration with the same patient sera whenever possible. The duration of the study should be at least **12 months** using appropriate route of administration by comparative parallel designs. At the time of submission, the study should have covered at least **6 months**.

***Note*:** Data at the end of the 12 months should be presented as part of the post-marketing commitment

In situations where an applicant is seeking to extrapolate immunogenicity data for one indication to other indications, the applicant should consider using the population and regimen for the RBPs for which development of immune responses with adverse outcomes is most likely to occur.

The selection of clinical immunogenicity endpoints or PD parameters linked to immune responses (e.g., antibody formation and cytokine levels) should take into consideration the immunogenicity issues that have emerged during the use of the RBPs. The clinical immune response criteria should be defined, using established criteria where available, for each type of potential immune responses.

Reference is to be made to the CHMP Guideline on Immunogenicity Assessment of Biotechnology-Derived Therapeutic Proteins (CHMP/BMWP/14327/06)

A warning statement on the risks associated with switching of products during treatment, and against product substitution, is to be included in the package insert of the SBPs;This should be done by prescriber.

Reference:

EMA guidelines

- Guidelines for non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins (EMA/CHMP/BMWP/3016636/2008).
- Guidelines for non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues (EMA/134217/2012
- Guidelines for non-clinical and clinical development of similar biological medicinal products containing recombinant Granulocyte Colony Stimulating factor (rG-CSF_) (EMEA/CHMP/BMWP/31329/2005).
- Guidelines for non-clinical and clinical development of similar biological medicinal products containing low-molecular-weight-heparins (EMEA/134870/2012).
- Guidelines for non-clinical and clinical development of similar biological medicinal products containing recombinant alfa-containing medicinal products (EMEA/CHMP/BMWP/102046/2006).
- Guidelines for non-clinical and clinical development of similar biological medicinal products containing recombinant beta-containing interferon

beta-containing medicinal products (EMEA/CHMP/BMWP/652000/2010).

- Guidelines for non-clinical and clinical development of similar biological medicinal products containing monoclonal antibodies- (EMEA/CHMP/BMWP/403543/2010).
- WHO TRS 977 Annex 2

5.6 Pharmacovigilance

As for most biological medicines, data from pre-authorization clinical studies are usually too limited to identify all potential unwanted effects of an SBP. In particular, adverse events are unlikely to be encountered in the limited clinical trial populations being tested with the SBP. Further close monitoring of the clinical safety of an SBP in all approved indications and a continued benefit-risk assessment are therefore necessary in the post-marketing phase. The manufacturer should submit a Periodic Benefit-Risk Evaluation Report (PBRER) and pharmacovigilance plan/risk management plan at the time of submission of the marketing authorization application. The principles of pharmacovigilance planning can be found in relevant guidelines such as ICH E2E.

Reference:

ICH E2E (Pharmacovigilance Planning)

- http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2E/Step4/E2E_Guideline.pdf

6.0 ACKNOWLEDGEMENTS

EAC Expert working group on Registration of Medicines

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8.0 REVISION HISTORY

Revision No.	Date	Author	Section(s) Revised	Description of the Change
1	11.01.2022	QAO	Document Number	Changed document number from PPB/PER/MED/GUD/014 to PPB/HPT/PER/GUD/014.
			Authorization Section	Changed authorization from Registrar to Chief Executive Officer (CEO).
2	14.07.2026	QAO	1.2 Language	Language previously referenced in HPT/PER/GUD/013 have been incorporated for ease of reference.
			1.3 Evaluation Pathways	Evaluation Pathways previously referenced in HPT/PER/GUD/013 have been incorporated for ease of reference.
			1.5 Fees	Fees previously referenced in HPT/PER/GUD/013 have been incorporated for ease of reference.
			1.6 Samples	Samples previously referenced in HPT/PER/GUD/013 have been incorporated for ease of reference.
			1.7 Timelines	Timelines for Evaluation of Applications for Marketing Authorization previously referenced in HPT/PER/GUD/013 have been incorporated for ease of reference.

Annex I: APPLICATION FORM FOR REGISTRATION OF BIOTHERAPEUTIC AND SIMILAR BIOTHERAPEUTIC PRODUCTS (SBPs)

Form 1	APPLICATION FOR REGISTRATION OF BIOTHERAPEUTIC AND SIMILAR BIOTHERAPEUTIC PRODUCTS
To	THE REGISTRAR PPB OFFICES, LENANA ROAD, DRUG REGISTRATION DEPARTMENT, P.O. BOX 27663-00506, NAIROBI.
Application Number	
Date of submission of the dossier	
CONCLUSION OF THE ASSESSMENT **RECOMMENDED** *(no outstanding issues)* **QUERY RAISED** *(Indicate the sections where query is raised)* **REJECTED** *(indicate the module(s) that led to the rejection)* ***(Please delete which does not apply)***	
TYPE OF APPLICATION – HUMAN PRODUCT	
MODULE 1: ADMINISTRATIVE INFORMATION	
SECTION 1: PARTICULARS OF THE PRODUCT	
1.11 Name and address of Applicant	
Company name: **Address:** **Country:** **Telephone:** **E-Mail:**	
1.12 Type of Medicinal Product Application (Tick where appropriate)	
New (Innovator) BIOTHERAPEUTIC PRODUCT **OR** SIMILAR BIOTHERAPEUTIC PRODUCT**.**	
For PPB use only	

1.2	**Trade/Proprietary name (prorietary Product name):**
For PPB use only	
1.3	**Approved / INN / generic name of the drug substance**
For PPB use only	
1.4	**Strength of drug substance(s) per unit dosage form of the product and specifications of the drug substance(s), including the reference/ monograph standard for each drug substance(s).**
For PPB use only	
1.5	**Dosage form**
1.5.1	**Pharmaceutical Dosage form of the product:**
1.5.2	**Specifications of the Finished Pharmaceutical Product:**
1.5.3	**Route(s) of administration (use current list of standard terms - European Pharmacopoeia):**
For PPB use only	
1.6	**Packing/Pack size of the product:**
1.6.1	**Pack size:**
1.6.2	**Primary packing materials:**
1.6.3	**Secondary packing materials:**
For PPB use only	
1.7	**Visual Description of the product (Add as many rows as necessary)**
For PPB use only	

1.8	**1.8 Proposed Shelf life of the product (in months):**
1.8.1	**Proposed shelf life (after reconstitution or dilution) (if applicable):**
1.8.2	**Proposed shelf life (after first opening container):**
1.8.3	**Proposed storage conditions:**
1.8.4	**Proposed storage conditions after first opening:**
For PPB use only	
1.9	**Pharmacotherapeutic group and ATC Code**
1.9.1	**Pharmacotherapeutic group:**
1.9.2	**ATC Code:**
1.9.3	**If no ATC code has been assigned, please indicate if an application for ATC code has been made:**

1.9.4	**Proposed indication(s) for the product:**
For PPB use only	
1.10	**Indicate Legal category**
1.10.1	**POM (Prescription only Medicine) unless otherwise, provide justification)**
For PPB use only	
1.11	**Country of origin or country of release:**
For PPB use only	
1.12	**Product Marketing Authorisation in the country of origin. (Attach certificate of pharmaceutical product from competent regulatory authority) If not registered, state reasons**

☐ **Authorised** **Country:** **Date of authorisation:** **Proprietary name:** **Authorisation number:** ☐ **Refused** **Country: Not applicable** **Date of refusal (dd-mm-yyyy):** **Reason for Refusal:**	☐ **Withdrawn (by applicant after authorisation)** **Country:** **Date of withdrawal (dd-mm-yyyy):** **Proprietary name:** **Reason for withdrawal:** ☐ **Suspended/revoked (by competent authority)** **Country: Not applicable** **date of suspension/revocation (dd-mm-yyyy):** **Reason for suspension/revocation:**

For PPB use only	
1.12.1	**Registration status from countries with Stringent Regulatory Authorities (SDRAs) where applicable** **SDRAs - Documents to be attached:**
For PPB use only	
1.12.2	**List of countries in which a similar application has been submitted**
For PPB use only	
1.12.3	**Statement on whether an application for the Marketing Authorisation has been previously rejected, withdrawn or repeatedly deferred in the EAC Partner States**
For PPB use only	
1.12.4	**Certificates of approval of Drug Substances(s)/ immunogenic s substance(s) Master (DMF) by Stringent Regulatory Authority**
For PPB use only	
1.12.5	Manufacturing Licence and Product Licence
For PPB use only	
1.13	Certificate of Analysis from a WHO Prequalified Laboratory in Kenya and the lot release certificate issued by the regulatory authority of country of origin for those samples submitted with the application

For PPB use only	
1.14	Name(s) and complete address (es) of the manufacturer(s)
1.14.1	Name and complete address(es)of the manufacturer(s) of the FPP, including the finished pharmaceutical product release if different from the manufacturer.

<u>Marketing Authorisation Holder:</u>
Company name:

Address:

Country:

Telephone:

E-Mail:

<u>Manufactured By:</u>

Company) Name:

Address:

Country:.

Telephone:

Telefax :

If the manufacturer is different to 1.1 above, explain the relationship

1.14.2	**Name(s) and complete address (es) of the manufacturer(s) of the** Drug substance

The active immunogenic substance: (Add as many rows as necessary)

Company) Name:

Office Address :

Country :

Telephone :

Fax :

Contact Person :

E-mail :

For PPB use only	
1.15	**Compliance to Good Manufacturing Practice (GMP) and Good Clinical Practice**
1.15.1	**Good Manufacturing Practice (GMP) from PPB**
1.15.2	**Good Clinical Practice (GCP) or Good Laboratory Practice (GLP)**
For PPB use only	
1.16 .1	**Name and complete address of the Local Technical Representative of Manufacture (for finished pharmcautical Product)** **Company name:** **Address:** **Country:** **Telephone:** **E-Mail:** **If the Local Technical Representative is different to 1.1 above, explain and provide evidence for the relationship:**
1.16 .2	**Name and address (physical and postal) of the person or company responsible for pharmacovigilance** **Company name:** **Address:** **Country:** **Telephone:** **E-Mail:**
For PPB use only	
1.17	**Product Information**
1.17.1	**Summary of Product Characteristics (SPC):**
1.17.2	**Prescribers/Patient information leaflet:**
.17.3	**Mock- Ups and photos scan of the product**

1.18

1.18 Batch number(s) and Batch Types of the final product used in
Clinical studies:
Stability studies:
Validation/production scale batches Validation/production scale batches:
Comments:

Comments: Provide Reasons for comments , e.g batch numbers N/A

Qualitative and Quantitative composition of the drug substance(s) and excipient(s)
A note should be given as to which quantity the composition refers (e.g. 1 Vial).

Name of drug substance(s) *	Quantity / dosage unit	Unit of measure	Reference/ monograph standard
1.			
2.			
e.t.c			
Name of excipient(s)			
1.			
2.			
e.t.c			

Note: * Only one name for each substance should be given in the following order of priority: INN**, Pharmacopoeia, common name, scientific name
** The drug substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.
Details of averages should not be included in the formulation columns but should be stated below:
- Drug substance(s):
- Excipient(s):

1.19	State the reference/monograph standard such as British Pharmacopeia, United States Pharmacopeia, Ph. Eur, Japanese Pharmacopeia, In-house monograph e.t.c. used for Finished Medicinal Product.
1.20	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the product were conducted. (If applicable)

Name: N/A

Company name:

Address:

Country:

Telephone:

Telefax:

E-Mail:

1.21 DECLARATION BY AN APPLICANT	
	I, the undersigned certify that all the information in this form and accompanying correct, complete and true to the best of my knowledge. I further confirm that the information referred to in my application dossier is avail verification during GMP inspection. I also agree that I shall carry out pharmacovigelance to monitor the safety of the p market and provide safety update reports to the National Medicines Regulatory Au I further agree that I am obliged to follow the requirements of Kenya, and Legislations and Regulations which are applicable to medicinal products. Name: Position in the company: Signature: Date: Official stamp:…….. ** Note: If fees have been paid, attach proof of payment*

PPB use only

OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE

Annex II: EXPERT DECLARATION FORM

The following is an example of a suitable declaration form:

Quality /Non-clinical / Clinical (delete those not appropriate)

I, the undersigned, declare that I have:

i. the suitable technical or professional qualifications to act in this capacity (for more information, refer to the enclosed curriculum vitae).

ii. fully examined the data provided by the applicant and have provided references to the literature to support statements made that are not supported by the applicant's original data. This report presents an objective assessment of the nature and extent of the data.

iii. provided a report based on my independent assessment of the data provided.

iv. based my recommendations, regarding suitability for registration, on the data provided herewith. I have considered the attached data and have recommended as to suitability for registration of the intended dose forms and presentations according to the proposed product information document.

I further declare that this expert report represents my own view.
Further, I declare the following to be the full extent of the professional relationship between the applicant and myself:
.....
.....
.....

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Website: www.pharmacyboardkenya.org,

Email: info@ppb.go.ke