Botswana Medicines Regulatory Authority

Approved By: _____ 20-04-2026

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Director – Licensing & Enforcement

Date of Approval (DD/MM//YY)

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Revision status sheet

Page	Changes made	Issue No	Process Owner (Title)	Initiated By (Name)	Reviewed By (Name)	Date
6	Added to clause 4 'This guideline shall be read in conjunction with the Guideline for Good Recognition and Reliance Practices- BOMRA/IL/IL/P08/G02 and other applicable BoMRA regulatory instruments.'	2.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	20/04/2026
1	Updated the name of the Director-DLE from Dr Dijeng to Ms. Raditladi	2.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	30/03/2026
2	Included WOAH and updated legal consideration to align with MRSA 2025	2.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	30/03/2026
6	• Refined the scope to include public and private manufacturers. • Provided a detailed step by step to licensing of a new pharmaceutical plant in Botswana	2.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	30/03/2026
7	• Updated the application process to include BRIMS	2.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	30/03/2026
8	• Under reliance and recognition-updated "SRA"to "WLA" • Defined the number of desk assessment cycles	2.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	30/03/2026

11	• Updated the GMP inspection reference guidelines	2.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	30/03/2026
12	• Added composition of the inspection team, types of inspections, inspection frequency, GMP compliance fees and licensing fees, license withdrawal, post licensure notifications	2.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	30/03/2026

1. Preamble

1.1 The Botswana Medicines Regulatory Authority (BoMRA) was established through the Medicines and Related Substances Act of 2013 and continues to operate under provisions of the Medicines and Related Substances Act, 2025. The Act provides the legal framework for the regulation of medicines, medical devices, and cosmetics in Botswana to promote human and animal health ensuring safety and efficacy.

1.2 The purpose of this guideline is to provide guidance to licensed and prospective manufacturers on the requirements for current Good Manufacturing Practice (cGMP). This guideline is applicable to the manufacturing of pharmaceutical products.

BoMRA adopts internationally recognised standards, including the cGMP guidelines published by the World Health Organisation (WHO) and relevant standards of the World Organisation for Animal Health for veterinary vaccines. Manufacturers are required to comply with these standards to ensure consistent production of safe, effective, and quality-assured products.

2. Laws, Regulations, Policies and Guidelines Applied

These guidelines were developed using principles from the following:

i. Medicines and Related Substances Act, 2025, (MRSA)
ii. Medicines and Related Substances Regulations, 2019
iii. WHO current Good Manufacturing Practice (cGMP) guidelines
iv. WOAH International Standards (manual of diagnostic tests and vaccines for terrestrial animals).

2.1 Legal Consideration

a) MRSA 2025, Section 7 (ii): The personnel, premises and practices employed to manufacture, promote, procure, store, distribute and sell regulated products comply with defined codes of practice and other requirements

b) MRSA 2025, Section 7 (e): Inspect or cause to be inspected, premises where medicated feeds are used, handled or stored

c) MRSA 2025, Section 7 (j): Inspect foreign manufacturing premises, clinical research organisations, and testing premises seeking marketing authorisations, and testing premises seeking marketing authorisation for their products, for compliance with good manufacturing practices.

d) MRSA 2025, Section 7 (t): All regulated products manufactured in, imported into, or exported from, Botswana are authorised, subjected to appropriate lot release procedures based on risk classification, and conform to established criteria of quality, safety and efficacy including batch-specific requirements

e) MRSA 2025, Section 55 (1); A person issued with a clinical trial authorisation under this part may manufacture, assemble, import or export any investigation product in compliance with the good manufacturing practices and international quality standards

f) MRSA 2025, section 58 (1); A person shall not manufacture, sell, supply, export, import, distribute, dispense or store a regulated product unless he or she is authorised or licensed by the Authority in accordance with good manufacturing practices and international quality standards

g) MRSA 2025, section 58 (2); A person who wishes to apply for an authorisation or licence under subsection (1) shall apply to the Authority in such form and manner and upon payment of such a fee as prescribed.

h) MRSA 2025, section 58 (7)(a); The Authority shall carry out necessary inspections to verify compliance with prescribed requirements and standards of good practice.

3. Definitions and abbreviations

3.1 Definitions

For the purpose of these guidelines, the following terms shall be defined as follows:

3.1.1 Active pharmaceutical ingredient (API) - Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

3.1.2 Authority: Means Botswana Medicines Regulatory Authority

3.1.3 Manufacture. An entity engaged in the production, packaging, labelling, or relabelling of pharmaceutical products.

3.1.4 Manufacturer. A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.

3.1.5 Medical product- Medicine, complementary medicine, vaccines, in-vitro diagnosis and medical devices

3.1.6 WHO-Listed Authority-is a regulatory authority (RA) or a regional regulatory system (RRS) that complies with all the relevant indicators and requirements specified by WHO for regulatory capability as defined by an established benchmarking and performance evaluation process.

3.1.7 ZAZIBONA - a collaborative medicines registration initiative in Southern Africa focusing on dossier assessments and good manufacturing practice (cGMP) inspections

3.2 Abbreviations

For the purpose of these guidelines, the following abbreviations shall be used:

3.2.1 **cGMP** - current Good Manufacturing Practice
3.2.2 **BoMRA** - Botswana Medicines Regulatory Authority
3.2.3 **HVAC** - Heating Ventilation and Air Conditioning
3.2.4 **SADC -** Southern African Development Community
3.2.5 **SMF** - Site Master File
3.2.6 **WHO** - World Health Organisation
3.2.7 **WOAH**-World Organisation for Animal Health

4. Scope

These guidelines apply to:

a) Public and private pharmaceutical manufacturers in Botswana (prospective and licensed)

b) Foreign and Local pharmaceutical manufacturers whose products are intended for registration, importation, or marketing in Botswana.

This guideline shall be read in conjunction with the Guideline for Good Recognition and Reliance Practices-***BOMRA/IL/IL/P08/G02*** and other applicable BoMRA regulatory instruments.

5. Licensing of a new domestic pharmaceutical manufacturing plant

Introduction

Setting up a pharmaceutical manufacturing plant is a capital-intensive investment and, as such, requires due diligence and compliance from the conceptual design stage. This will ensure that newly constructed plants meet the acceptable cGMP standards. In this context, the Authority will facilitate Greenfield and Brownfield projects by reviewing their plans from conceptual design through plant licensing.

5.1 Steps towards licensing of a new pharmaceutical manufacturing premise in Botswana

5.1.1 Step 1- Conceptual Facility Design

Prospective pharmaceutical manufacturers must compile and email the following documentation to inspections@bomra.co.bw and then seek a review meeting with the BoMRA Inspections and Licensing Unit:

a) Floor plan drawn to scale
b) Personnel flow
c) Process and material flow
d) Spatial surrounding environment

e) HVAC classification zoning schematic diagrams
f) HVAC pressurization diagram
g) Dust extraction schematic diagram (for oral solid dosage forms).
h) Drainage schematic and Effluent treatment
i) A brief description of the proposed utilities applicable, e.g, Water system
j) Quality Control laboratory schematic drawing, including the microbiology laboratory, where applicable

5.1.2 Step 2-GMP Design Review

The Authority shall evaluate the proposed facility design within ten (10) working days to ensure

a) Compliance with cGMP facility requirements
b) Adequate contamination control measures

Pre-approved designs shall remain valid for a period of twenty-four (24) months. Any proposed changes must be submitted to the Authority for review and approval.

5.1.3 Step 3- Facility Construction and System Development

The manufacturer shall:

a) Construct the facility
b) Install equipment and utilities
c) Establish quality management systems

Note:
Product dossiers may be submitted for registration concurrently while facility construction and system implementation are ongoing

5.1.4 Step 4- Application for Premises License

Upon completion, the manufacturer shall submit the following through the BRIMS portal:

a) Completed Application for Premises License; ***BOMRA/IL/IL/P01/F02***
b) A certified copy of the responsible person's registration certificate issued by a professional body
c) A certified copy of a valid BHPC registration (blue card) or Botswana Veterinary Council (BVC) registration certificate
d) A copy of the current site master file
e) A list of products to be manufactured
f) Proof of payment (use facility name as reference)
g) Certified copy of identity card or passport

5.1.5 Step 5- GMP Compliance Inspection

The Authority shall conduct an inspection to verify;

a) Compliance with approved design
b) Qualification of systems and utilities
c) Implementation of quality systems

5.1.6 Step 6- Licensing Decision

a) Compliant facility
   i. After a satisfactory inspection, the site shall be issued a pharmaceutical manufacturing license.
   ii. cGMP approval granted after successful process validation

b) Non-compliant facility
   i. Inspection report issued outlining deficiencies issued with sixty (60) 0alendar days to submit a corrective and preventative action plan (CAPA)
   ii. Re-inspection may be required with the applicable fee.

NB: Kindly note that the premises shall be expected to comply with the requirements of other national regulatory agencies, such as licenses, permits, or any other approvals.
Any queries, clarifications, contributions and feedback should be submitted to the Chief Executive Officer, Plot 112, Gaborone International Finance Park Gaborone, Botswana; email the Inspections and Licensing Unit at inspections@bomra.co,bw

6. Renewal of GMP Approval

6.1 Application for GMP Renewal

The manufacturer shall submit the following:

a) Completed Application Form ***BOMRA/IL/IL/P08/G01/F01***
b) A copy of the current master file (not more than a year old)
c) A list of products submitted to BoMRA for registration
d) A proof of payment (use facility name as reference)

Applications are to be submitted through the BRIMS Portal https://brims.bomra.co.bw. All applications must be emailed to inspections@bomra.co.bw with the TRC (Tracking Number) number as the subject line. A step-by-step guidance is as follows;

a) On the Home page click facility inspections & licensing
b) On the Dashboard, click in GMP & Pharmaceutical Licenses on the left panel
c) On the drop down click either Pharmaceutical License & Inspection (Domestic Facility) or GMP Inspection (Foreign-Based Facility).

d) Click on Renewal Inspection

7. Variation of Premises License

All changes must be submitted as variations.

a) **Major variations** – Significant changes affecting product quality or safety, e.g., change of manufacturing site, active ingredient source, or formulation.

b) **Minor variations** – Minor changes with limited impact on product quality or safety, e.g., minor changes in labelling, manufacturing process adjustments.

Variations may trigger inspection based on risk.

7.1 Application requirements for variations:

a) Completed Variation Application Form ***BOMRA/IL/IL/P05/F01***
b) Updated Site Master File
c) Proof of payment of the applicable variation fee

8. Inspection type

8.1 Pre-approval Inspections

a) Pre-approval inspections are conducted to support product registration before the granting of marketing authorisation. The inspections are typically product-based and are triggered by the submission of a dossier for registration, particularly where the manufacturing site has not previously been inspected or recognised by the Authority for the manufacture of the concerned product.

b) The pre-approval inspection may include the collection of samples for validation of analytical methods. Sample sizes may be taken depending on the dosage form of the product.

8.2 Routine inspections

a) Risk-based routine inspections

The Authority conducts routine quality assurance surveillance activities on all medicines registered in Botswana through risk-based cGMP inspections. This type of inspection should be announced and is conducted under the following circumstances:

a) Significant changes to manufacturing methods, processes, or facilities, including the introduction of new manufacturing lines, blocks, utilities, or critical equipment.

b) Renewal of cGMP approval or pharmaceutical manufacturing licence, requiring verification of continued compliance before renewal.
c) If a facility has a history of non-compliance

8.3 Follow-up inspection (reassessment or reinspection)

a) The Authority shall conduct follow-up inspections to verify the implementation and effectiveness of corrective and preventative actions arising from previous inspections.

b) Follow-up inspections shall be scheduled within a defined timeframe, typically ranging from two (2) months to six (6) months after the initial inspection, depending on the severity of the deficiencies and the complexity of the corrective actions required

c) The scope of the follow-up inspection shall be targeted and limited to the specific GMP deficiencies previously identified as not complied with or inadequately addressed, including verification of the effectiveness of the implemented CAPA.

d) Where deficiencies are deemed critical or where there is insufficient evidence of CAPA implementation, the Authority may conduct a full reinspection or take additional regulatory action

8.4 For cause inspection

The Authority shall conduct for-cause inspections in response to specific triggers, including but not limited to:

a) Reported or suspected quality defects
b) Complaints related to product quality, safety, or efficacy
c) Regulatory concerns, including arising from pharmacovigilance activities, recalls, non-compliance, or information received from other regulatory authorities.

8.5 Remote Inspections

The Authority may conduct remote (virtual) inspections where:

a) Physical onsite inspection is not feasible due to logistical, public health, or other constraints.
b) The inspection can be adequately supported by submitted documentation, electronic system access, and a documented risk assessment demonstrating that the objectives of the inspection can be achieved.

9. Inspection planning and risk-based approach

Inspection scheduling shall be risk-based and informed by the following factors:

a) Public health importance of the product
b) Product risk, including but not limited to sterile products and biological medicinal products
c) Compliance history of the manufacturing site
d) Reliance or recognition status of the site, including the availability of recent inspection outcomes from recognised authorities.

10. Inspection frequency

10.1 Local Manufacturers

a) Local manufacturers shall be inspected at least once every year, or at a frequency determined using a risk-based approach, based on the outcome of the previous inspection and the facility's compliance history.
b) Compliant facilities will be inspected and licensed within 45 calendar days.

10.2 Foreign Manufacturers

a) Foreign manufacturers, inspections are conducted on a product-based basis, with the frequency of routine inspections determined through a risk-based approach, typically ranging from one to four years.
b) Compliant facilities will be inspected and licensed within 100 calendar days for foreign-based manufacturers.

11. Inspection Team Composition

The inspection team shall be comprised of the following officers:

a) Lead Inspector
- An experienced and competent inspector with adequate knowledge, training, and qualifications to conduct inspections of the relevant dosage form.
- Responsible for leading and coordinating the inspection process, including finalizing the inspection report.

b) Co-Inspector

i. An experienced and competent inspector with adequate knowledge, training, and qualifications in the relevant dosage form.
ii. May be at a competence level below that of the Lead Inspector, to gain experience to independently lead similar inspections in the future.

c) Subject-Matter Expert (SME) (where required)

i. An individual with expertise in a specific technical area relevant to the scope of the inspection. SMEs may be drawn from specialised regulatory units or external technical institutions and may support inspections involving complex manufacturing processes or specialised product categories.

d) Observer Inspector

i. An inspector undergoing training on GMP inspections, who participates as part of capacity building and competence development.

12. Recognition

12.1 The authority recognises the manufacturers inspected and recommended for approval by SADC countries through the ZAZIBONA collaborative initiative and the African Medicines Agency.

12.2 These manufacturers are exempted from onsite GMP inspections.

13. Reliance

13.1 The Authority relies on the work done by other regulatory agencies to make risk-informed regulatory decisions. This is done through desk assessment of inspection reports from other regulatory Authorities within SADC or WHO-Listed Authorities, and the WHO Pre-qualification programme.

13.2 To qualify for GMP clearance through desk assessment, the manufacturing site must have been routinely inspected (i.e., more than 2 consecutive inspections) and approved by WHO-Listed Authorities, including WHO Pre-qualification inspections, covering the same dosage form, manufacturing block, and production line.

13.3 The manufacturer shall provide complete and unredacted documentation to support the desk assessment. This shall include, but is not limited to:

a) Inspection reports issued by recognised regulatory authorities
b) Corrective and Preventive Action (CAPA) plans and evidence of implementation
c) Valid GMP certificates
d) Annual Product Quality Reviews (APQRs)
e) Relevant batch manufacturing and control records

Notwithstanding the above, the Authority reserves the right to determine the appropriate inspection modality, including the requirement for an on-site or remote inspection, based on risk.

13.4 For manufacturers located outside WLA jurisdictions, reliance through desk assessment shall be limited to a maximum of two (2) consecutive cycles. Thereafter, an on-site inspection shall be required to verify continued compliance with current GMP.

13.5 Manufacturers located within WLA jurisdictions may be considered for continued reliance through desk assessment without a predefined limit, provided that:

a) A valid GMP certificate is maintained,
b) Routine inspections are conducted by the WLA within an acceptable timeframe, and
c) There is no evidence of compliance concerns or regulatory action.

13.6 The Authority reserves the right to conduct an on-site or remote inspection at any time based on risk.

13.7 The validity of GMP clearance granted through desk assessment shall not exceed the validity period of the referenced GMP certificate or two (2) years, whichever is shorter.

13.8 Manufacturers are expected to send a formal request for a GMP Desk Clearance to BoMRA at inspections@BoMRA.co.bw.

13.9 BoMRA reserves the right to inspect any facility, irrespective of reliance status

14. Collaboration and work sharing

The authority collaborates with other SADC countries in a work-sharing model called the ZAZIBONA harmonisation initiative. The member countries select representatives to participate in harmonised GMP inspections, and the outcome compliance recommendations are used for internal decision-making at individual country level. This reduces the work burden on the Authority and promotes harmonisation within the African region.

To participate in the ZAZIBONA Inspection process, manufacturers must visit the ZAZIBONA website at www.zazibona.com, and correspondence can be sent to the MCAZ GMP inspectorate at gmp@mcaz.co.bw as the coordinating agency.

15. GMP Compliance Fees

The Authority conducts product-based and cost recovery inspections for all international manufacturers. The inspection fees applicable vary depending on the scope of products marketed in Botswana or submitted for registration. The manufacturing site factors are also taken into consideration. Manufacturers are accordingly expected to send a formal request for a GMP inspection to inspections@BoMRA.co.bw and provide the current Site Master File, and list of products marketed or to be marketed in Botswana. This will allow the Authority to accurately calculate the relevant inspection fees applicable, including the cost recovery

fee. Local manufacturers do not pay for inspection fees as this cost is factored into the licensing fees. However, if there is a need for re-inspections within the same calendar year, re-inspection fees are applicable in line with the published fee schedule.

Region	Fee (USD)
SADC	3 500
Rest of Africa	5 000
Asia	6 500
Rest of the world	7 000
Desk Review	3 500
Additional manufacturing block	1 000

Licensing fees (Local manufacturer)

Facility type	Fee (Botswana Pula)
Licensing fees- non-sterile	
Full manufacturing	4 200
Part manufacturing	7 500
Licensing fees-Sterile	
Full manufacturing	7 500
Part manufacturing	15 000
Clinical trial site	7 500
Re-inspection	2 500

16. Premises License suspension and withdrawal

a) Where the license holder does not meet the required standards and guidelines, the authority may cancel, suspend, withdraw, or revoke an authorisation or license. (MRSA 2025, sec 58(4)).

b) In general, the procedure for suspension and/or withdrawal of licence shall be guided by the applicable risk score profile of the facility as defined in the determination of compliance (Document no. BOMRA/IL/IL/P08/G01/A01)
c) The Authority shall notify the license holder of the decision and may indicate the actions to be taken by the license holder and give the license holder seven days to respond (MRSR 2019, sec 23(2)).
d) The facility shall remain closed for the suspension duration of 30 days while action is being taken to address non-conformances.
e) Where a license is withdrawn, the facility shall cease to operate. (MRSR 2019, sec 23(4)).
f) The license holder shall re-apply for a license and pay the prescribed fees as set out in schedule 5 of the MRSR, 2019.

16.1 Post licensure notification

a) A notification shall be made by the licensee to inform the authority of any post licensure notifications i.e. prolonged absence of more than thirty (30) days, closure of facility, resignation of authorised person and any other.
b) Where there are more than one authorised personnel working for the wholesaler, the authorised persons shall notify BoMRA and submit their proof of registration
c) Change of the responsible person in charge shall be communicated to the Authority within 30 working days.

16.2 Release of customer information

a) BOMRA Inspections and licensing department holds the information relating to customers in strict confidence as the terms and conditions of services provided. Except for information that the customer places in the public domain or when agreed between the Inspectorate and the customer, all other information is considered proprietary information and shall be regarded as confidential.
b) The inspection body shall seek authorization and clearance from the Chief Executive Officer before any customer information is placed in the public domain or shared with a third party.
c) The inspection body shall notify the customer in advance, unless prohibited by law, when the inspection body is required, by law or authorized by contractual arrangements, to release confidential customer information.
d) Information about the customer obtained from other sources other than the customer (e.g. complainant), shall remain confidential between the inspection body and the customer. Identity of the source can only be shared with the customer if the source has agreed to it in writing.

e) The following information about the customer shall be shared through BoMRA public domains
   1. Company Name (license and business name)
   2. License number or cGMP approval number
   3. Business address (physical address)
   4. Type of business (authorized activity)
   5. Premises contact details (email, telephone line)
   6. Authorised Person's Name (facility contact person)
   7. License validity
   8. Facility compliance status (authorised, licensed, cancelled, suspended, withdrawn, revoked, varied and other change of the premises)

17. References

a) Medicines and Related Substance Act, 2025
b) Medicines and Related Substances Regulations, 2019
c) WHO good manufacturing practices for pharmaceutical products: main principles. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva*, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2
d) WHO Technical Report Series No. 996, 2016, Annex 4: Guidance on good manufacturing practices: Inspection report
e) SADC Guideline for Good Manufacturing Practice (GMP) Inspections

Annexure - GMP inspection reference guidelines

NB: The reference guideline documents listed below are the current WHO guidelines and maybe updated from time to time.

	GMP TOPIC/AREA	REFERENCE GUIDANCE DOCUMENT
1.	**GMP main principles**	WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2*** TRS 986 - Annex 2: WHO good manufacturing practices for pharmaceutical products: Main principles
2.	**Active Pharmaceutical Ingredients**	WHO good manufacturing practices for active pharmaceutical ingredients (bulk drug substances). WHO Expert Committee on Specifications for Pharmaceutical Preparations. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2*** TRS 957 - Annex 2: WHO good manufacturing practices for active pharmaceutical ingredients (bulk drug substances)
3.	**Excipients**	WHO Good manufacturing practices for excipients used in pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 2. ***Short name: WHO TRS No. 1052, Annex 2*** TRS 1052 - Annex 2: WHO good manufacturing practices for excipients used in pharmaceutical products

4.	**Water for Pharmaceutical Use**	WHO Good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-six Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3. ***Short name: WHO TRS No. 1033, Annex 3*** TRS 1033 - Annex 3: Good manufacturing practices: water for pharmaceutical use TRS 1025 Annex 3; Production of water for injection by means other than Distillation.WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fouth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3. ***Short name: WHO TRS No. 1025, Annex 3*** TRS 1025 - Annex 3: Production of water for injection by means other than distillation
5.	**Heating Ventilation and Air-conditioning, HVAC**	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8** TRS 1010 - Annex 8: Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report. Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019, Annex 2). **Short name: WHO TRS No. 1019 Annex 2** TRS 1019 - Annex 2: WHO good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (part 2): interpretation of guidelines

6.	**Good practice in Quality Control**	WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052, Annex 4. ***Short name: WHO TRS No. 1052, Annex 4*** TRS 1052 - Annex 4: WHO good practices for pharmaceutical quality control laboratories **Good chromatography practices**. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025, Annex 4. ***Short name: WHO TRS No. 1025, Annex 4*** TRS 1025 - Annex 4: WHO good chromatography practices **WHO good practice considerations for the prevention and control of nitrosamines in pharmaceutical products**. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-eighth report. Geneva, World Health Organization, 2025 (WHO Technical Report Series, No. 1060, 2025, Annex 2) **Short name: *WHO TRS No. 1060, Annex 2*** TRS 1060 - Annex 2: WHO good practice considerations for the prevention and control of nitrosamines in pharmaceutical products
7.	**Pharmaceutical Microbiology**	WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2. ***Short name: WHO TRS No. 961, Annex 2*** TRS 961 - Annex 2: WHO good practices for pharmaceutical microbiology laboratories
8.	**Sterile products**	WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth report. Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044, 2022), Annex 2. ***Short name: WHO TRS No. 1044, Annex 2***

		TRS 1044 - Annex 2: WHO good manufacturing practices for sterile pharmaceutical products
9.	**Finished goods transportation validation**	Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex 9*** TRS 961 - Annex 9: Model guidance for the storage and transport of time and temperature sensitive pharmaceutical products WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5*** TRS 992 - Annex 5: Technical supplements to Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products
10.	**Quality risk management**	WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2. ***Short name: WHO TRS No. 981, Annex 2*** TRS 981 - Annex 2: WHO guidelines on quality risk management
11.	**Data integrity**	Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS No. 1033, Annex 4*** TRS 1033 - Annex 4: WHO Guideline on data integrity

12.	**Hold time studies**	WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4*** TRS 992 - Annex 4: General guidance on hold-time studies
13.	**Site Master File**	WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. ***Short name: WHO TRS No. 961, Annex 14*** TRS 961 - Annex 14: WHO guidelines for drafting a site master
14.	**Sampling**	WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4. ***Short name: WHO TRS No. 929, Annex 4*** TRS 929 - Annex 4: WHO guidelines for sampling of pharmaceutical products and related materials
15.	**Validation** -HVAC -Water system -Analytical methods -Computerised systems -Cleaning - Guideline on qualification of	WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-third report (WHO Technical Report Series, No. 1019). ***Short name: WHO TRS No. 1019, Annex 3*** TRS 1019 - Annex 3: Good manufacturing practices: guidelines on validation Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. ***Short name: WHO TRS No. 1033, Annex 2***

	equipment and systems - Non sterile process validation	
16.	**Hazardous substances**	WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 3*** TRS 957 - Annex 3: WHO good manufacturing practices for pharmaceutical products containing hazardous substances
17.	**Chemical reference standards**	General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3*** TRS 943 - Annex 3: WHO general guidelines for the establishment, maintenance and distribution of chemical reference substances
18.	**Technology transfer**	WHO guidelines on technology transfer in pharmaceutical manufacturing**.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth report. Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4. ***Short name: WHO TRS No. 1044, Annex 4*** TRS 1044 - Annex 4: WHO guidelines on technology transfer in pharmaceutical manufacturing
19.	**Biological products**	WHO Expert Committee on Biological Standardization Sixty-sixth report **WHO Technical Report Series, No. 999, 2016 Annex 2. Short name: WHO TRS No. 999 Annex 2** WHO Good Manufacturing Practices for biological products, Annex 2, TRS No 999

		Principles of veterinary vaccine production as outlined in the OIE Terrestrial Manual- https://www.woah.org/fileadmin/Home/eng/Health_standards/tahm/2.03.03_MANU_SITES_VACCINE_ORG_MANAGE_RQ-CCOIE.pdf
20.	**Blood products**	WHO guidelines on good manufacturing practices for blood establishments, WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-eight report. Geneva, World Health Organization, 2025 Annex 4; World Health Organization WHO Technical Report Series, No. 1060, 2025. **Short name: WHO TRS No. 1060 Annex 4** TRS 1060 - Annex 4: Good practices for blood establishments
21.	**Stability studies**	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-second report. Geneva, World Health Organization, 2018, Annex 10. WHO Technical Report Series, No. 1010, Annex 10. **Short name: WHO TRS No. 1010 Annex 10** TRS 1010 - Annex 10: WHO guidelines on stability testing of active pharmaceutical ingredients and finished pharmaceutical products
22.	**Herbal medicines**	WHO Guidelines on good manufacturing practices for the manufacture of herbal medicines. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-second report. Geneva, World Health Organization, 2018 Annex 2; WHO Technical Report Series, No. 1010, Annex 2. **Short name: WHO TRS No. 1010 Annex 2** TRS 1010 - Annex 2: WHO good manufacturing practices for the manufacture of herbal medicines WHO guidelines on good herbal processing practices for herbal medicines. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-second report. Geneva, World Health Organization, 2018 Annex 1; WHO Technical Report Series, No. 1010, Annex 1. **Short name: WHO TRS No. 1010 Annex 1**

		TRS 1010 - Annex 1: WHO good manufacturing practices for the manufacture of herbal medicines
23.	**Medical gases**	WHO good manufacturing practices for medicinal gases. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-six report. Geneva, World Health Organization, 2022 Annex 5; WHO Technical Report Series, No. 1010, Annex 5. **Short name: WHO TRS No. 1010 Annex 5** TRS 1044 - Annex 5: WHO good manufacturing practices for medicinal gases
24	**Packaging & Storage**	WHO Guidelines on packaging for pharmaceutical products; WHO Technical Report Series, No. 902, Annex 9. **Short name: WHO TRS No. 902 Annex 9** **TRS 902 - Annex 9: Guidelines on packaging for pharmaceutical products** WHO Good storage and distribution practices for medical products; WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-fourth report. Geneva, World Health Organization, 2020 Annex 7; WHO Technical Report Series, No. 1025, Annex 7. **Short name: WHO TRS No. 1025 Annex 7** TRS 1025 - Annex 7: Good storage and distribution practices for medical products
25.	**Pharmacovigilance**	reportadr@bmra.co.bw
26.	**New premises**	The manufacturers are free to use any reference engineering texts that help them attain the WHO cGMP Compliance. The following organization can be used as an example; 1. International Society of Pharmaceutical Engineering https://ispe.org/

		The supplementary guidance in this document also assist with the process for establishing acceptable new pharmaceutical plants within Botswana.