South African Health Products Regulatory Authority

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Licence number: 0000001314.-.1

LICENCE TO MANUFACTURE MEDICINES

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965

This licence is granted to:

Licence Holder
V + M Analytical Toxicology Services (Pty) Ltd
83 Victoria Street, George, 6529

On the following terms and conditions:

The licence holder and the persons described and named in Annexure 1 shall at all times ensure that all medicines manufactured in this facility, irrespective of its registration status, comply with all the provisions of the Medicines and Related Substances Act, 1965, as amended and in particular with sections 14, 18, 18A, 18B, 18C, 19, 20, 22A, 22C, 22G, 33, Regulations 7, 10, 11, 12, 13, 14, 15, 40, 42, 53 and all relevant SAHPRA Guidelines.

This facility is authorised to perform the manufacturing activities depicted in Annexure 1 to this licence.

CHIEF EXECUTIVE OFFICER

ISSUE DATE: 23 March 2020

EXPIRY DATE: 23 March 2025

ANNEXURE 1

0000001314.-.1

AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

1. MANUFACTURING ACTIVITIES	YES	NO
Sterile, Non-biological Manufacture (includes filling, but not cartoning or labelling)		
Large volume parenteral products		NO
Small volume parenteral products		NO
Other sterile dosage forms:		NO
Non-sterile Manufacture		
Tablets		NO
Capsules		NO
Liquids		NO
Semi-solids		NO
Suppositories		NO
Other non-sterile dosage forms:		NO
Biological Manufacture		
Vaccines		NO
Sera and other immunologicals		NO
Blood and other blood products		NO
Other biological products:		NO
Medical Gas Manufacture		NO
Radioactive Medicines Manufacture		NO
Complementary Medicines Manufacture		
2. PACKAGING ACTIVITIES		
Packaging of bulk products and labelling		NO
Re-labelling or redressing		NO
Cartoning or secondary packaging		
3. TESTING ACTIVITIES		
Analytical	YES	
Microbiological		NO
Sterility		NO
Stability	YES	
Animal		NO
Other Testing Activities:		NO
4. DISTRIBUTION ACTIVITIES		
Bulk distribution to wholesale pharmacies		NO
Fine distribution to retail pharmacies and others		NO
5. MATERIALS HANDLED OR STORED AT THIS SITE	YES	
Penicillins (Finished Packed Products Only)		NO
Cephalosporins (Finished Packed Products Only)		NO
Hormones (Finished Packed Products Only)		NO
Cytostatics/Cytotoxics (Finished Packed Products Only)	YES	
Bulk Pesticides, Herbicides or Rodenticides (Finished Packed Products Only)		NO
Potent Steroids (Finished Packed Products Only)	YES	
Other potent, toxic, sensitising or hazardous materials (Finished Packed Products Only)		
6. IMPORT		NO
7. EXPORT		NO
Specific Products Exported:		

8. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATION ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER

Responsible Pharmacist	Head of Production	Quality Control Person
-	-	Mauritz Wentzel
-	-	PhD. Chemistry, M. Phil Chemistry

9. PARTICULARS OF THE NATURAL PERSON RESPONSIBLE TO THE MEDICINES CONTROL COUNCIL TO ENSURE COMPLIANCE WITH THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

Responsible Person	Designation	Residential Address
Mauritz Wentzel	Responsible Pharmacist	83 Victoria Street, George, 6529
PhD. Chemistry, M. Phil Chemistry		

10. LICENCE SPECIFIC CONDITIONS

1. The holder of the licence shall conduct all manufacturing, wholesaling or distribution operations in respect of those medicines for which a registration certificate has been obtained, so as to ensure that the medicines shall conform to the standards of quality, strength and purity applicable to them in accordance with the specifications made by the person to whose order they are manufactured, wholesaled or distributed or the specifications under which the medicines are sold or supplied.
2. Medicine for export for which a registration certificate has not been obtained from the SAHPRA may not be exported without the relevant "Certificate of a Pharmaceutical Product" or alternatively a "Licensing Status of a Pharmaceutical Product" issued by the SAHPRA in terms of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce.

11. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)

1. Products: Testing of medicinal products

   General: The laboratory comply with cGMP principles as stipulated in the SA Guide to GMP

   The licence is restricted to activities listed only; any additional activities must be approved by SAHPRA prior to implementation,

   Any critical changes (Refer to S.A. Guideline Amendments) to the facility must be approved by SAHPRA prior to implementation.
2. A follow-up inspection be conducted within six to twelve months from the date of this letter in order to confirm all outstanding corrective actions and implementation thereof.

SAHPRA
South African
Health Products
Regulatory Authority

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

Enquiries: Jerry Molokwane
Tel: 012 842 7584
Reference: 0000001314 – 1

The Responsible Pharmacist
V + M Analytical Toxicology Services (Pty) Ltd
PostNet Suite 254
Private Bag X6590
George
6350

Tel: 044 874 8484
Email: mauritz@vm-atls.com

Dear Ms./Mr.

RE: LICENCE TO ACT AS a **Testing Laboratory** IN TERMS OF SECTION 22C (1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT,1965

Testing Laboratory Licence ***0000001314.-.1***

Your licence to act as **Testing Laboratory** in terms of section 22C (1)(b) of the Medicines and Related Substances Act has been approved and is attached herewith. This document replaces any licence document previously issued to you.

This licence authorizes the acting as **Testing Laboratory** by the licence holder named; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing acting as a Testing Laboratory of products.

This licence is subject to the limitations specified in the licence and to the statutory provisions contained in the Regulations to the Act.

Activities may only be carried out in accordance with the terms of the relevant product licence, unless a specified exemption applies which allows it to take place other than in accordance with the licence.

The licence relates to the acting as a **Testing Laboratory** of products on the premises and under the supervision of the persons specified. If any change of premises or of those persons to take place, prior approval must be sought from Licensing Authority. Any proposal to make structural alterations to the premises must also be notified to the Licensing Authority.

The Licensing Authority has power to revoke licences in terms of section 22E should the inspection result in a negative SAHPRA resolution.

Yours faithfully

Jerry Molokwane
MANAGER: LICENSING UNIT
Date: 23/03/2020