SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

Enquiries: Jerry Molokwane
Email: Jerry.molokwane@sahpra.org.za
Tel: 076 422 4934
Reference: 0000000543.-.14

The Responsible Person
Institute for Pharmaceutical Services (Pty) Ltd
130 16th Road, Halfway House Estate,
Midrand,
Gauteng
1685

Tel: 082 456 9817
Email: marc.gardiner@ipslabs.co.za

Dear Sir/Madam.

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

Testing Laboratory Licence 0000000543.-.14

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
Jerry Molokwane
SIGNFLOW

Jerry Molokwane
UNIT MANAGER: LICENSING

Date: 23 December 2025

South African Health Products Regulatory Authority

SAHPRA
South African Health Products Regulatory Authority

Licence number: 0000000543.-.14

LICENCE TO MANUFACTURE MEDICINES – Testing Laboratory Only

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

This licence is granted to:

Licence Holder
Institute for Pharmaceutical Services (Pty) Ltd
130 16th Road, Halfway House Estate, Midrand, Gauteng, 1685

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.

Boitumelo Semete-Makokotela
Boitumelo Semete-Makokotela
DocuSigned by:

24 December 2025

CHIEF EXECUTIVE OFFICER

ORIGINAL ISSUE DATE:	**07 November 2010**
FIRST RENEWAL DATE:	11 November 2015
SECOND RENEWAL DATE:	**22 February 2021**
THIRD RENEWAL DATE:	**22 December 2025**
AMENDMENT DATE:	27 March 2015
AMENDMENT DATE:	22 February 2021
AMENDMENT DATE:	**07 November 2025**
EXPIRY DATE:	**22 December 2030**

ANNEXURE 1 *0000000543.-.14*

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		NO
2. PACKAGING ACTIVITIES		
Packaging of bulk products and labelling		NO
Re-labelling or redressing		NO
Cartoning or secondary packaging		NO
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 (Distribution of own products only)		NO
Fine distribution to retail pharmacies and others (Distribution of own products only)		NO
5. MATERIALS HANDLED OR STORED AT THIS SITE		
Penicillins	YES	
Cephalosporins	YES	
Hormones	YES	
Cytostatics/Cytotoxics	YES	
Bulk Pesticides, Herbicides or Rodenticides (Finished Packed Products Only)		NO
Potent Steroids (Finished Packed Products Only)		NO
Other potent, toxic, sensitising or hazardous materials (Finished Packed Products Only)	-	NO
6. IMPORT (Reference standards only for analytical testing as per inscription in the **Gazetted -Schedules)**	YES	-
7. EXPORT		NO

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
Mark Gardiner	-	Nicolene Roode
Dip. Pharm, MBA	-	BSc. Biological Sciences

9. PARTICULARS OF THE NATURAL PERSON RESPONSIBLE TO THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY TO ENSURE COMPLIANCE WITH THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

Responsible Person	Designation	Residential Address
Mark Gardiner	Responsible Person	130 16th Road, Halfway House Estate, Midrand, Gauteng, 1685
Dip. Pharm, MBA		

10. GENERAL LICENCE 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)

GENERAL CONDITIONS:

- The Laboratory to comply with cGMP principles,
- The licence is restricted to activities listed only; any additional activities must be approved by SAHPRA prior to implementation, and
- That any critical changes (Refer S.A Variations Guideline and Regulation23(7) of the Medicines Act) to the facility be approved by SAHPRA prior to implementation.

12. LICENCE SPECIFIC CONDITIONS:

Effective implementation of CAPAs to be verified in the next inspection.

DOCUMENT HISTORY:

REVISION	REASON FOR AMENDMENT	DATE
1	First Issue of Licence	07 November 2010
10	Amendment (Change in Key Personnel)	27 March2015
11	First Renewal issue of Licence	11 November 2015
12	Second renewal & Amendment (Relocation) issue of Licence	22 February 2021
13	Amendment (Change in Key Personnel)	07 November 2025
14	Third Renewal issue of Licence. **NB:** According to the application form, the owners are the Crossome Group	22 December 2025