South African Health Products Regulatory Authority

Licence number: 0000001433.-.1

LICENCE TO MANUFACTURE MEDICINES – Testing Laboratory

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

This licence is granted to:

Licence Holder
Qure (Pty) Ltd
98 Bath Street, Montagu, Western Cape, 6720

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.

Digitally Signed by:
Boitumelo Semete-Makokotlela
CEO
53e72d92-3391-4cd7-8da3-b6116e65c520
12/01/2023 11:31:50 AM

CHIEF EXECUTIVE OFFICER

ORIGINAL ISSUE DATE: **22 December 2022**
RENEWAL DATE: N/A
AMENDMENT DATE: N/A
EXPIRY DATE: **22 December 2027**

ANNEXURE 1 *0000001433.-.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		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	YES	
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 (Finished Packed Products Only)		NO
Cephalosporins (Finished Packed Products Only)		NO
Hormones (Finished Packed Products Only)		NO
Cytostatics/Cytotoxics (Finished Packed Products Only)		NO
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		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
-	-	Brenda Marx
-	-	D. Nat. Med, MSc Chem

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
Brenda Marx	Laboratory Director	98 Bath Street, Montagu, Western Cape, 6720
D. Nat. Med, MSc Chem		

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 Quality Control Laboratory to comply with cGMP (GPPQCL) 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 to S.A Guideline Amendments) to the facility be approved by SAHPRA prior to implementation.

SITE SPECIFIC CONDITIONS:

- The testing of schedule 6 substances can proceed at Qure (Pty) Ltd, provided a possession permit is acquired in terms of Section 22A(9)(a) of the Medicines and Related Substances Act, Act 101 of 1965 as amended

- The Company Qure (Pty) Ltd to submit responses and/or progress reports to outstanding and open deficiencies monthly.
- An onsite verification inspection related to the CAPA implementation and effectiveness to be scheduled within three (03) – six (6) months of the date of the of receipt of the licence.

DOCUMENT HISTORY:

REVISION	REASON FOR AMENDMENT	DATE
1	First issue of Licence	22 December 2022