

LICENCE NUMBER: DL01-B35A60

LICENCE TO MANUFACTURE, IMPORT OR EXPORT COMPLEMENTARY MEDICINES (CATEGORY D)

This licence is issued in terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and regulation 23 of General Regulations made in terms of the same Act, to the Licence Holder indicated herein and licenses this party to manufacture, import or export Complementary medicines (Category D), inclusive of the activities stipulated herein.

Licence Holder	Portfolio Pharmaceuticals (Pty) Ltd
Address	39 Barney Road, Benrose Johannesburg, Gauteng 2001

LICENSED ACTIVITIES	Manufacturing	Contract Manufacturing	Packaging
	Secondary Packaging	Labelling	Storage
	Importing	Exporting	

This licence consists of one page in addition to the letter of granting and the complete product list and is issued in terms of section 22C(1)(b) on the following conditions:

1. The licence holder and the persons described and named in this licence must:
 - a. at all times ensure that all Complementary Medicines (Category D) associated with this licence, irrespective of registration status, comply with the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended and the General Regulations made in terms of this Act;
 - b. be inspected at least once within a period of **FIVE (5) years** for verification of compliance with the minimum requirements as attested to; and
 - c. pay annual licence retention fees.
2. Verification of appropriate standards and certification thereof will only be undertaken after successful inspection of the premises.
3. Only products listed or attached to this licence will be permitted association with this licence as Category D medicines and continued rights of sale, provided that an application is submitted for their registration by the prescribed deadlines of the applicable notice issued in terms of section 14 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
4. This licence is issued to the licence holder based on SAHPRA's acceptance of the applicant's attestation of compliance with minimum requirements relevant to Category D medicines at the time of application and the payment of the required licence application and desktop evaluation fees.
5. This licence is not a confirmation of applicable GMP standards, unless presented together with a valid SAHPRA GMP certificate.

The validity and content of this licence as the appended product list may be verified at

Digitally Signed by:
Boitumelo Semete-Makokotlela
53e72d92-3391-4cd7-8da3-b6116e65c520

www.sahpracm.org.za – Registers – Category D Licences.

CHIEF EXECUTIVE OFFICER

DATE OF ISSUE: 01 September 2023

EXPIRY DATE: 31 September 2025

AMENDMENT DATE: N/A



This licence remains the property of the South African Health Products Regulatory Authority. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Chief Executive Officer.

Licence to manufacture, import or export Complementary Medicines (Category D)