South African Health Products Regulatory Authority

Licence number: 0000001495.-.1

LICENCE TO DISTRIBUTE SCHEDULED SUBSTANCES

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

This licence is granted to:

Licence Holder
Alura Pharmaceuticals (Pty) Ltd
Unit 15, Lower Ground Floor, Sappi Technology Centre, Corner of Aaron Klug and Max Theiler Street, Innovation Hub, Persequor, Pretoria, 0022

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 scheduled substances distributed from the site, irrespective of its registration status, comply with all the provisions of the Medicines and Related Substances Act, 1965, as amended, Regulations to the Act and all relevant SAHPRA Guidelines.

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

Boitumelo Semete-Makokotlela

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SIGNIFLOW

12 September 2025

CHIEF EXECUTIVE OFFICER

ORIGINAL ISSUE DATE:	**04 September 2025**
FIRST RENEWAL DATE:	N/A
AMENDMENT DATE:	N/A
EXPIRY DATE:	**04 September 2030**

AUTHORISED IMPORTING AND DISTRIBUTION ACTIVITIES

1. SCHEDULED SUBSTANCES IMPORTED AND HANDLED AT THE SITE	YES	NO
Scheduled Substances: S0	YES	-
Scheduled Substances: S1 – S4	YES	-
Controlled Substances: S5 – S6	YES	-
Time and Temperature Sensitive Scheduled Substances (Below 25ºC, within specified %RH limits)	YES	-
Time and Temperature Sensitive Scheduled Substances (2 - 8ºC, within specific %RH limits)	-	NO

2. DISTRIBUTION ACTIVITIES		
Distribution to Lawfully Authorised/Licensed Facilities	YES	-
Distribution to Lawfully Authorised/Licensed Professionals	YES	-

3. METHOD OF DISTRIBUTION		
Courier / Van service	YES	-
Own courier / Van service	YES	-
Customer collection	YES	-
Other methods of distribution: Air Freight	YES	-

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

Responsible Pharmacist	Head of Production	Quality Control Person
Carel Johannes Stefanus Viljoen	-	Carel Johannes Stefanus Viljoen
Dip. Pharm	-	Dip. Pharm

5. 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
Pieter Johannes Herman	Managing Director	Unit 15, Lower Ground Floor, Sappi Technology Centre, Corner of Aaron Klug and Max Theiler Street, Innovation Hub, Persequor, Pretoria, 0022
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6. GENERAL LICENCE CONDITIONS:

The holder of the licence shall conduct all distribution operations in respect of scheduled substances, so as to ensure that the scheduled substances 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 imported, stored or distributed or the specifications under which the scheduled substances are sold or supplied.

7. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)

GENERAL CONDITIONS:

1. The company must comply with GWP requirements and principles as stipulated in the cGWP Guidelines and GWP Guideline for the Importers and Distributors of Scheduled Substances (2024).
2. No stock should be sold directly to the public.
3. Appropriate procedural systems must be in place for management of spillages of products being handled on site (especially the hazardous products).
4. Appropriate procedural systems must be in place for handling and storage of products requiring storage below 25°C and specified % RH limits (as per substance specific recommended storage conditions).
5. This licence is restricted to recommended activities listed only; any additional activities must be approved by the Authority, SAHPRA.
6. Any changes as per Regulation 23(7) of the Medicines Act be approved by SAHPRA prior to implementation.
7. The Company is only allowed to keep scheduled substances, which do not include finished products which are subject to Section 15 and Regulation 5 of the Medicines Act.
8. If the intention of importing or wholesaling a scheduled substance is NOT to produce a medicine, but for an industrial product (including a consumer item such as a foodstuff), then it is not considered an "active pharmaceutical ingredient" and is not subject to the control measures in section 22A. However, if the intention is to produce a medicine, whether in category A, C or D, then it would be subject to the Medicines Act. Even a health supplement is a category D medicine.
9. The wholesaler is not allowed to perform compounding activities.

10. The wholesaler is to comply with Section 22H of the Act, in terms of purchase and sale of medicines, medical devices, IVDs and scheduled substances by wholesalers.
11. The wholesaler should have processes in place to track batches of scheduled substances, to execute recall of scheduled substances, in terms of Section 19 of the Act.
12. The wholesaler must ensure that all incoming stock is received at the premises, as per the physical address indicated on the licence. The stock received must undergo the prescribed checking, as per the SOP for stock received, which must include a physical check of the stock at the warehouse.
13. Scheduled substances supplied to the finished product manufacturer must be sourced from the approved scheduled substance manufacturer, as noted in the product registration dossier.
14. The wholesaler must be operational within 120 days of issuing of the licence.

SITE SPECIFIC CONDITIONS:

1. All outstanding projects are to be completed, in line with the agreed timelines.
2. Evidence of completion of all projects is to be submitted in line with the agreed timelines.

DOCUMENT HISTORY:

REVISION	REASON FOR AMENDMENT	DATE
1	First issue of Licence	04 September 2025