

South African Health Products Regulatory Authority



Licence number: 0000001417.-.1

LICENCE TO MANUFACTURE MEDICINES: LACTULOSE API

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

This licence is granted to:

Licence Holder
LACSA (Pty) Ltd
72 Ballantrae Road, Merebank, Durban, 3201

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.

A small, handwritten signature in black ink, appearing to be 'B. ...', is located to the left of the date.

08/06/2022

CHIEF EXECUTIVE OFFICER

ORIGINAL ISSUE DATE: 07 June 2022
FIRST RENEWAL DATE: N/A
FIRST AMENDMENT DATE: N/A
EXPIRY DATE: 07 June 2027

