CERTIFICATE OF GOOD MANUFACTURING PRACTICE (GMP) for ACTIVE PHARMACEUTICAL SUBSTANCES

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Written confirmation for active substances exported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Confirmation no: **API26/7/3/3/1/G0036/2022**

1. *Name of Site (including building number, where applicable):* **Lacsa (Pty) Limited**
   ***Address:* 72 Ballantrae Road, Merebank, Durban, 4052, Kwa-Zulu Natal, South Africa.**

2. *Manufacturer's license number*: **00000001417**

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

Active substance(s) (INN name):	Activity(ies):[1]
Lactulose	**Chemical synthesis**

THE INSPECTORATE AND REGULATORY COMPLIANCE SENIOR MANAGER OF SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY OF THE REPUBLIC OF SOUTH AFRICA, HEREBY CONFIRMS THAT:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (=GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the Registrar of Medicines, South Africa without delay to the EU at email: *qdefect@ema.europa.eu*

3. *Date of the inspection of the plant under (1):* **07th – 08th March 2022**
4. *Name of the inspecting authority if different from the issuing regulatory authority:* **SAHPRA**
5. *This written confirmation remains valid until:* **09th June 2023**

The authenticity of this written confirmation may be verified with the Acting Chief Executive Officer of Medicines, South African Health Products Regulatory Authority, South Africa.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC

Address of the issuing regulatory authority:
CHIEF EXECUTIVE OFFICER, SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY, BUILDING A, LOFTUS PARK, 2ND FLOOR, KIRKNESS ROAD, ARCADIA, PRETORIA, 0083, RSA

Name and function of the responsible person: **Mr Deon Poovan, Senior Manager: Inspectorate and Regulatory Compliance**
E-mail: deon.poovan@sahpra.org.za *Telephone no.* **027 (0) 12 501 0419**

SIGNATURE
DATE: 2022/06/09

[1] Activities: example: "Chemical synthesis, Extraction from natural sources, Biological processes, Finishing steps"

SAHPRA
SAHPRA South African Health Products Regulatory Authority
REPUBLIC OF SA