Rwanda Food and Drugs Authority
Rue. KG 9 Avenue, Nyarutarama Plaza
P.O. Box 1948, Kigali, Rwanda.
email: info@rwandafda.gov.rw;
website: www.rwandafda.gov.rw

QMS N°: DIS/FMT/018
Rev. N°: 0
Effective date: 16/04/2021
Revision date: 16/04/2024
Ref. Doc.: DIS/GDL/002

CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE

(Issued in accordance with Article 23 of the Regulations N° DIS/TRG/001 Rev. N° 0)

Certificate N°: 3429 Issue Date: **25/08/2022** Valid up to:**25/08/2025**

This is to certify that the pharmaceutical manufacturing facility with following details:
Name of facility: **NEAPOLIS PHARMA**
Physical address: **Route de Tunis-Km 7, BP 206, 8000 Nabeul, Tunisia**
License number: **MS.U.PH.M No. 007878-2019**
Country: **Tunisia**
E-mail: contact@labomedis.com Telephone: **(+216) 31338420**

Has been assessed by the Rwanda Food and Drugs Authority for compliance with the Good Manufacturing Practice Guidelines.
On the basis of the **physical inspection** carried out on **23th and 24th May 2022,** it is certified that the pharmaceutical manufacturing facility indicated on this certificate complies with Good Manufacturing Practice for dosage forms listed in Table below:

N°	Dosage form	Category	Activities
1.	Sterile products (lyophilisates, small volume)	Cytotoxic	All manufacturing activities
2	Oral solid dosage forms(tablet ,capsules)	Cytotoxic	All manufacturing activities
3	Sterile products (lyophilisates, small volume)	High potent compounds	All manufacturing activities
4	Oral solid dosage forms(tablet ,capsules)	High potent compounds	All manufacturing activities
5	Dry powder for inhalation(capsules)	General products	All manufacturing activities

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.
This certificate becomes invalid if the activities or the categories certified change or if the facility is no longer rated to be in compliance with Good Manufacturing Practice.

Dr Emile BIENVENU
Director General

RWANDA FOOD AND DRUGS AUTHORITY • RWANDA FDA