Malta Medicines Authority

CERTIFICATE NUMBER: ***MT/018HM/2026***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Malta confirms the following:
The manufacturer: ***Panaxia Pharmaceutical Malta (Operations) Limited***
Site address: ***Hhf001a Industrial Estate, Hal Far, BBG 3000, Malta***
Additional details on units inspected: ***includes unit HHF001E which is part of the same building***
OMS Organisation Id. / OMS Location Id.: ***ORG-100040694*** / ***LOC-100066920***

Other
(Human) is a manufacturer of Cannabis for Medicinal Purposes and has been inspected in accordance with Art 4 (2d) of the Production of Cannabis for Medicinal and Research Purposes Act (Chapter 578 of the Laws of Malta)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-02-22*** , it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use
	1.2.2 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

This certificate is limited in scope to cannabis products (cannabis oils) for medicinal use. Therefore medicinal products are not within the scope of this certificate.

2026-03-12

Name and signature of the authorised person of the Competent Authority of Malta

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Confidential
Malta Medicines Authority
Tel:***Confidential***
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