

Certificate No: MT/022HM/2024

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**

The Malta Medicines Authority of Malta confirms the following:

The manufacturer: **Actavis Ltd.**Site address **BLB015-016, Bulebel Industrial Estate, Zejtun ZTN3000, Malta**Has been inspected under the national inspection programme in connection with manufacturer's licence no. **ML001** in accordance with Art. 40 of Directive 2001/83/EC/Art. 13 of Directive 2001/20/EC* transposed in the following national legislation **Medicines Act 2003 (Ch.458)Part III Title II Art 37, Regulation 3 of Subsidiary Legislation 458.36.**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **4-7th March 2024**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 as appropriate.

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.

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.

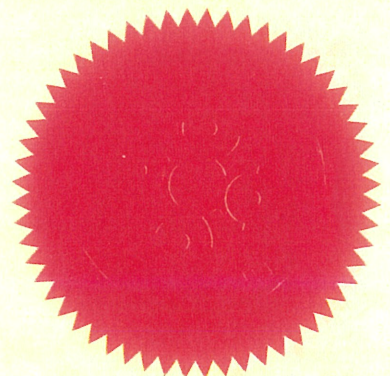
5th June 2024
.....
Dr Mark Cilia¹**Director Inspectorate and Enforcement Directorate
Malta Medicines Authority
Tel: 00356 234 39 119****A certified true copy of the original.**This, **20th September 2024.****Emma Amato LL.D.**

Notary Public in Malta

Emma Amato LL.D.
Notary Public in Malta51/1, Old Bakery Street,
Valletta VLT 1454
Malta

Tel: 4356 79949696

Email: emma@emmaamato.com



1 The certificate referred to in paragraph 111(5) of Directive 2001/83/EC, is 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.

Part 2

Human Medicinal Products*	
Human Investigational Medicinal Products*	
1 MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS *	
1.2	Non-sterile products <i>1.2.1 Non sterile products (processing operations for the following dosage forms)</i> 1.2.1.13 Tablets <i>1.2.2 Batch certification</i>
1.5	Packaging <i>1.5.1 Primary packing</i> 1.5.1.13 Tablets <i>1.5.2 Secondary packing</i>
1.6	Quality Control testing <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

5th June 2024

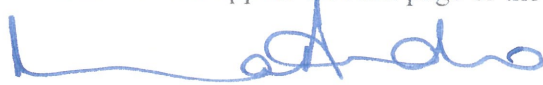

Dr. Mark Cilia¹
 Director Inspectorate and Enforcement Directorate
 Malta Medicines Authority
 Tel: 00356 234 39 119

A certified true copy of the original.
This, 20th September 2024.

Emma Amato LL.D.
 Notary Public in Malta

51/1, Old Bakery Street,
 Valletta VLT 1454
 Malta
 Tel: +356 79949696
 Email: emma@emmaamato.com

¹ The signature, date and contact details should appear on each page of the certificate



2 IMPORTATION OF MEDICINAL PRODUCTS*	
2.1	Quality control testing of imported medicinal products 2.1.2 Microbiological: non-sterility 2.1.3 Chemical/Physical
2.3	Other importation activities 2.3.2 Importation of intermediate which undergoes further processing

Any restrictions or clarifying remarks related to the scope of this certificate:

Importation is limited to non-sterile products in bulk form for packaging and subsequent release.

5th June 2024


Dr. Mark Cilia¹
 Director Inspectorate and Enforcement Directorate
 Malta Medicines Authority
 Tel: 00356 234 39 119
 Fax: 00356 234 39 161

A certified true copy of the original.
 This, **20th September 2024.**

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Apostille Certificate
Convention de La Haye du 5 octobre 1961

1. Country: **Malta**

This public document

2. has been signed by: **Emma Amato**

3. acting in the capacity of: **Notary Public**

4. bears the seal / stamp of: **Same**

Certified

5. at **Ministry for Foreign and European Affairs and Trade,
Valletta**

6. the **02 OCT 2024**

7. by **Karen Montebello - Legalisation Officer**

8. No: **564997**

9. Seal / Stamp

10. Signature



According to the rules enshrined in The Hague Convention, the Apostille / Legalisation only certifies the authenticity of the signature and the capacity of the person who has signed the public document and where appropriate, the authenticity of the seal or stamp it bears and not the content of the document.

