



Certificate No: MT/031HM/2018

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 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 Part III Title II Art 37 and Legal Notice 490 of 2004 Regulation 13 & 14**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **26th -29th November 2018**, it is considered that it complies with the Good Manufacturing Practice requirements¹ referred to in the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³.

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.

20th December 2018


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



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



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Part 2

Human Medicinal Products*	
Human Investigational Medicinal Products*	
1 MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS *	
1.2	Non-sterile products 1.2.1 Non sterile products (<i>processing operations for the following dosage forms</i>) 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets 1.2.2 Batch certification
1.5	Packaging 1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets 1.5.2 Secondary packing
1.6	Quality Control testing 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

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

Section 1.2.1.8 does not apply to Human Investigational Medicinal Products

20th December 2018


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GVZH

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HMA



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

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

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

20th December 2018


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PM 171 ISO 9001:2015

Apostille Certificate
Convention de La Haye du 5 octobre 1961

1. Country: **Malta**

This public document

2. has been signed by: **Joseph J Vella**

3. acting in the capacity of: **Advocate**

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

Certified

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

6. the **31 OCT 2019**

7. by **Kenneth Burnell - Legalisation Officer**

8. No: **385606**

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

