

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER<sup>1,2</sup>

### Part 1

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

The Malta Medicines Authority confirms the following:

The manufacturer **ASG Pharma Ltd.**

Manufacturer's alternative name **N/A**

Site address **Level 3 and Level -1 ADC Building Triq l-Esportaturi Central Business District  
CBD1040 Mriehel Malta.**

Additional details on units inspected **N/A**

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/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 and/or Art. 61(1) of Regulation (EU) No 536/2014\*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **25<sup>th</sup> – 28<sup>th</sup> August 2025**, it is considered that it complies with the Good Manufacturing Practice requirements<sup>3</sup> referred to in the principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572<sup>3</sup> 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. 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.

6<sup>th</sup> April 2026



**Dr. Mark Cilia<sup>1</sup>**  
**Director Inspectorate &  
Enforcement Directorate**  
**Malta Medicines Authority**  
**Tel: 00356 234 39 119**



<sup>1</sup> The certificate referred to in paragraph 111(5) of Directive 2001/83/EC is also applicable to importers.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

<sup>3</sup> These requirements fulfil the GMP recommendations of WHO

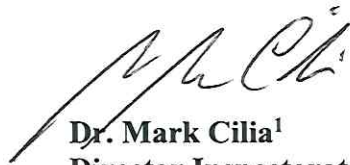
**Part 2**

|  |   |
|--|---|
| <input type="checkbox"/> Human Medicinal Products*       |   |
| <b>1 MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS *</b> |   |
| <b>1.6</b>   | <b>Quality Control testing</b>              |
|  | <i>1.6.2 Microbiological: non-sterility</i> |
|  | <i>1.6.3 Chemical/Physical</i>              |

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

None

6<sup>th</sup> April 2026



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