



Certificate No: GMP 134/5

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

### Part 1

Issued following an inspection in accordance with the requirements of Good Manufacturing Practice, of the Israeli laws and regulations (Pharmacist Regulations [Good Manufacturing Practice for Medicinal Products ] 2008)

and

Issued under the provisions of the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel

The competent authority of Israel confirms the following:

#### The manufacturer

**Arnie Miller Laboratories Ltd.**

#### Site address

**60/126 Derch Hevron, Be'er Sheva 84899, Israel**

Has been inspected under the Israeli inspection programme, in accordance with the above mentioned laws and regulations

and

Has been inspected as a contract laboratory that performs Physical / Chemical QC testing for other parties

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **19-20 November 2019**, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel and the above mentioned Israeli laws and regulations (\*).

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 EudraGMP. If it does not appear, please contact the issuing authority.

(\* ) these requirements fulfill the GMP recommendations of WHO

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## Part 2

### 1. MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

1.6 Quality Control Testing

1.6.3 Chemical / Physical

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

3.6 Quality Control Testing

3.6.1 Physical / Chemical

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

Arnie Miller is a contract laboratory that carries out Physical / Chemical QC testing of Pharmaceuticals for other parties

#### Name and signature of the authorized person of the Competent Authority of Israel:

Michael Carmi, Pharmacist - GMP inspector

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