



Certificate No: GMP 169/3

## 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 SAVYON DIAGNOSTICS LTD.**

**Site address 3 HABOSEM ST., POB 12013, ASHDOD 7761003, ISRAEL**

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

and

Is a contract laboratory, performing analysis for other parties (biochemical analysis for proteins by HPLC including Glycoanalysis)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **16-17 November 2016**, 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



## Part 2

### 1. MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

- 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

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

- 3.6 Quality Control Testing  
 3.6.1 Physical / Chemical testing

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

*SAVYON DIAGNOSTICS is a contract laboratory, performing biochemical analysis for proteins by HPLC including Glycoanalysis, for other parties*

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

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