

Certificate No: GMP 139/6

## 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** Dead Sea Bromine Company Ltd. Magnesia Products SBU  
P.O.B. 180, Be'er Sheva, 8410101, Israel

**Site address** Dead Sea Periclase  
Mishor Rotem, M.P. Arava, 8680600 , Israel

is an active substance manufacturer, that has been inspected in accordance with the above mentioned laws and regulations and ICH Q7

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **19-21 July 2022**, 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

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substances:

**Magnesium Carbonate, Magnesium Hydroxide, Magnesium Oxide**

3.1 Manufacture of Active Substance by Chemical Synthesis

3.5 General Finishing Steps

3.5.1 Physical processing steps : *drying, milling, micronizing, sieving*

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)  
*(performed by contract laboratories)*

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

*The plant manufactures Magnesium Carbonate, Magnesium Hydroxide, Magnesium Oxide*

*Microbiological tests are outsourced to contract laboratories*

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

Michael Carmi, Pharmacist - GMP Inspector

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*phone: office 972 -2-6551795*

*cell 972-50-6242452*



## *Institute for Standardization and Control of Pharmaceuticals*

CERTIFICATE NUMBER: 139/6

### **CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**

#### **Part 1**

Issued under the provisions of the Agreement on Conformity Assessment and Acceptance of industrial products (ACAA) between the European Union and *Israel*

The competent authority of Israel confirms the following:

The manufacturer: *Dead Sea Periclase Ltd.*

Site address: *Mobile Post Arava, Industrial Zone, Mishor Rotem, 86800, Israel*

OMS Location: *LOC-100028036*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *2022-07-21*, it is considered that it complies with

The Good Manufacturing Practice requirements referred to in the Agreement on Conformity Assessment and Acceptance of industrial products (ACAA) between the European Union and *Israel*

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. 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.



*25 -07- 2022*

## Part 2

Human Medicinal Products

4. Other Activities - Active Substances:

**3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES** *Manufacture of Active Substance by Chemical Synthesis General Finishing Steps 3.5.1 Physical processing steps : drying, milling, micronizing, sieving 3.5.2 Primary Packaging 3.5.3 Secondary Packaging Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing (excluding sterility testing) : performed by contract laboratories*

Clarifying remarks (for public users)

***The plant manufactures Magnesium Carbonate, Magnesium Hydroxide, and Magnesium Oxide ; Microbiological tests are outsourced to contract laboratories***

2022-07-25

Name and signature of the authorised person of the  
Competent Authority of Israel



25 -07- 2022

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**Michael Carmi**  
**Institute for Standardization and Control of**  
**Pharmaceuticals**

Tel:  
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