CHIEF PHARMACEUTICAL INSPECTOR

2023 -10- 02

ISF.405.22.2023.IP.1
WTC/0642_01_01/192

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

BAZELET NEHUSHTAN Ltd.
Or Akiva, 35 Ha'Ilan Street, Israel

site address

BAZELET NEHUSHTAN Ltd.
Or Akiva, 35 Ha'Ilan Street, Israel

has been inspected in connection with marketing authorization(s) listing manufacturer located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022, item 2301 as amended).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **03-07/07/2023,** it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive (EU) 2017/1572.

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.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

12 Senatorska str, 00-082 Warsaw, POLAND
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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.17 Other non-sterile medicinal products: raw materials used for preparing medicinal products in the pharmacy according to doctor's prescription of Pharmacopoeia formula.
1.4	**Other products or processing activity**
	1.4.1 Manufacture of: 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.17 Other non-sterile medicinal products: raw materials used for preparing medicinal products in the pharmacy according to doctor's prescription of Pharmacopoeia formula. **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:

Points 1.2.1.17 and 1.5.1.17 concern dried Cannabis flowers / liquid Cannabis extract.

The certificate was issued on the basis of a remote inspection.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

On the Chief Pharmaceutical Inspector authority

Paweł Kulka

Deputy Chief Pharmaceutical Inspector

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