Certificate No: **GMP 21/6**

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

BEN SHIMON FLORIS LTD.

Site address

IND. PARK, MISGAV, 2017400 ISRAEL

Has been inspected under the Israeli inspection programme in connection with manufacturing authorization no. **MIA 21** in accordance with the above mentioned laws and regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **27 February - 1 March 2017**, 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

The Institute for Standardization And Control of Pharmaceuticals
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המכון לביקורת ותקנים של חומרי רפואה
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ת.ד. 34410, ירושלים 9134302
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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

1.2 Non-sterile products

1.2.1 Non-sterile

1.2.1.1 Capsules, hard shell

1.2.1.5 Liquids for external use

1.2.1.6 Liquids for internal use

1.2.1.11 Semi-solids

1.2.1.12 Suppositories (*Rectal & Vaginal)*

1.2.1.13 Tablets: *Progesterone Vaginal Tablets (produced in a dedicated suite)*

1.2.1.17 Other non-sterile medicinal products: *Powders*

1.2.2 Batch certification

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

1.5.1.1 Capsules, hard shell

1.5.1.5 Liquids for external use

1.5.1.6 Liquids for internal use

1.5.1.11 Semi-solids

1.5.1.12 Suppositories

1.5.1.13 Tablets*: Progesterone Vaginal Tablets (primary packed in a dedicated suite)*

1.5.1.17 Other non-sterile medicinal products: *Powders*

1.5.2 Secondary packing

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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:

The Progesterone Vaginal Tablet are produced and primary packed in a dedicated suite.

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

Michael Carmi, Pharmacist, GMP Inspector

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MINISTRY OF HEALTH, JERUSALEM
Gov. Institute for Control & Standard of Pharmaceuticals
משרד הבריאות

03 -04- 2017

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