

Institute for Standardization and Control of Pharmaceuticals

CERTIFICATE NUMBER: 21/7

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: **BEN SHIMON FLORIS LTD.**

Site address: **IND. PARK, MISGAV, 2017400, Misgav, 2017400, Israel**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2017-03-01**, 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.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> <ul style="list-style-type: none">1.2.1.1 Capsules, hard shell1.2.1.5 Liquids for external use1.2.1.6 Liquids for internal use1.2.1.11 Semi-solids1.2.1.12 Suppositories1.2.1.13 Tablets<ul style="list-style-type: none">Special Requirements7 Other: Progesterone Vaginal Tablets (produced in a dedicated suite)(en)1.2.1.17 Other: Powders(en)
	<i>1.2.2 Batch certification</i>
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of</i> <ul style="list-style-type: none">1.4.1.1 Herbal products
1.5	Packaging
	<i>1.5.1 Primary Packing</i> <ul style="list-style-type: none">1.5.1.1 Capsules, hard shell1.5.1.5 Liquids for external use1.5.1.6 Liquids for internal use1.5.1.11 Semi-solids1.5.1.12 Suppositories1.5.1.13 Tablets1.5.1.17 Other non-sterile medicinal products: powders(en)
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

2018-05-28

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

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Institute for Standardization and Control of
Pharmaceuticals
Tel: *Confidential*
Fax: *Confidential*