



אישור יצרן / יבואן תכשירים רפואיים MANUFACTURER'S / IMPORTER'S AUTHORIZATION

Authorization number	מספר האישור
MIA 21/2017/A	
Name of authorization holder	שם בעל האישור
Ben Shimon Floris Ltd.	בן שמעון פלוריש בע"מ
Address of manufacturing site	כתובת אתר הייצור
Ind. Park, Misgav, 2017400, Israel	פארק תעשייה, משגב 2017400
Address of manufacturing site	כתובת בעל האישור
Ind. Park, Misgav, 2017400, Israel	פארק תעשייה, משגב 2017400
Scope of authorization and dosage forms	תחומי האישור וצורות המינון
See Annexes 1, 2	ראה נספחים 1, 2
Legal basis of authorization	הבסיס החוקי לאישור
Pharmacist Regulations [Good Manufacturing Practice] 2008	תקנות הרוקחים [תנאי ייצור נאותים] תשס"ח
Responsible officer of Health Israeli Ministry Of granting the authorization	בעל התפקיד ברשות האחראי למתן האישור
Michael Carmi, Pharmacist GMP inspector	מיכאל כרמי, רוקח רכז ארצי בקרת מפעלים
Signature, stamp and date	חתימה, חותמת ותאריך
<i>e-mail: michael.carmi@moh.gov.il phone: office 972-2-6551795, cell 972-50-6242452 fax: 972-2-6551781</i>	  05-04-2017



Annexes attached	רשימת הנספחים המצורפים
Annex 1 and/or Annex 2	נספח 1 ו/או נספח 2
Optional Annexes	רשימת נספחי רשות
Annex 3 – Contract Manufacturers	נספח 3 – אתרי ייצור בקבלנות משנה
Annex 4 – Contract Laboratories	נספח 4 – מעבדות בקבלנות משנה
Annex 5 – Qualified Person(s)	נספח 5 – הרוקחים האחראים
Annex 6 - Responsible persons(s)	נספח 6 – העובדים האחראיים לאיכות ולייצור
Annex 7 – Date of inspection on which authorization granted, scope of last inspection	נספח 7 – תאריך הביקורת שעל בסיסה ניתן האישור, היקף הביקורת האחרונה
Annex 8 – Manufactured/imported products authorized	נספח 8 – רשימת התכשירים הכלולים באישור



SCOPE OF AUTHORIZATION

ANNEX 2 - INVESTIGATIONAL MEDICINAL PRODUCTS

Name and address of the site

Ben Shimon Floris Ltd.
Ind. Park, Misgav, 2017400, Israel

Not Relevant

The authorization holder does not manufacture/import/release investigational medicinal products



ANNEX 3

Contract Manufacturers

None



ANNEX 4

Contract Laboratories

QC Testing – microbiology

Aminolab Ltd
1 Pinchas Sapir St., Weizmann Science Park, Ness Ziona, Israel

Institute for Food Microbiology and Consumer Goods Ltd.
9 HaShalom Rd., Nesher, Israel

QC Testing – chemistry (of raw materials)

laboratories located abroad are not inspected by the Israeli competent authority

Simec AG
Areal Bleiche West, 4800 Zofingen, Switzerland

ALS Czech Republic, s.r.o.
Na Harfe 336/9, 190 00 Prague 9, Vysocany, Czech Republic



ANNEX 5

Qualified Person(s)

Irena Shmaraev , Pharmacist, PhD. - QP

Raphael Ben Shimon – Pharmacist in Charge , back up QP



ANNEX 6

Person(s) responsible for quality control

Ofer Avni - QA Manager

Shifris Beya - QC Manager

Person(s) responsible for production

Amir Cohen, Operation Manager

Moshe Grinberg, Production Manager



ANNEX 7

Date of inspections on which authorization was granted

14-16 June 2009 <i>MIA was issued after this inspection</i>
27-29 December 2011
17-18 April 2013
1-3 March 2015
21-24 November 2016
27-28 February - 1 March 2017

Scope of last inspections

General GMP inspections

The manufacturing plant conforms to the requirements of Good Manufacturing Practice, as recommended by the World Health Organization, and complies to the national laws and regulations (Pharmacist Regulations [Good Manufacturing Practice for Medicinal Products] 2008)



ANNEX 8

Manufactured/imported products authorized

Manufacturing activity

The authorization holder manufactures medicinal products.

Importation activity

The authorization holder does not import medicinal products.

Products authorized to be released to the market by the Qualified Person(s)

Medicinal products which are manufactured on site,
And registered by the following Marketing Authorization Holders:

- Ben Shimon Floris Ltd.
- Ferring Pharmaceuticals Ltd.
- Neopharm Ltd.
- Fischer Pharmaceuticals Ltd.
- Mediline Ltd.