

אישור העתק

אני הח"מ, אלימלך רשף
נוטריון ב רח' יפה אברהם 1 חולון
מאשר כי המסמך המצורף והמסומן באות/במספר "A"1-2
הוא העתק מדויק של המסמך המקורי שהוצג בפני.

ולראיה הנני מאשר את דיוק ההעתק הנ"ל בחתימת ידי ובחותמי, היום 25.06.2018

שכר בטר 70 ₪ נדרש + מע"מ



חתימה

אלימלך רשף, עו"ד ונוטריון
רשיון מס' 7919
טל. 03-5044777
רח' יפה אברהם 1 חולון 5849101

חותם הנוטריון

CERTIFICATION OF COPY

I the undersigned Elimelech Resheff

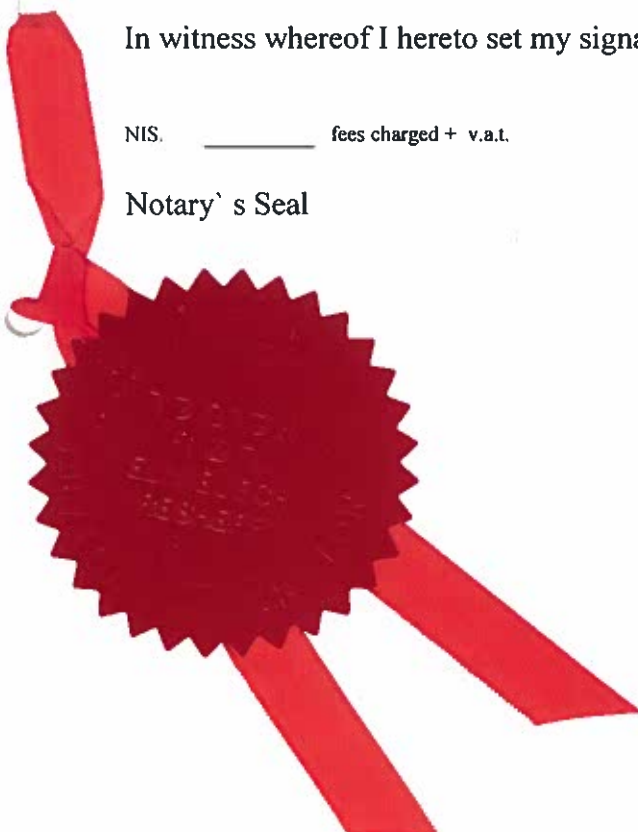
Notary at 1 Yafe Abraham st. Holon, Israel

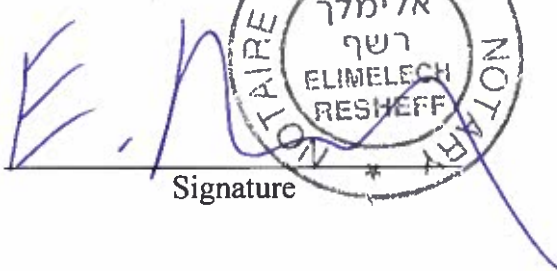
hereby certify that the attached document marked with the letter/number "A"1-2
is a correct copy of the original document which has been produced to me.

In witness whereof I hereto set my signature and seal, this June 25, 2018

NIS. _____ fees charged + v.a.t.

Notary's Seal




Signature

ELIMELECH RESHEFF
ADVOCATE & NOTARY
License No. 7919
1 Yafe Abraham St. Holon, Israel

יעל צימן
Yael Ziman

26-06-2018

RISHON LEZION

ראשון לציון

APOSTILLE

(Convention de la Haye du 5 Octobre 1961)

1. STATE OF ISRAEL

This public document

2. Has been signed by

Advocate

אלימלך רשף

3. Acting in capacity of Notary ELIMELECH RESHEFF

4. Bears the seal/stamp of

the above Notary

Certified

5. At the Magistrates Court of Rishon Lezion

6. Date

58004 1

7. By an official appointed by

26-06-2018

Minister of Justice under the

Notaries Law, 1976.

8. Serial number

9. Seal/Stamp

10. Signature

Yael Ziman

26-06-2018

RISHON LEZION ראשון לציון

יעל צימן

Yael Ziman

26-06-2018

RISHON LEZION

ראשון לציון

1. מדינת ישראל

מסמך ציבורי זה

2. נחתם בידי

עו"ד

אלימלך רשף

3. המכהן בתור נוטריון.

4. נושא את החותם/החותמת

של הנוטריון הנ"ל

אושר

5. בבית משפט השלום בראשון לציון

6. ביום

58004 1

7. על ידי מי שמונה בידי שר

המשפטים לפי חוק הנוטריונים,

התשל"ו - 1976

8. מס' סידורי

9. החותם / החותמת

10. חתימה

יעל צימן

Yael Ziman

26-06-2018

RISHON LEZION ראשון לציון





Certificate No: GMP 165/3

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 **PLANTEX Ltd.**

Site address **1 HaKadar St., Ind. Zone, Netanya 4210101, Israel**

Has been inspected under the Israeli inspection programme, in accordance with the above mentioned laws and regulations

and

is an active substance manufacturer that has been inspected in accordance with the ICH Q7 guideline



From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **11-14 February 2018**, 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



Part 2

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance(s):

- 3.1 Manufacture of Active Substance by Chemical Synthesis
- 3.1.1 Manufacture of active substance intermediates
- 3.1.2 Manufacture of crude active substance
- 3.1.3 Salt formation / Purification steps : *crystallization, precipitation*
- 3.5 General Finishing Steps
- 3.5.1 Physical processing steps : *drying, milling/micronization, sieving*
- 3.5.2 Primary Packaging
- 3.5.3 Secondary Packaging
- 3.6 Quality Control Testing
- 3.6.1 Physical / Chemical testing
- 3.6.3 Microbiological testing (including sterility testing)
performed off-site, at other sites of Teva group

**4. OTHER ACTIVITIES PERFORMED ON SITE**

- *Batch release of APIs by QA*
- *Analytical chemical testing, and stability studies of a finished medicinal product :
Glatiramer Acetate, pre-filled syringes*

Any restrictions or clarifying remarks related to the scope of this certificate: None

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

Michael Carmi, Pharmacist, GMP Inspector

E-mail: michael.carmi@moh.gov.il

Phone: office 972-2-6551795, cell 972-50-6242452

Fax: 972-2-6551781

27-02-2018



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