No. 10199-20 מס'

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 מדוייק של המסמך המקורי שהוצג בפני.

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

שכר בסך 70 ₪ נדרש + מע"מ

חותם הנוטריון

אלימלך רשף, עו"ד ונוטריון
רשיון מס' 7919
טל. 03-5044777
רח' יפה אברהם 1, חולון 5849191

חתימה

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

APOSTILLE

(Convention de la Haye du 5 Octobre 1961)

1. STATE OF ISRAEL — 1. מדינת ישראל

This public document — מסמך ציבורי זה

2. Has been signed by — 2. נחתם בידי

Advocate אלימלך רשף — עו"ד

3. Acting in capacity of Notary ELIMELECH RESHEFF — 3. המכהן בתור נוטריון.

4. Bears the seal/stamp of the above Notary — 4. נושא את החותם/החותמת של הנוטריון הנ"ל

Certified — אושר

5. At the Magistrates Court of Rishon Lezion — 5. בבית משפט השלום בראשון לציון

6. Date 26 -06- 2018 — 6. ביום

7. By an official appointed by Minister of Justice under the Notaries Law, 1976. — 7. על ידי מי שמונה בידי שר המשפטים לפי חוק הנוטריונים, התשל"ו - 1976

8. Serial number 58004 (1) — 8. מס' סידורי

9. Seal/Stamp — 9. החותם / החותמת

10. Signature — 10. חתימה

בית משפט השלום בראשון לציון * Magistrates Court of Rishon Lezion *

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

The Institute for Standardization And Control of Pharmaceuticals
Pharmaceutical Administration
MTIR Division, Ministry of Health
9 Ya'akov Eliav St., Giv'at Sha'ul, Jerusalem
P.O.B 34410 Jerusalem 9134302
Tel: +972-2-6551717 Fax: +972-2-6551777

המכון לביקורת ותקנים של חומרי רפואה
אגף הרוקחות
חטיבת טכנולוגיות רפואיות, מידע ומחקר
משרד הבריאות
רחוב יעקב אליאב 9, גבעת שאול, ירושלים
ת.ד. 34410, ירושלים 9134302
טל: 02-6551717 פקס: 02-6551777

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

NOTAIRE * נוטריון * NOTARY
אלימלך רשף
ELIMELECH RESHEFF

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

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

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