Form No. 21/16

CERTIFICATION OF COPY

I URIEL RODNEI JUGEND, Notary, at 19 Weizmann St. GIVATAIM hereby certify that the attached document marked A1 – A2 is, to the best of my knowledge a correct copy of the original document that has been produced to me.

In witness where of I hereto set my own signature and seal today 30.8.16

Fees paid: 661 NIS including VAT.

מספר רץ 21/16

אישור העתק

אני החתום מטה אוריאל רודני יוגנד, נוטריון, מרחוב וייצמן 19 גבעתיים, מאשר כי המסמך המצורף והמסומן באות א1 -א2 הוא העתק מדוייק של המסמך המקורי שהוצג בפני.

ולראיה הנני מאשר/ת את דיוק ההעתק הנ"ל, בחתימת ידי ובחותמי, היום 30.8.16.

שכרי בסך 661 ש"ח כולל מע"מ שולם.

נוטריון * NOTAIRE * NOTARY
אוריאל רודני יוגנד
URIEL RODNEI JUGEND

חותם הנוטריון
Notary's Seal

חתימת הנוטריון
SIGNATURE

APOSTILLE

(Convention de la Haye du 5 Octobre 1961)

1. STATE OF ISRAEL

This public document

2. Has been signed by

Advocate Uriel [illegible]

3. Acting in capacity of Notary

4. bears the seal/stamp of

the above Notary

Certified

5. At the District Court of Tel Aviv Jaffa

6. Date _____

7. By an official appointed by

Minister of Justice under the

Notaries Law, 1976.

8. Serial number _____

9. Seal/Stamp _____

10. Signature _____

31-08-2016

1. מדינת ישראל

מסמך ציבורי זה

2. נחתם בידי

עו"ד אוריאל [illegible]

3. המכהן בתור נוטריון.

4. נושא את החותם/החותמת

של הנוטריון הנ"ל

אושר

5. בבית משפט המחוזי בתל אביב יפו

6. ביום _____

7. על ידי מי שמונה בידי שר

המשפטים לפי חוק הנוטריונים,

התשל"ו - 1976

8. מס' סידורי 12505/16

9. החותם / החותמת _____

10. חתימה _____

בית המשפט המחוזי בתל אביב-יפו * District Court of Tel Aviv-Jaffa * ישראל

OSHRA HAVIV

31-08-2016

בית משפט מחוזי ת"א

DISTRICT COURT OF TEL-AVIV

המינהל לטכנולוגיות רפואיות ותשתיות
אגף הרוקחות | המכון לביקורת ותקנים של חומרי רפואה
The Institute for Standardization and Control of Pharmaceuticals

משרד הבריאות
לחיים בריאים יותר

Certificate No: **GMP 137/4**

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 **PERRIGO API LTD.**

Site address **NEOT HOVAV ECO-IND. PARK, POB 3593, BE'ER SHEVA 8413502, 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 above mentioned laws and regulations and ICH Q7

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **12-14 APRIL 2016**, 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

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 :

decantation, phase separation, distillation, slurry, crystallization, precipitation

3.5 General Finishing Steps

3.5.1 Physical processing steps :

drying, milling / micronization, sieving, saturation, mixing, blending.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

3.6.4 Biological Testing *(LAL)*

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:

Rachel Shimonovitz,- Head of GMP Inspectorate

e-mail: rachel.shimonovitz@moh.health.gov.il
phone: office 972 -2-6551796, cell 972-50-6243564
fax: 972-2-6551781

24 -08- 2016