

***Institute for Standardization and Control of Pharmaceuticals***

CERTIFICATE NUMBER : 137/12

**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 : *Wavelength Enterprises Ltd.*

Site address : *Neot Hovav Eco-Ind. Park, P.O.B. 3593, Be'er Sheva, 8413502, Israel*

OMS Location :

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2021-12-23** , 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.

4. Other Activities - Active Substances :

**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**  
**General Finishing Steps**  
**3.5.1 Physical processing steps : drying, lyophilizing, milling / micronization, sieving, saturation, mixing, blending**  
**3.5.2 Primary Packaging**  
**3.5.3 Secondary Packaging**  
**Quality Control Testing**  
**3.6.1 Physical / Chemical testing**  
**3.6.2 Microbiological testing (excluding sterility testing)**  
**3.6.4 Biological Testing (LAL)**

Clarifying remarks (for public users)

**List of active substances marketed in Europe: Cetirizine Dihydrochloride, Cisatracurium Besylate, Fenofibrate, Flumazenil, Fluticasone Propionate, Granisetron HCL, Midazolam Base, Modafinil, Mometasone Furoate Monohydrate, Moxonidine, Naltrexone HCl, Permethrin, Temozolomide, Tiotropium Bromide, Tramadol HCl .**

2022-01-04

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

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**Confidential**  
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**Pharmaceuticals**  
Tel : **Confidential**  
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