

Institute For Standardization And Control Of Pharmaceuticals

CERTIFICATE NUMBER: 256/7

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: *Sorvan Radiation Ltd.*

Site address: *Soreq Nuclear Research Center, Yavne, 8180000, Israel*

OMS Organisation Id. / OMS Location Id.: *ORG-100043466 / LOC-100071898*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2023-05-01**, 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.



משרד הבריאות
המכון לביקורת ותקינה של חומרי רפואה
מיכאל כרמי
רכז ארצי בקרת מפעלים

Part 2

1 MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.6 Electron beam Special Requirements 7 Other: (for bioburden reduction, see clarifying remarks section)(en)
	1.4.3 Other: Batch certification(en)

Clarifying remarks (for public users)

1.4.2 : SorVan Radiation Ltd. is a contract manufacturer that performs bioburden reduction of starting materials and APIs, including Cannabis flowers, by electron beam irradiation • 1.4.3 : The Responsible Person certifies the irradiation process according to the process validation and he technical agreement with the contract giver • Pursuant to Section 2 of the Extension of Periods and Postponement of Deadlines Law (Temporary Provision - Iron Swords) (Regulatory Approvals, Financial Penalties and Gas Installation Inspections), 5784-2023, this regulatory approval has been automatically extended by three (3) months beyond its original expiration date.

2026-05-04



04 -05- 2026

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

Michael Carmi
Institute For Standardization And Control Of
Pharmaceuticals

Tel: 972-50-6242452

e-mail Fax: michael.carmi@moh.gov.il

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