

מדינת ישראל  
STATE OF ISRAEL

MINISTRY OF HEALTH  
PHARMACEUTICAL ADMINISTRATION  
THE INSTITUTE FOR STANDARDIZATION  
AND CONTROL OF PHARMACEUTICALS

משרד הבריאות  
אגף הרוקחות  
המכון לבקורת ולתקנים של חומרי רפואה

Cert. No. 1176/10

**Certificate of Good Manufacturing Practice**

This is to certify that

**Rotem Industries Ltd.,**

a licensed company with a manufacturing plant located at

**Rotem Industrial Park, Mishor Yamin, Mobile Post Arava 86800, Israel,**

is authorized to manufacture the following products:

**Precursors & Intermediates for synthesis of PET tracers**

**Oxygen-18 enriched water**

**Reagent kits**

**Plastic cassettes for radiopharmaceutical synthesis**

That the manufacturing plant conforms to the requirements of the ICH Q7  
Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.

That the manufacturing plant conforms to the requirements of Good Manufacturing  
Practice (GMP) as recommended by the World Health Organization (WHO),  
and complies to the laws and regulations in Israel.

That the manufacturing plant is periodically inspected. Last inspection was  
conducted on 11-12 January 2010.

This certificate is valid until 31 January 2012.

Stamp, Date & Signature of Authorized Person:



*Handwritten signature of Michael Carmi*

Michael Carmi, B. Pharm.  
GMP Inspector  
Institute for the Standardization  
and Control of Pharmaceuticals,  
Ministry of Health, Jerusalem

Certified hereby that the seal and signature  
appearing above are the seal of the  
Ministry of Health and the signature of  
Michael Carmi, B. Pharm.,  
Institute for the Standardization  
and Control of Pharmaceuticals,  
Ministry of Health, Jerusalem

ניתן בזה אישור כי החותם והחתימה  
המופיעים לעיל הם חותם  
משרד הבריאות וחתימת ידו של  
מר מיכאל כרמי,  
המכון לבקורת ולתקנים של חומרי  
רפואה, משרד הבריאות,  
ירושלים

Director of the Consular Division,  
Ministry of Foreign Affairs, Jerusalem

מנהל המחלקה הקונסולרית,  
משרד החוץ, ירושלים