

**Imatinib-Trima 400mg, Film coated tablets**

<u>Manufacturer:</u>	<b>Trima Pharmaceutical Products Maabarot Ltd., Israel</b>
<u>Dossier status:</u>	Complete CTD file
<u>Dossier date:</u>	Dossier ready, submitted to Israeli MOH in 12/2014 and approved Dec 2016.
<u>Dosage form:</u>	Film-coated tablets

Bioequivalence reference:

**Glivec** 400mg film coated tablets, manufactured by Novartis Pharma AG Basel Switzerland, MA holder: Novartis Pharma AG Israel (source country of reference product: Israel).

<u>Stability data:</u>	3 batches, 3 months at 40°C, 75% RH 3 batches, 3 years at 25°C, 60% RH
<u>Packaging:</u>	Tablets are packed in Alu/PVC blisters of 10 tablets/blister.

The European Union (EU) has in place an agreement (2013/1/EU) on conformity assessment and mutual acceptance of Pharmaceutical Good Manufacturing Practice (GMP) with Israel. The Trima manufacturing facility is therefore considered as EU-GMP compliant.

**For further information, please contact:**

Products protected by patents in force are neither offered for sale nor marketed in jurisdictions where such activities would constitute patent infringement.

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