Voriconazole-Trima 200mg Tablets Voriconazole 200 mg

Manufacturer: Trima Israel Pharmaceutical Products

Maabarot Ltd.

<u>Dossier status:</u> Complete CTD file

<u>Dossier date</u>: Dossier is ready, submitted to Israeli

MOH 05/2013 and approved March 2014.

<u>Dosage form</u>: Tablets

Bioequivalence reference:

The reference product is **VFEND** (Voriconazole) 200mg tablets, manufactured by Pfizer Germany, Source country: Israel.

Stability data: 3 batches, 3 months at 40°C, 75% RH

3 batches, 3 years at 25°C, 60% RH

Packaging: Tablets are packed in PVC and Aluminum

foil blister packs

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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