

## Trospium hydrochloride

Manufacturer:	CTS Ltd., Israel
Dossier status:	Complete CTD file
Dossier date:	20mg - ready 15 and 30mg - December 2016
Dosage forms:	15mg, 20mg, 30mg Film-coated tablets
Bioequivalence reference:	Regurin 20mg (for 20mg dossier) Spasmex 15mg (for 15 and 30mg dossier)
Stability data:	2 years at 25°C, 60% RH (stability program is up to 3 years)
Packaging:	Alu/PVC Blisters of 7 or 10 tablets Bulk 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 CTS 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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