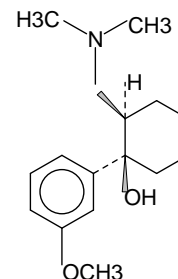


TRAMADOL HYDROCHLORIDE

Eur. Ph.



Globe Reference:
CPE 5010127

Formula	C ₁₆ H ₂₆ Cl N O ₂ Mr = 299,8
Action and use	Analgesic
Characteristics	White crystalline powder
Solubility	Conform
IDENTIFICATION	
B. Infrared spectrum	Conform
D. Reaction (a) of Chlorides or A. Melting range	Positive 180°C to 184°C
C. Thin-layer chromatography	Conform
D. Reaction (a) of Chlorides	Positive
ESSAYS	
. Aspect of solution	Colourless, clear
. Acidity	Conform
. Optical rotation	-0.10° to +0.10°
. Impurity E	Not more than 0.2 per cent
. Related impurities:	
- Impurity A	Not more than 0.2 per cent
- Other impurities, each one	Not more than 0.1 per cent
- Impurities total	Not more than 0.4 per cent
. Heavy metals	Not more than 20 ppm
. Water content	Not more than 0.5 per cent
. Sulphated ash	Not more than 0.1 per cent
ASSAY	
. Tramadol Hydrochloride in g by 100 g calculated with reference to the anhydrous substance	99.0 to 101.0 per cent
Armazenamento	In well-closed containers
Acondicionamento	25 Kg fiber drum with double polyethylene bags



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