

**PRODUCT: TRAMADOL HYDROCHLORIDE**

ITEMS	SPECIFICATIONS
<b>APPEARANCE</b>	White crystalline powder
<b>SOLUBILITY</b>	Freely soluble in water and methanol, practically insoluble in acetone
<b>IDENTIFICATION</b>	As per Ph. Eur.
<b>APPEARANCE OF 5% AQUEOUS SOLUTION</b>	The solution should be clear
<b>ACIDITY</b>	As per Ph. Eur.
<b>OPTICAL ROTATION</b>	-10° ~ +10° (C=5, Water)
<b>RELATED SUBSTANCES</b> a) Mannich base (by TLC) b) Impurity A (by HPLC) c) Individual impurity (by HPLC) d) Total impurities (As tramadol hydrochloride)(by HPLC)	NMT 0.2% NMT 0.2% NMT 0.1% NMT 0.4%
<b>WATER</b>	NMT 0.5% w/w
<b>SULPHATED ASH</b>	NMT 0.1% w/w
<b>HEAVY METALS</b>	NMT 0.001% w/w
<b>ASSAY BY CHEMICAL</b>	99.0% w/w ~ 101.0% w/w (C <sub>15</sub> H <sub>26</sub> CLNO <sub>3</sub> , on the dried basis)