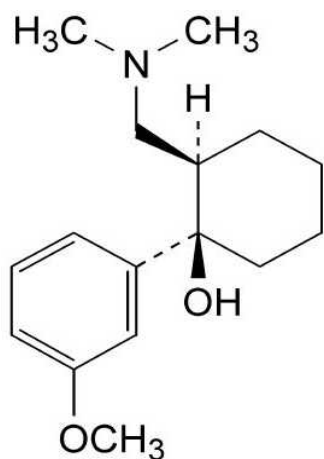


M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINISHED PRODUCT INFORMATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : TRAMADOL HCL
MSDS no. : BPPL 018	SPECIFICATION NO. : FP-018

1. NOMENCLATURE : TRAMADOL HYDROCHLORIDE
: (1RS,2RS)-2-[(Dimethylamino)Methyl]-1-(3-Methoxyphenyl) Cyclohexanol Hydrochloride.
2. CAS NO. : 36282-47-0
3. EMPIRICAL FORMULA : C₁₆H₂₆ClNO₂
4. MOL. WT. : 299.80
5. STRUCTURAL FORMULA :



and enantiomer , HCl

6. DESCRIPTION : White Crystalline Fine Powder;
Soluble in Water
7. THERAPEUTIC USE : Used as Analgesic
: Used in making Tablets, Capsules & Injections.

M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINISHED PRODUCT PHARMACOPEIAL SPECIFICATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : TRAMADOL HCL
MSDS no. : BPPL 018	SPECIFICATION NO. : FP-018

1. DESCRIPTION : White Crystalline Fine Powder.
2. SOLUBILITY : Freely soluble in Water and in Methanol,
Very slightly soluble in Acetone.
3. IDENTIFICATION :
 - A) Melting Point : 180°C to 184°C
 - B) Infrared absorption Spectrophotometry : To be concordant with reference spectrum.
 - C) TLC : Corresponds with std. Chromotogram
 - D) Test For Chloride : The principle spot is corresponds to the Reference Solution it gives reaction of Chlorides.
4. CLARITY & COLOUR OF SOLUTION
(APPEARANCE OF SOLUTION) : 05% Solution in Water is Clear and Colorless
5. ACIDITY : NMT 0.4 ml. Of 0.01M NaOH.
6. OPTICAL ROTATION : -0.10° to +0.10°
7. IMPURITY E BY TLC : Maximum 0.2%

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QUALITY CONTROL AND ASSURANCE	PRODUCT : TRAMADOL HCL
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8. RELATED SUBSTANCES BY HPLC :
- A) Impurity A : NMT 0.2%
 - B) Any Impurity : NMT 0.1%
 - C) Total Impurity : NMT 0.4%
9. HEAVY METALS : Not more than 20 ppm.
10. WATER CONTENT : Not more than 0.5%
11. SULPHATED ASH : Not more than 0.1%
12. ASSAY (ODB) : 99% to 101%