

WRS
T28-1

CENTURION LABORATORIES PVT.LTD.
FORM 39 RULE 150E (i)
THE DRUG & COSMETIC ACT, 1940 & THE RULES THERE UNDER.
QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS OF WORKING STANDARD

| | | |
|---------------------|---|---------------------------|
| Material Name | : | Tramadol Hydrochloride BP |
| Batch No. | : | CLR-0789-15-14 |
| Date of Preparation | : | 29/10/2015 |
| Specification | : | BP |
| | | Retest Date |
| | : | 29/10/2016 |
| | | Exp. Date |
| | : | 06/2018 |
| | | Mfg. Date |
| | : | 07/2015 |

| Sr. No. | Test | Specification | Result |
|---------|------------|--|--|
| 1. | Appearance | White or almost white, crystalline powder. | White to off-white powder. |
| 2. | Solubility | Freely soluble in water and in methanol, very slightly soluble in acetone. | Freely soluble in water and in methanol, very slightly soluble in acetone. |

| | | | |
|----|-----------------------|--|--|
| 3. | Identification | Test A: Melting point Test B: IR Test C: TLC | 180°C to 184°C IR absorption spectrum of the test solution should correspond to that of standard solution. The principal spot in the chromatogram obtained with test solution should be similar in position and size to the principal spot in the chromatogram obtained with reference solution. |
| | Test D: Chloride Test | A curdled, white precipitate is formed. | A curdled, white precipitate is formed. |

| | | | |
|----|------------------------------------|--|-------------------------------------|
| 4. | Related substances | Impurity A Unspecified impurities Total impurities | NMT 0.2 % NMT 0.1 % NMT 0.4 % |
| 5. | Water | NMT 0.5 % | 0.30% |
| 6. | Assay of Tramadol Hydrochloride BP | 99.0% to 101.0% | 100.44 % |

Remarks: The material Tramadol Hydrochloride BP is tested against Tramadol Hydrochloride BP working reference.

Q.C. Chemist: D.PATEL

Q.C. Manager: MR. DR SHAH

