

CARBAMAZEPINE BP/USP

SPECIFICATIONS

TESTS

STANDARDS

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| 1. DESCRIPTION | : WHITE TO ALMOST WHITE CRYSTALLINE POWDER. IT EXHIBITS POLYMORPHISM. |
| 2. SOLUBILITY | : FREELY SOLUBLE IN DICHLOROMETHANE, SPARINGLY SOLUBLE IN ACETONE AND IN ETHANOL(96%). PRACTICALLY INSOLUBLE IN WATER & ETHER. |
| 3. IDENTIFICATION | : IR SPECTRA |
| 4. X-RAY DIFFRACTION | : PATTERN CONFORMS TO CARBAMAZEPINE R.S. |
| 5. ACIDITY | : NMT 1.0 ML |
| 6. ALKALINITY | : NMT 1.0 ML |
| 7. LOSS ON DRYING | : NMT 0.5 % |
| 8. RESIDUE ON IGNITION | : NMT 0.1 % |
| 9. CHLORIDE | : NMT 0.014 % |
| 10. HEAVY METALS | : NMT 0.001 % |
| 11. CHROMATOGRAPHIC PURITY | : (HPLC)ANY SINGLE IMPURITY NMT 0.2 % TOTAL IMPURITIES NMT 0.5 % |
| 12. ORGANIC VOLATILE IMPURITIES | : SHOULD MEET THE REQUIREMENTS |
| 13. ASSAY | : BETWEEN 98.0 % & 102.0 % CALCULATED ON DRY BASIS. |
