

Name of the Product : **PROMETHAZINE HYDROCHLORIDE EP8.0**

Batch No. : HPHCPI059

Date of manufacture : NOVEMBER 2014 Quantity : 250.0kgs(25kgsX 8 & 10kgs x 5)

Date of Expiry : OCTOBER 2019 Nature of Packing : HDPE DRUMS

C E R T I F I C A T E O F A N A L Y S I S

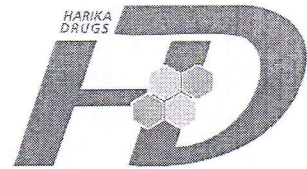
| S.No | TEST | RESULTS | SPECIFICATION |
|------|--------------------------------|---|--|
| 1. | Characters | White Crystalline Powder Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride. It melts at about 222.6°C with decomposition | White or faintly yellowish Crystalline powder. Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride. It melts at about 222 °C with decomposition |
| 2. | Identification | | |
| | Test A. IR absorption spectrum | Complies | The infra-red absorption spectrum is concordant with the reference spectrum of Promethazine Hydrochloride. |
| | Test B. By TLC | Complies | It complies with the identification test for phenothiazines. |
| | Test C. Test for Nitric acid | Complies | The solution becomes orange and an orange-red precipitate is formed. |
| | Test D. Test for chlorides | Complies | Shall comply the test. |
| 3. | pH 10% w/v solution | 4.29 | 4.0 to 5.0 |

HARIKA DRUGS PRIVATE LIMITED

Office : 7-2-1813/5/A/1, 2nd floor, Classic Arcade, Road No. 1, Czech Colony, Sanath Nagar, Hyderabad - 500 018. Andhra Pradesh, INDIA.


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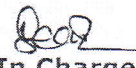
Factory : Gummadidala, Medak District, Andhra Pradesh, INDIA. Tel : +91-08458-275369, ✉ : harikasite@yahoo.com



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| S.No | TEST | RESULTS | SPECIFICATION |
|---|--|---|--|
| 4. | Related substances by HPLC: Impurity A Impurity B Impurity C Impurity D Unspecified Impurities Total Impurities | Not detected 0.22% 0.12% Not detected 0.05% 0.39% | Not more than 0.1% Not more than 0.8% Not more than 0.2% Not more than 0.1% Not more than 0.10% Not more than 1.2% |
| 5. | Heavy Metals | Less than 10 ppm | Not more than 10 ppm |
| 6. | Loss on drying at 105°C | 0.17% | Not more than 0.5% |
| 7. | Sulphated Ash | 0.04% | Not more than 0.1% |
| 8. | Assay (on dried substance) | 99.9% | 99.0% to 101% |
| 9. | Residual solvents Class 1 Solvents Class 2 Solvents o-Xylene Class 3 Solvents Isopropyl alcohol | Nil 986 ppm 562 ppm | Not used in our manufacturing process ICH Limits: 2170 ppm ICH Limits: 5000 ppm |
| 10. | Microbial Limits Total Bacterial count Total Fungal count Pathogens: E.Coli Salmonella Pseudomonas Staphylococcus | 35 cfu/gm Less than 10cfu/gm Absent Absent Absent Absent | Not more than 1000 cfu/ gm Not more than 100 cfu/gm Shall be absent Shall be absent Shall be absent Shall be absent |
| RESULT : The sample complies with prescribed standards as per EP8.0 | | | |

Analyst 
Date: 17-01-2015

QC In Charge 
Date: 17-01-2015

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