## QUALITY CONTROL LABORATORY

| CERTIFICATE OF ANALYSIS | | | | | |
|---|---|---|---|---|---|
| 1 | Name of the Product | **Pseudoephedrine HCl BP / Pharm.Eur** | | | |
| 2 | Batch No. | 210118 | 7 | QC Analysis No. | FP/PSE/1809/02 |
| 3 | Quantity Manufactured | 1035.270 Kg | 8 | Date of Analysis | September 04 , 2018 |
| 4 | Manufacturing Date | September - 2018 | 9 | Expiry Date | August- 2023 |
| 5 | Quantity Dispatched as per Pack | 500.0 Kg (20 x 25.0 Kg ) | 10 | Date of Release | September 06 , 2018 |
| 6 | CAS No. | [345-78-8] | | | |

**RESULT OF ANALYSIS**

| Sr. No. | TESTS | RESULTS | LIMITS |
|---|---|---|---|
| 1 | Characters | | |
| | 1.1 Appearance | White crystalline powder | White or almost white crystalline powder, or colourless crystals |
| | 1.2 Solubility | Passes | Freely soluble in water and in ethanol (96%), sparingly soluble in methylene chloride |
| | 1.3 Melting Point (°C) | 183.4 | About 184.0 |
| 2 | Identification | | |
| | A) Specific Optical Rotation ( Dried substance) (αD) (°) ( At 20.0 ± 0.5°C) | Passes | Between + 61.0 and + 62.5 |
| | B) IR | Complies | IR absorption spectrum of sample must be concordant with the reference spectrum of Pseudoephedrine Hydrochloride. |
| | D) Chlorides | Positive | Solution gives reaction of chlorides. |
| 3 | Appearance of Solution | Clear & Colourless | Must be clear & colourless |
| 4 | Acidity or Alkalinity | Passes | On addition of 0.1mL of 0.01M NaOH Solution, the Solution is yellow. On addition of 0.2 mL of 0.01M HCl the Solution is red |
| 5 | Loss on Drying (% w/w) ( At 105°C to constant weight ) | 0.13 | NMT 0.5 |
| 6 | Specific Optical Rotation ( Dried substance) (αD) (°) ( At 20.0 ± 0.5°C) | + 62.0 | Between + 61.0 and + 62.5 |
| 7 | Sulphated Ash (% w/w) | 0.03 | NMT 0.1 |
| 8 | Assay (Potentiometric on dried basis) (% w/w) | 100.3 | Between 99.0 and 101.0 |



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**RESULTS OF ANALYSIS**

| Sr. No. | TESTS | RESULTS | LIMITS |
|---|---|---|---|
| *9 | Related Substances by HPLC (%w/w) | | |
| | a) Impurity 'A' Ephedrine | BDL | NMT 0.5 |
| | b) Any other impurity | BDL | NMT 0.1 |
| | c) Total Impurities other than 'A' | BDL | NMT 1.0 |
| #10 | Impurities by HPLC (%w/w) | | |
| | a. Individual Specified Impurities | | |
| | i) l-Ephedrine HCl | Below LOD (0.006) | NMT 0.10 |
| | ii) Acetylephedrine | Below LOD (0.009) | NMT 0.10 |
| | iii) Benzaldehyde | Below LOD (0.007) | NMT 0.10 |
| | b. Individual Unspecified Impurities | Below LOD (0.002) | NMT 0.10 |
| | c. Total Unspecified Impurities | Below LOD (0.002) | NMT 0.20 |
| | d. Total Impurities | Below LOD (0.002) | NMT 0.40 |
| #11 | Residual Solvents by GC (ppm) | | |
| | A) Acetone | 136 | NMT 1000 |
| | B) Toluene | Below LOD (11) | NMT 100 |

**REMARK : *Disregard Limit : Below 0.05%**

**REPORT** : The material referred above complies with the prescribed standard Quality of BP 2018/ PHARM.EUR 9.0-2017 and # Q/SOP/TMD-054.

**REF:RDP-PSE/P11-12/70**

| Prepared By: | Checked By: | Approved By: |
|---|---|---|
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