

Quantum Drugs & Chemicals

Reg.Off: 25, Bharathi Ula Road, Race Course, Madurai-625002, Tamilnadu, India.
Tel: ++91(452)4345116/2569019 FAX: 91(452)2568580 e-mail: quantumdrugs@gmail.com

CERTIFICATE OF ANALYSIS

Product : **CHLORPROPAMIDE BP**

Batch No : CP/EXP-

Quantity :

Mfg. Date :

Exp. Date :

| S. No | Tests | Standards | |
|--|----------------------------------|--|---------------------|
| 1. | Characters | A White, crystalline powder, Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in alcohol. It dissolves in dilute solutions of alkali hydroxides. | |
| 2. | A. Melting point | 126° C to 130° C | |
| | B. By UV | Dissolve 0.10g in methanol R and dilute to 50.0 ml with the same solvent. Dilute 5.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid. Dilute 10.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid. Examined between 220 nm and 350 nm, the solution shows an absorption maximum at 232 nm. The specific absorption at the maximum is 570 to 630. | |
| | C. Infrared Absorption | Compare spectrum with the reference spectrum of Chlorpropamide CRS | |
| | D. Chloride | A Curdy white precipitate is formed | |
| 3. | Related substances by TLC | | |
| | p-chlorobenzene sulphonamide | Not more than 0.3 % | |
| | p-chlorobenzene sulphonylurea | Not more than 0.3 % | |
| | 1,3-dipropylurea | Not more than 0.3 % | |
| | Secondary spots | Not more than two such spots 0.1% | |
| 4. | Heavy metals | Not more than 20 ppm | |
| 5. | Loss on drying | Not more than 0.50 % | |
| 6. | Sulphated Ash | Not more than 0.10 % | |
| 7. | Assay (dried basis) | 99.0 to 101.0 % | |
| REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF CHLORPROPAMIDE BP | | | |
| | <i>Analysed by:</i> | <i>Checked by:</i> | <i>Approved by:</i> |
| <i>Name:</i> | | | |
| <i>Designation:</i> | | | |
| <i>Signature:</i> | | | |
| <i>Date:</i> | | | |

Manufacturing Site: C-21, Sipcot Industrial Complex, Manamadurai – 630 606. India. Phone No.: ++91-4574-258349.



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CERTIFICATE OF ANALYSIS

Product : **CHLORPROPAMIDE EP**
Batch No : CP/EXP-
Quantity :

Mfg. Date :
Exp. Date :

| S. No | Tests | Standards | |
|--|----------------------------------|--|---------------------|
| 1. | Characters | A White, crystalline powder, Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in alcohol. It dissolves in dilute solutions of alkali hydroxides. | |
| 2. | A. Melting point | 126° C to 130° C | |
| | B. By UV | Dissolve 0.10g in methanol R and dilute to 50.0 ml with the same solvent. Dilute 5.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid. Dilute 10.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid. Examined between 220 nm and 350 nm, the solution shows an absorption maximum at 232 nm. The specific absorption at the maximum is 570 to 630. | |
| | C. Infrared Absorption | Compare spectrum with the reference spectrum of Chlorpropamide CRS | |
| | D. Chloride | A Curdy white precipitate is formed | |
| 3. | Related substances by TLC | | |
| | p-chlorobenzene sulphonamide | Not more than 0.3 % | |
| | p-chlorobenzene sulphonylurea | Not more than 0.3 % | |
| | 1,3-dipropylurea | Not more than 0.3 % | |
| | Secondary spots | Not more than two such spots 0.1% | |
| 4. | Heavy metals | Not more than 20 ppm | |
| 5. | Loss on drying | Not more than 0.50 % | |
| 6. | Sulphated Ash | Not more than 0.10 % | |
| 7. | Assay (dried basis) | 99.0 to 101.0 % | |
| REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF CHLORPROPAMIDE EP | | | |
| | <i>Analysed by:</i> | <i>Checked by:</i> | <i>Approved by:</i> |
| <i>Name:</i> | | | |
| <i>Designation:</i> | | | |
| <i>Signature:</i> | | | |
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CERTIFICATE OF ANALYSIS

Product : **CHLORPROPAMIDE USP**
Batch No : CP/EXP-
Quantity :

Mfg. Date :
Exp. Date :

| S. No | Tests | Standards | |
|---|---|---|---------------------|
| 1 | Identification | | |
| | A.Infrared Absorption | Compare spectrum with the reference spectrum of USP Chlorpropamide RS | |
| | B.Thin Layer Chromatography | Compare spectrum with the reference spectrum of USP Chlorpropamide RS | |
| 2 | Melting Range | between 126° C and 129° C | |
| 3 | Loss on drying (in vacuum at 60° C for 2 hours) | Not more than 1.0 % | |
| 4 | Residue on ignition | Not more than 0.4 % | |
| 5 | Selenium | Not more than 0.003 % | |
| 6 | Heavy metals | Not more than 0.003 % | |
| 7 | Assay by HPLC (ODB) | 97.0 to 103.0 % | |
| Additional Tests | | | |
| 8 | Appearance | White crystalline powder | |
| 9 | Odor | Practically odorless | |
| 10 | Solubility | Practically insoluble in water, Freely soluble in acetone and in alcohol. It also dissolves in dilute solutions of alkali hydroxides. | |
| REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF CHLORPROPAMIDE USP | | | |
| | <i>Analysed by:</i> | <i>Checked by:</i> | <i>Approved by:</i> |
| <i>Name:</i> | | | |
| <i>Designation:</i> | | | |
| <i>Signature:</i> | | | |
| <i>Date:</i> | | | |

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