



ASIATIC DRUGS & PHARMACEUTICALS PRIVATE LIMITED

GMP CERTIFIED MANUFACTURER

CEPHALEXIN MONOHYDRATE

| Test Parameter | Specifications (in house) | Test Result Trend |
|---|------------------------------|-------------------|
| Appearance | White or almost white powder | Complies |
| Identification | By IR & HPLC | Complies |
| Crystallinity | Crystalline | Complies |
| Solubility | Sparingly soluble in water, | Complies |
| pH (0.5 % solution in water, w/v) | 4.0 - 5.5 | 4.6 - 5.1 |
| Water (Karl Fischer, w/w) | 4.0 - 8.0% | 5.5 - 6.5% |
| Sulphated Ash, w/w | NMT 0.2% | 0.06 - 0.11% |
| Specific Optical Rotation (0.5% solution in Phthalate buffer solution pH 4.4) | 149° - 158° | 151° - 155° |
| N,N - Dimethyl Aniline | Not Tested | -- |
| Assay Anhydrous Basis (HPLC %) | NLT 98.0% or 980 µg/mg | 98.5 - 99.5% |
| Any Individual Impurity | NMT 1.0% | 0.1 - 0.5% |
| Total Impurities | NMT 2.0% | 0.80 - 1.2% |

Confirmation:

- We certify that the above mentioned product is in conformity with the specifications of IP, BP, USP & EP.
- N,N'-Dimethylaniline, is not used in the manufacturing process.
- The product tested according to the IP, BP, USP & EP.

Storage Conditions:

- Preserve in well closed (air tight) containers, in a dry place, at a temperature not exceeding 25°C.

Packing:

- Material packed in double liner poly bags and further packed in HDPE / Fiber board drums.

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