

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

| | | | |
|----------------|---------------------------|---------------|------------|
| Product name | DICLOFENAC DIEHYLAMINE | Batch No. | 20171103 |
| Manuf. Date | 2017-11-26 | Expiry Date | 2021-11-25 |
| Batch Quantity | 500Kgs | Test Standard | BP2009 |

| TEST | SPECIFICATIONS | RESULTS |
|--|--|------------------------------|
| Description | White or slightly yellowish crystalline powder, slightly hygroscopic. | Conforms |
| Solubility | Sparingly soluble in water and in acetone, freely soluble in Methanol, Ethanol (96%); practically insoluble in 1 mol/l sodium hydroxide. | Conforms |
| Identify | (A) IR-Spectrum (B) TLC chromatogram | (A) Conforms (B) Conforms |
| Appearance of solution | Clear Absorption at 440nm max 0.05 | Conforms 0.023 |
| PH of 1% m/V solution in ethanol (10% V/V) | 6.4-8.4 | 7.40 |
| Clarity(5% w/V solution in methanol) | Clear | Conforms |
| Colour(5% w/V solution in methanol) | The absorbance measured at 440 nm is not greater than 0.05 | Conforms |
| Sulphated ash | Not more than 0.1% | Conforms |
| Related substances | Single impurity max 0.2%; total impurity max 0.5% | 0.02% 0.04% |
| Heavy metals | Max 10ppm | Conforms |
| Loss on drying | Max 0.50% | 0.29% |
| Assay | 99.0~101.0% | 99.44% |

Storage: Closed keep in cool,dry and dark place ;keep from heat and strong light

Conclusion: The product complies with the requirements of BP2009

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Quality Manager:

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