

Lot: 0250320

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	DICLOFENAC DIEHYLAMINE	Batch No.	20191209
Manuf. Date	2019-12-18	Expiry Date	2023-12-17
Batch Quantity	100Kgs	Test Standard	BP2015

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 0.020
PH of 1% m/V solution in ethanol (10% V/V)	6.4-8.4	7.4
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%	0.01% 0.03%
Heavy metals	Max 10ppm	Conforms
Loss on drying	Max 0.50%	0.30%
Assay	99.0~101.0%	99.8%

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

Conclusion: The product complies with the requirements of BP2015

Quality Manager:

吴永章

Rechecker:

易洪成

Analyst:

刘媛

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