Hallochem Group Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	DICLOFENAC DIEHYLAMINE	Batch No.	DIA20201205
Manuf. Date	2020-12-26	Expiry Date	2024-12-25
Batch Quantity	200Kgs	Test Standard	BP2015

TEST	SPECIFICATIONS	RESULTS	
Description	White or slightly yellowish crystalline powder, slightly hygroscopic.	- I LANIARMS	
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 0.024	
PH of 1% m/V solution in ethanol (10% V/V)	6.4-8.4	7.14	
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% 0.04%	
Heavy metals	Max 10ppm	Conforms	
Loss on drying	Max 0.50%	0.28%	
Assay	99.0~101.0%	99.45%	

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:

Rechecker:

Analyst:

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