

Zhejiang Anglikang Pharmaceutical Co., Ltd.
No.1000 Shengzhou North Road, Shengzhou City, Shaoxing Zhejiang, China 312400

Certificate of Analysis



Product Name:	Cefradine(Compacted)		
Batch No.:	32052201074	Package Size:	25kg/drum
Specification:	BP2019	Batch Size:	866.31kg
Mfg. Date:	27 January 2022	LAB Record No.:	BPAC04-2201005
Report Date:	09 February 2022	Exp. Date:	December 2024
ITEMS	SPECIFICATIONS		RESULTS
Appearance	White or slightly yellow, hygroscopic powder.		Slightly yellow, hygroscopic powder
Identification	The IR spectrum conforms to that of reference standard.		Complies
Tests			
Appearance of solution	Less opalescent than reference suspension II		< reference suspension I
	The absorbance at 450 nm is not greater than 0.60		0.05
pH	3.5~6.0		5.0
Specific optical rotation	+80.0°~+90.0°		+83.2°
Related substances	D-dihydrophenylgicine NMT 0.25%		N.D.
	Impurity A NMT 0.25%		N.D.
	Impurity C NMT 0.25%		N.D.
	Impurity D NMT 0.25%		0.02%
	Impurity E NMT 0.25%		0.02%
	Impurity F NMT 0.25%		N.D.
	Impurity G NMT 0.25%		N.D.
	Any other impurity NMT 0.25%		0.09%
Total impurities NMT 2.0%		0.25%	
Dimethylformamide	NMT 0.088%		N.D.
Acetone	NMT 0.5%		0.004%
Methylene chloride	NMT 0.06%		0.004%
Water Content	NMT 6.0%		4.2%
Sulfated ash	NMT 0.2%		0.07%
Assay	Cefradine : minimum 90.0 per cent(anhydrous substance)		98.2%
	Cefalexin: maximum 5.0 per cent (anhydrous substance)		1.6%
	4,5-dihydrocefradine: maximum 2.0 per cent (anhydrous substance)		0.7%
	Sum of the percentage contents of cefradine, cefalexin and 4,5- dihydrocefradine : 96.0 per cent to 102.0 per cent (anhydrous substance)		100.5%
Bulk Density	For Information only		0.67g/ml
Tapped Density	For Information only		0.92g/ml
Remarks:	N,N-Dimethylaniline in this process is not utilized		
Conclusion:	The product complies with specification BP2019.		

Reporter:

王意 2022.02.09

Reviewer:

朱璇 2022.02.10