NQCL-WRS-C23-3

MEDPHARMA
PHARMA. & CHEM. IND'S (L.L.C.)
SHARJAH - U.A.E.

CERTIFICATE OF ANALYSIS
Working Reference Standard

Material name: Cefaclor monohydrate	**Date of Analysis:** 16/01/2012
WRS No. : QC/WRS/013-2	**Manufacturing Date:** 07/2011
Batch No. : 660202 0006 1	**Material Expiry Date:** 07/2016
Quantity : 500 mg	**Material Reference No.:** RM/0003/01/12
Specification Ref. : QC/SPCM/139 & QC/ANM/422	

Test	Specification	Result
Description	A white or slightly yellowish granular material.	Complies
Solubility	Slightly soluble in water, practically insoluble in methanol and in methylene chloride.	Complies
Identification	IR: the absorption spectrum shall be in concordance with the spectrum obtained with *Cefaclor RS*.	Complies
Water content	3.0 % to 6.5 % on 0.2 g	4.715 %
pH	The pH of solution (2.5 % w/v) is between 3.0 to 4.5	3.57
Specific optical rotation	+ 101 to + 111, calculated with reference to the anhydrous substance.	+ 101.99
Related substances	Individual impurity: NMT 0.5 %	0.18 %
	Total impurities: NMT 2.0 %	0.43 %
Heavy metals	NMT 30 ppm	< 30 ppm
Particle size distribution	2% to 6% shall be retained on 1.0 mm	3.19 %
	20% to 35% shall be retained on 500 µm	33.47 %
	35% to 50% shall be retained on 250 µm	47.99 %
	50% to 90% shall be retained on 125 µm	86.58 %
Bulk density	Untapped: 0.65 to 0.80 g/ml	0.7436 g/ml
	Tapped (100 taps): 0.80 to 0.95 g/ml	0.8720 g/ml
	Tapped (constant volume): 0.90 to 1.10 g/ml	0.95 g/ml
Assay	96.0 % to 102.0 % on anhydrous basis	101.60 %

Comment : Certify that the above material has been tested as per specifications mentioned above and has been found to meet the requirements.

Issue date: 16/12/2012

16/12/2012
Analysed By

MEDPHARMA PHARMACEUTICAL & CHEMICAL IND'S L.L.C. SHARJAH - U.A.E.
16 DEC 2012
Checked By

Approved By

RELEASED
QUALITY CONTROL DEPARTMENT