NQCL-WRS-C10-1 C3-1

MEDPHARMA

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

C3-1

CERTIFICATE OF ANALYSIS
Working Reference Standard

Material name: Cefuroxime axetil	**Date of Analysis:** 06/11/2012
WRS No. : QC/WRS/027-2	**Manufacturing Date:** 08/2012
Batch No. : AGAK12R0060007	**Material Expiry Date:** 07/2015
Quantity : 500 mg	**Material Reference No.:** RM/0373/11/12
Specification Ref. : QC/SPCM/204	

Test	Specification	Results
Description	White or almost white powder.	Complies
Identification	1) Infrared Absorption spectroscopy. 2) Examine the chromatogram obtained in the assay. The principal peaks in the test are similar in retention time and size to that of standard.	Complies
Solubility	Slightly soluble in water, soluble in acetone, in ethyl acetate and in methanol, slightly soluble in ethanol (96 %)	Complies
Related substances	Impurity A: Max 1.5 % for the sum of the pair of peaks Impurity B: Max 1.0 % for the sum of the pair of peaks Any other impurity: for each impurity, Max 0.5 % Total impurities: Max 3.0 %	0.225 % 0.205 % 0.213 % 0.784 %
Water	NMT 1.5 %	0.58 %
Diastereoisomer ratio	0.48 to 0.55	0.512
Acetone	Maximum 1.0 %	0.32 %
Assay	96.0 % to 102.0 % (on anhydrous basis)	98.39 % (on anhydrous basis, as Cefuroxime axetil)

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

Issue date: 19/03/2013

EJAZ

Analysed By

MEDPHARMA PHARMACEUTICAL & CHEMICAL IND'S L.L.C.
Checked By - U.A.E.
19 MAR 2013
RELEASED
QUALITY CONTROL DEPARTMENT

Approved By