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Julphar
Quality Control Department

شركة الخليج للصناعات الدوائية
رأس الخيمة - ص.ب. ٩٩٧
تليفون: ٢٤٦١٤٦١-٩٧١٧+ فاكس: ٢٤٦٢٤٦٢-٩٧١٧+
الامارات العربية المتحدة

C21-2

C21-2.

NATIONAL QUALITY CONTROL LABORATORY RECEIVED 28 JUL 2016 P.O. Box 29726

Certificate of Analysis
Secondary Reference Standard

Name: Cefotaxime Sodium
Material No: 10000153

Batch No: CTFX160002

Test	Specification	Result
Description	Off-white to pale yellow crystalline powder, free from extraneous substances like black particles.	Conform
Identification	To pass tests under analytical method.	Conform
Loss on drying	NMT 3.0 %	1.74%
Organic impurities (Procedure I)	1- Deacetylcefotaxime: NMT 1.0% 2- Cefetamet: NMT 1.0% 3- Cefotaxime related compound E: NMT 1.0% 4- N-Formyl cefotaxime: NMT 1.0% 5- E-Cefotaxime: NMT 1.0% 6- Cefotaxime dimer: NMT 1.0% 7- Cefotaxime dioxime: NMT 0.20% 8- Any individual unspecified impurity: NMT 0.20% 9- Total impurities: NMT 3.0%	0.27% 0.27% 0.00% 0.00% 0.00% 0.37% 0.14% 0.00% 1.05%
Assay	NLT 916 µg/mg and NMT 964 µg/mg of Cefotaxime ($C_{16}H_{17}N_5O_7S_2$), calculated on the dried basis.	935.48 µg/mg of cefotaxime (as is basis) 952.05 µg/mg (on dried basis)

Standardization date: 14/04/2016

Standardized by: Sathya

Exp. date: 04/2017

Weight per vial: 500mg

Standardized against: Cefotaxime Sodium USP Reference Standard (Lot No: K0I356)

Checked by: Pensee Mohamed, B. S. Pharm
Quality Control Deputy Manager

QUALITY CONTROL Julphar DEPARTMENT

Head of Quality Control Department
Sheikha Khamis