

GULF PHARMACEUTICAL INDUSTRIES

Has Al Khaimah, Post Box No. 997
Tel.: +9717-2461461, Fax: +9717-2462462
United Arab Emirates

Julphar**Quality Control Department**

مصرفة الخليج للصناعات الدوائية

رأس الخيمة - ص.ب. ٩٩٧
تليفون: +٩٧١٧-٢٤٦١٤٦١ فاكس: +٩٧١٧-٢٤٦٢٤٦٢
الإمارات العربية المتحدة



Certificate of Analysis
Secondary Reference Standard

Batch No: 0000035657/II
Insp. Lot No: 10000036380

Test	Specification	Result
Description	White or almost white, crystalline powder or colourless crystals, free from extraneous substances like black particles.	Conform
Identification	To pass tests under analytical method.	Conform
Related substances	Impurity A: NMT 0.50%	0.00%
	Unspecified impurities: NMT 0.50%	0.00%
	Total impurities: NMT 1.0%	0.00%
Assay	NLT 98.0 % and NMT 102.0 % of $C_8H_8O_3$.	99.56% (as is basis)

Standardization date: 01/03/2016

Standardized by: Sathya

Exp. date: 03/2017

Weight per vial: 500mg

Standardized against: Methylparaben USP Reference Standard (Lot No: K1H071)

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



Head of Quality Control Department
Sheikha Khamis

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Julphar**Quality Control Department****شركة الخليج للصناعات الدوائية**

رأس الخيمة - ص.ب. ٩٩٧
تليفون: +٩٧١٧-٢٤٦١٤٦١ فاكس: +٩٧١٧-٢٤٦٢٤٦٢
الإمارات العربية المتحدة

Certificate of Analysis
Secondary Reference Standard

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 ₅ O ₇ S 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

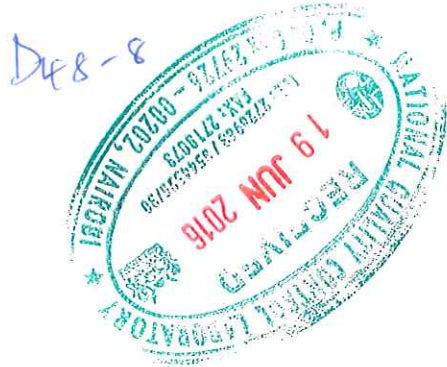
Exp. date: 04/2017

Weight per vial: 500mg.

Standardized against: Cefotaxime Sodium USP Reference Standard (Lot No: K01356)

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

Sheikha
Head of Quality Control Department
Sheikha Khamis



نيوفارما
neopharma

Works : Plot No.A-1, 89-95
Industrial City of Abu Dhabi (ICAD), Mussafah
P. O. Box 72900, Abu Dhabi, UAE
Tel. : 00971 2 550 1000, Fax : 00971 2 550 1199
E-mail : neopharma@neopharma.ae

D48-8

Certificate of Analysis - Working Standard

Certificate of Analysis - Working Standard				
Name of the Working Standard		:	Diclofenac Potassium BP	
Working Standard Reference No.		:	WS877	
Effective Date		:	20/07/2015	
		Valid Up to	:	30/06/2017
Raw Material A. R. No.		:	GPRM40250	
		Page No.	:	1 of 1

S. No.	TEST	SPECIFICATION	RESULT
1.	Description	A white or slightly yellowish, crystalline powder, slightly hygroscopic.	A white crystalline powder, slightly hygroscopic.
2.	Identification (By IR)	The transmission minima (absorption maxima) in the spectrum obtained with the sample being examined correspond in position and relative size to those in the spectrum obtained with Diclofenac Potassium CRS.	The transmission minima (absorption maxima) in the spectrum obtained with the sample being examined corresponds to the position and relative size to those in the spectrum obtained with Diclofenac Potassium CRS.
3.	Loss on Drying (%w/w)	Not more than 0.5	0.10
4.	Assay On dried basis (%w/w)	99.0 to 101.0	100.0
5.	Content (%w/w) On as is basis	-	99.89

Storage Condition: Store in a well closed container protected from light at a temperature between 2° and 8°C.

Remarks: The sample can be used for routine analysis as working standard.

Direction for use: Use as such.

Checked By		Approved By	
Sign/Date	: 05/15/06/16	Sign/Date	: 05/15/06/16
Name	: Mr. Vijay Kumar B.N	Name	: Mr. Sunnynchan T.D.
Designation	: Sr. Executive - Quality Control	Designation	: Manager - Quality Control



Form: 9A34/02R2