GULF PHARMACEUTICAL INDUSTRIES
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United Arab Emirates

Julphar
Quality Control Department

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

M35-2

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
28 JUL 2016
P.O. BOX

M35-2

Certificate of Analysis
Secondary Reference Standard

Name: Methylparaben
Material No: 10000444

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

QUALITY CONTROL
Julphar

Head of Quality Control Department
Sheikha Khamis

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شركة الخليج للصناعات الدوائية
رأس الخيمة - ص.ب. ٩٩٧
تليفون : ٢٤٦١٤٦١-٠٧١٧+ فاكس : ٢٤٦٢٤٦٢-٠٧١٧+
الامارات العربية المتحدة

C21-2

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

C21-2.

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 1)	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

D48-8

neopharma
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Tel. : 00971 2 550 1000, Fax : 00971 2 550 1199
E-mail : neopharma@neopharma.ae

D48-8

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	:	15/06/16	Sign/Date	:	15/06/16
Name	:	Mr. Vijay Kumar B.N	Name	:	Mr. Sunnychan T.D.
Designation	:	Sr. Executive – Quality Control	Designation	:	Manager - Quality Control

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Form: 9A34/02R2