GULF PHARMACEUTICAL INDUSTRIES

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Julphar

Quality Control Department

شردة الخليج للصناعات الدوانية

اس الخيمة - ص.ب. ٩٩٧ لليفون : ٢٤٦٢٤٦١ - ٩٧١٧ فاكس : ٢٤٦٢٤٦٢ - ٩٧١٧. لامارات العربية المتحدة

WRS H12-1

Name: Hydrocortisone

Material No: 10000367

Certificate of Analysis
Secondary Reference Standard

2 4 MAY 2016

Batch No: 00000 16798/11/0

		Box 29726 - 0310	
Test	Specification	Result	
Description	White or almost white crystalline powder, free from extraneous substances like black particles.	Conform	
Identification	To pass tests under analytical method.	Conform	
Loss on drying	NMT 1.0%	0.12%	
Related substances	Impurity A: NMT 0.20%	0.051%	
	Impurity B: NMT 0.20%	0.00%	
	Impurity C: NMT 0.50%	0.00%	
	Impurity D: NMT 0.50%	0.00%	
	Impurity E: NMT 0.50%	0.00%	
	Impurity F: NMT 0.30%	0.00%	
	Impurity G: NMT 0.20%	0.058%	
	Impurity H: NMT 0.15%	0.00%	
	Impurity I: NMT 0.50%	0.00%	
	Impurity N: NMT 0.15%	0.00%	
	Unspecified impurities (for each impurity): NMT 0.10%	0.071%	
	Total impurities: NMT 2.0%	0.18%	
Assay	NLT 97.0 % and NMT 103.0 % of C ₂₁ H ₃₀ O ₅ , calculated on the dried substance.	99.28% (as is basis) 99.40% (on dried basis)	

Standardization date: 05/04/2016

Standardized by: Ejaz

Exp. date: 04/2017

Weight per vial: 500mg

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

Head of Quality Control Department

Ilphar

Sheikha Khamis