



of Human & Veterinary Medicines

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CERTIFICATE OF ANALYSIS

WORKING STANDARD

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	WS1405046
	13 x 5g
	140128
	01/2019

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Working standard name: PREDNISOLONE	Working standard Ref No: WS1405046
Date of standardization: 05/05/2014	Working standard Quantity: 13 x 5g
Raw material source: TIANJIN TIANMAO TECHNOLOGY DEVELOPMENT CORPLED	Raw material Batch No: 140128
Raw material manufacturing date: 01/2014	Raw material Expiry date: 01/2019
Chemical Reference standard Batch number: 2766	Chemical Reference standard catalogue number:464
Chemical Reference standard source: BP	Intended use of working standard: Analysis of raw materials and finished products

RESULTS OF ANALYSIS

TESTS	SPECIFICATIONS	RESULTS
Physical appearance	A white or almost white, crystalline powder, hygroscopic.	A white crystalline powder
identification i.IR	The infrared absorption spectrum is concordant with the reference spectrum of Prednisolone.	Complies
ii. Liquid chromatography	The principal peak in the chromatogram obtained with test solution (b) is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (d).	Complies
Loss on drying	Not more than 1.00 percent	0.19%
Assay	96.50 per cent to102.00 per cent, calculated with reference to the dried substance.	99.81%
Conclusion: The working	standard has been qualified for use.	

Name of Analyst : J. Tati	Name of QCM :C. Otieno	Name of QAM :Dr. S. Muigai
Signature:	Signature:	Signature:
Date: 05/05/2014	Date: osloslik	Date: OS) ps/2014