5. Estándar de trabajo - Working Stadard

a) Certificado de análisis

Estándar de trabajo #WS/GMS/15/01 elaborado por Ciron Drugs & Pharmaceutical PVT LTD.

CIRON DRUGS & PHARMACEUTICALS PVT. LTD.
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Quality Control Department

T.		CATE OF ANALYSIS RENCE (WORKING) STANDARD		
Standard Name	Gentamycin Sulphate BP		88	
Reference Specification No.	CI/RM/QA/994/02	Sampled Qty. & Sampling Date	14.0 gm	
- 2000000000000000000000000000000000000		Analytical Report No.	QC/WS/GMS/15/01	
Batch No.	WS/GMS/15/01	Analysis Started Date	30/04/2015	
Quantity Standardized	14.0 gm	Analysis Completed Date	02/05/2015	
Standard Valid up to	01/05/2016	Reported Date	02/05/2015	

Raw Material Details (Selected for Standardization)				
Batch No.	14122899	GRN No.& Date	15/IRM/01/0537	
Mfg. Date	18/12/2014	Manufacturer	Yantaj Justware Pharma	
Exp. Date	17/11/2018	Supplier	Prime Pharmachem	

Primary Reference Standard Name	CRS of Gentamycin Sulphate BP			
Batch/Lot No.	2898	GRN No.& Date	NA	
Mfg. Date	NA	Quantity Received	50 mg	
Exp. Date	NA	Manufacturer	BP	

Sr. No.	Name of tests	Specifications	Results
1	Description	White or almost white, hygroscopic powder.	Almost white, hygroscopic powder.
2	Identification	Gives reaction of sulfates	A white precipitate is formed.
3	Water NMT 15.0% 12.51%		12.51%
4	Assay	NLT 590 IU/mg	605.05 IU/mg (As is basis) 691.56 IU/mg (On anhydrous basis)

Remarks	:	The above sample has been evaluated against primary reference standard Gentamycin Sulpahte BP CRS LOT 2898 and Complies/ Does Not Complies as per BP specification.
Conclusion	1	The sample is standardized & qualified for use as Gentamycin Sulphate BP Secondary Reference (Working) Standard till date 02/05/2016
Packing	:	10 ml amber glass vial, USP type I plugged with 20 mm rubber plug and sealed with 20 mm tear-off aluminum seal.
Storage Condition	1	Store below temp. 25°C. Protected from light

	Prepared By	Reviewed By	Approved By /	Authorized By
Sign & Date	(F) 2015	? Juggostoors	Mullian Room	(Mawhan 201201
Name	Pritam Gosavi	Shankar Shinde	Balaji Jadhav	Hemangi Chawhan
Designation	QC Officer	Micro Asst. Manager	Quality Control Manager	Quality Assurance Asst. Manager

Format No.: C1QC/F/199-00

