

5. Estándar de trabajo - Working Standard

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

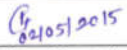
CERTIFICATE OF ANALYSIS SECONDARY REFERENCE (WORKING) STANDARD			
Standard Name	Gentamycin Sulphate BP		
Reference Specification No.	CI/RM/QA/994/02	Sampled Qty. & Sampling Date	14.0 gm
Batch No.	WS/GMS/15/01	Analytical Report No.	QC/WS/GMS/15/01
Quantity Standardized	14.0 gm	Analysis Started Date	30/04/2015
Standard Valid up to	01/05/2016	Analysis Completed Date	02/05/2015
		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	Yantai 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%
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 Sulphate BP CRS LOT 2898 and Complies/ Does Not Complies as per BP specification.
Conclusion	: 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	: Store below temp. 25°C. Protected from light

	Prepared By	Reviewed By	Approved By	Authorized By
Sign & Date	 02/05/2015	 02/05/2015	 02/05/2015	 02/05/2015
Name	Pritam Gosavi	Shankar Shinde	Balaji Jadhav	Hemangi Chawhan
Designation	QC Officer	Micro Asst. Manager	Quality Control Manager	Quality Assurance Asst. Manager

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