

CERTIFICATE OF ANALYSIS

Product : **GENTAMICIN SULPHATE**
Product number : G0124
Batch number : 006616
Date of production : xx-06-2009
Date of analysis : xx-06-2009
Date of expiry : 31-05-2014

Packaging and storage : Store at room temperature

	SPECIFICATION	RESULT	UNITS	REMARKS
Description	white or almost white, powder	complies		hygroscopic
Identification	conform	complies		
Appearance of solution	clear and colour $\leq$ ref. sol. 6	complies		4% in H ₂ O
pH	3.5 – 5.5	4.9		4% in H ₂ O
Specific optical rotation	+107 - +121	+119	°	10% in H ₂ O
Composition:				HPLC
- Gentamicin C1	20.0 – 40.0	29	%	
- Gentamicin C1a	10.0 – 30.0	28	%	
- Σ (Gentamicin C2, C2a, C2b)	40.0 – 60.0	43	%	
Related substances:				HPLC
- any impurity	$\leq$ 3.0	1.3	%	
- total	$\leq$ 10.0	3.2	%	
Methanol	$\leq$ 1.0	complies	%	GC
Sulphate	32.0 – 35.0	34.2	%	anhydrous substance
Water	$\leq$ 15.0	9.7	%	Karl Fischer
Sulphated ash	$\leq$ 1.0	0.2	%	
Potency:				
- anhydrous substance	$\geq$ 590	633	I.U./mg	
- as it is		572	I.U./mg	

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

drs. J.A.M. Rutgers, pharmacist
Department of Quality Control Duchefa BV

Date: 15-07-2011

