

CERTIFICATE OF ANALYSIS

Product : **GLYCINE**
Product number : **G0709**
Batch number : **006938**
Date of manufacturing : **23-06-2009**
Expiry date : **23-06-2013**

	SPECIFICATION	RESULT	UNITS	REMARKS
Description	white crystalline powder	complies		
Identity:				
- A (IR-spectrum)	conform	complies		
- C (resorcinol)	conform	complies		
Appearance of solution	clear and colour $\leq Y_7$	complies		10% in H ₂ O
Residual solvents	conform	complies		USP
pH	5.90 – 6.40	6.10		5% in H ₂ O
Chlorides	≤ 40	6	ppm	
Heavy metals	≤ 10	< 10	ppm	EP/USP
Loss on drying	≤ 0.2	0.04	%	USP
Hydrolysable substances	conform	complies		USP
Ninhydrine-positive substances	≤ 0.5	complies	%	EP
Sulphated ash	≤ 0.1	< 0.01	%	EP
Sulphate	≤ 50	< 50	ppm	USP
Residue on ignition	≤ 0.1	< 0.01	%	USP
Arsenic	≤ 1	< 0.2	ppm	AAS
Iron	≤ 10	< 0.2	ppm	ICP
Ammonium	≤ 200	57	ppm	
Monochloroacetic acid	≤ 0.025	complies	%	HPLC
Iminodiacetic acid	≤ 0.05	complies	%	HPLC
Methanol	≤ 200	64	ppm	GC
Hexamethylenetetramine	≤ 0.03	complies	%	HPLC
Microbiology:				
- endotoxines	≤ 3.0	< 1.25	IU/g	
- total bacteriological counts	≤ 100	2	CFU/100 g	
Assay	98.5 – 101.0	99.4	%	EP/USP

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: 08-11-2010.

