

CERTIFICATE OF ANALYSIS

Product : **TICARCILLIN DISODIUM / CLAVULANATE POTASSIUM 15:1**
 Product number : T0190
 Batch number : 007809
 Date of production : 09-02-2011
 Date of analysis : 11-04-2011
 Date of expiry : 31-01-2013

Packaging and storage : Store dry at 2 – 8 °C. This product is hygroscopic.

	SPECIFICATION	RESULT	UNITS	REMARKS
Description	white to pale yellow powder	white powder		
Identification:	conform	complies		HPLC
pH	5.5 – 7.5	7.3		1% in H ₂ O
Constituted solutions	conform	complies		
Water	≤ 4.2	0.95	%	Karl Fischer
Bacterial endotoxins	< 0.07	complies	EU/mg Tiracillin	USP
Sterility	conform	complies	%	
Particulate matter	≥10 µm ≤1500	268	pc/g	
	≥25 µm ≤150	14	pc/g	
Assay ticarcillin	≥ 75.4	84.3	%	HPLC, anhydrous
Assay clavulanic acid	≥ 4.8	5.1	%	HPLC, anhydrous
Ratio ticarcillin : clavulanic acid	13.5 – 16.5	16.5		anhydrous basis

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

Conclusion: approved

Released by:

drs. D. Blok, pharmacist

Department of Quality Control Duchefa BV

Date: 01-07-2011.

p/o
[Signature]
S. de Bree