

CERTIFICATE OF ANALYSIS

Product : **AMOXICILLIN SODIUM/CLAVULANATE POTASSIUM 5:1 (Augmentin)**
 Product number : A0189
 Batch number : 018308
 Date of production : 12-03-2019
 Date of analysis : 13-03-2019
 Date of expiry : 31-03-2025

Packaging and storage : in a well-closed container, protected from light at a temperature of 2 – 8 °C

	SPECIFICATION	RESULT	UNITS	REMARKS
Description	white or almost white powder	complies		
Identification	conform	complies		HPLC
pH	8.0 – 10.0	9.0		
Appearance of solution	clear and colour ≤ ref. sol. Y ₆ or YG ₆	complies		
Water	≤ 4.0	0.65	%	
Related substances:				
- any impurity	≤ 2.0	0.17	%	
- total impurities	≤ 5.0	0.29	%	
Particle matter:				
- NLT 10 µm	≤ 6000	354	pc/1.2g	
- NLT 25 µm	≤ 600	4	pc/1.2g	
Assay:				
- Amoxicillin	≥ 660	733	µg/mg	
- Clavulanic acid	≥ 132	143	µg/mg	
- Ratio	(4.65 – 5.35):1	5.13:1		

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

Conclusie: goedgekeurd

Vrijgifte door:

drs. M. van Wissen, apotheker
Kwaliteitsbewaking Duchefa Biochemie B.V.

Datum: 31-01-2024



The buyer is responsible to test each batch to ensure the product is suitable for their specific purpose.

Duchefa Biochemie B.V.