



V.M.D nv/sa
Hoge Mauw 900
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Tel : 32 (0)14 67 20 51
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Certificate of analysis

P000054
Clavucill 200 mg/50 mg, 10 x 10 tablets
Batch number : 23296008B10
Expiry date : 09/2025
Manufacturing date : 08/09/2023

Control number : COA005169
Quality order : QQ017210/Pass

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Test	Requirements	Results
Appearance	CF Pale pink, rounded, one side scored, uncoated tablet with a diameter of 14.5 mm	CF
Water content (by K.F.) :	0.0 - 5.5 %	4.1 %
Thickness	4.20 - 4.50 mm	4.33 mm
Diameter	14.40 - 14.70 mm	14.57 mm
Uniformity of dosage units	CF - Complies if the acceptance value is less than or equal to 15.0 calculated with the first 10 dosage units. - If the acceptance value is greater than 15.0 the test complies if the acceptance value, calculated with the first 10 + 20 additional dosage units, is less than or equal to 15.0 and no individual content of the dosage unit is less than 0.75 nor more than 1.25 of the mean of the individual contents (expressed as percentage of the label claim).	CF
Hardness	10 - 30 kp	26 kp
Average weight	855.0 - 945.0 mg Not more than 2 individual tablets deviate more than 7,5% from the average weight. No individual tablet deviates more than 10% from the average weight.	898.7 mg mg
Friability	0.0 - 1.0 %	0.0 %
Desintegration time	0 - 15 min	8 min
Dissolution of Amoxicillin	≥ 85.0 % Minimum 85% within 15 minutes, Q = 80%	81.9 % %
Remarks :	Test results digitally approved by Jo Wouters, on 16/04/2024 Batch disposition code RELEASED on : 17/04/2024 Electronically signed by : Leo Aerden: Qualified Person	



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Test	Requirements	Results
Dissolution of Clavulanic acid	≥ 85.0 % Minimum 85% within 15 minutes, Q = 80%	104.8 % %
Identification of Amoxicillin (HPLC) :	Positive The retention times, peak shapes and peak sizes of the main peaks in the chromatograms obtained during the assay of the test solution should be exactly the same as those obtained with the reference solution.	Positive
Identification of Clavulanic acid (HPLC)	CF The retention times, peak shapes and peak sizes of the main peaks in the chromatograms obtained during the assay of the test solution should be exactly the same as those obtained with the reference solution.	CF
Identification of Amoxicillin (TLC) :	Positive The principle spots in the chromatogram obtained with the test solution are similar in position, shape and colour to those in the chromatogram obtained with the reference solution.	Complies if tested
Identification of Clavulanic acid (TLC)	CF The principle spots in the chromatogram obtained with the test solution are similar in position, shape and colour to those in the chromatogram obtained with the reference solution.	Complies if tested
Identification of Erythrosine (UV-VIS Spectrophotometry)	Positive The spectrum of the test	Complies if tested

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Test	Requirements	Results
	solution, between 350 and 700 nm, must be similar in shape and size compared to the reference spectrum. The maximum absorbance is observed at 530 nm.	
Assay of Amoxicillin	190.0 - 210.0 mg/tablet	200.0 mg/tablet
Assay of Clavulanic acid	50.0 - 55.0 mg/tablet	51.4 mg/tablet
Degradation products Amoxicillin:Max impurity p-OH-phenylgly	0.0 - 1.0 %	0.1 %
Degradation products Amoxicillin:Max Impurity D (RRT~0.7)	0.0 - 1.0 %	0.1 %
Degradation products Amoxicillin: Max Impurity A (RRT~0.8)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max Impurity B (RRT~0.9)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max Impurity E (RRT~2.6)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max impurity C;2R (RRT~3.3)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max impurity C;2S (RRT~3.4)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max Impurity J;n=1 (RRT~4.1)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max Impurity J;n=2 (RRT~5.7)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max impurity UI1 (RRT~0.65)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max impurity UI2 (RRT~1.2)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max impurity UI3 (RRT~1.5)	0.0 - 1.0 %	0.1 %
Degradation products Amoxicillin:Max impurity UI4 (RRT~3.6)	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max impurity UI5 (RRT~4.2)	0.0 - 1.0 %	0.2 %
Degradation products Amoxicillin:Max impurity UI6 (RRT~4.3)	0.0 - 1.0 %	0.5 %
Degradation products Amoxicillin:Max of any unspecified	0.0 - 1.0 %	0.1 %
Degradation products Amoxicillin:Max	0.0 - 4.0 %	0.5 %

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Test	Requirements	Results
Total impurities		
Degradation products Clavulanic acid: Max Imp 1(RRT~0.30)	0.0 - 1.0 %	0.0 %
Degradation products Clavulanic acid:Max Imp 2 (RRT~0.50)	0.0 - 1.0 %	0.0 %
Degradation products Clavulanic acid:Max Imp 3 (RRT~0.63)	0.0 - 1.0 %	0.0 %
Degradation products Clavulanic acid:Max Imp 4 (RRT~0.71)	0.0 - 1.0 %	0.0 %
Degradation products Clavulanic acid:Max Imp 5 (RRT~1.05)	0.0 - 1.0 %	0.1 %
Degradation products Clavulanic acid:Max Imp 6 (RRT~1.35)	0.0 - 1.0 %	0.0 %
Degradation products Clavulanic acid: Max of any unspecified	0.0 - 1.0 %	0.0 %
Degradation products Clavulanic acid:Max Total impurities	0.0 - 2.0 %	0.0 %
Total aerobic microbial count (TAMC)	0 - 1000 CFU/g Maximum 10 ³ bacteria/g	Complies if tested
Absence of Escherichia coli :	CF Absent in 1g	Complies if tested
Total combined yeasts/moulds count (TYMC)	0 - 100 CFU/g Maximum 10 ² yeasts-mould/g	Complies if tested

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