



V.M.D nv/sa
Hoge Mauw 900
2370 Arendonk
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Certificate of analysis

P000043

Clavucill 40 mg/10 mg, 10 x 10 tablets

Batch number : 23296009C11

Expiry date : 10/2025

Manufacturing date : 07/10/2023

Control number : COA005171

Quality order : QO017105/Pass

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Test	Requirements	Results
Appearance	CF Pale pink, rounded, one side scored, uncoated tablet with a diameter of 8mm	CF
Water content (by K.F.) :	0.0 - 5.5 %	5.1 %
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 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.	Positive
Identification of Erythrosine (UV-VIS Spectrophotometry)	Positive The spectrum of the test 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.	Positive
Assay of Amoxicillin	38.0 - 42.0 mg/tablet	38.0 mg/tablet
Assay of Clavulanic acid	10.0 - 11.0 mg/tablet	10.4 mg/tablet
Degradation products Amoxicillin:Max impurity p-OH-phenylgly	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max Impurity D (RRT~0.7)	0.0 - 1.0 %	0.2 %
Degradation products Amoxicillin: Max Impurity A (RRT~0.8)	0.0 - 1.0 %	0.0 %
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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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 %	0.2 %
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 %	0.2 %
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 %	0.1 %
Degradation products Amoxicillin:Max impurity UI3 (RRT~1.5)	0.0 - 1.0 %	0.0 %
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 %	0.7 %
Degradation products Amoxicillin:Max of any unspecified	0.0 - 1.0 %	0.0 %
Degradation products Amoxicillin:Max Total impurities	0.0 - 4.0 %	0.7 %
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 %	0.0 %
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 %

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Test	Requirements	Results
Degradation products Clavulanic acid:Max Total impurities	0.0 - 2.0 %	0.0 %
Dissolution of Amoxicillin	≥ 85.0 % Minimum 85% within 15 minutes, Q = 80%	87.3 % %
Dissolution of Clavulanic acid	≥ 85.0 % Minimum 85% within 15 minutes, Q = 80%	105.2 % %
Average weight	171.0 - 189.0 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.	180.5 mg mg
Thickness	2.70 - 2.90 mm	2.74 mm
Diameter	7.90 - 8.05 mm	8.04 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 - 15 kp	13 kp
Friability	0.0 - 1.0 %	0.0 %
Desintegration time	0 - 15 min	7 min

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Test	Requirements	Results
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
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 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.	CF

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