SZMU-RU-09_6_2.sz.melléklet

Livestock **pharma**

BIZONYLAT

A készítmény neve:	Clavucill 400mg/100mg tabletta kutyák részére A.U.V
Kiszerelés:	50 x 2 tabletta (100x)
Gyártási szám:	21296004B
Gyártás időpontja:	2021.03.03
Lejárati idő:	03/2023
Átadott mennyiség:	160 db
Gyártó/Felszabadító:	V.M.D. nv
Felszabadítási bizonylat száma:	NKR-VMD-013/21/01

A mellékelt 2021.06.03.-i dátummal kiállított gyártói késztermék felszabadítási bizonylat alapján a készítmény 21296004B gyártási számú tétele kielégíti a magyarországi forgalomba hozatali engedélyben foglalt követelményeket.

A 160 db 21296004B gyártási számú „Clavucill 400mg/100mg tabletta kutyák részére A.U.V" készítményt nagykereskedelmi forgalomba bocsátom.

Budapest, 2021. 06. 22.

dr. Nagy Beáta
V.M.D. Állatgyógyászati Kft.
Minőségügyi felelős

V.M.D. nv/sa
BTW/TVA: BE0413.622.648
IBAN: BE13 4134 5131 0139

CERTIFICATE OF ANALYSIS

Product: ***CLAVUCILL 400 mg/100 mg***
Tablets, aluminium foil strip
Product code: ***BO-AMOXI-0008-A1803 (HUN)***
Batch N°: ***21296004B***
Manufacturing Date: ***03/03/2021*** **Expiry Date:** ***03/2023***
Quantity: ***160 boxes of 100 tablets***

TESTS	*SPECIFICATIONS*	*RESULTS*
Appearance:	Pale pink, rounded, one side scored, uncoated tablet with a diameter of 18.3 mm.	*Complies*
Water content:	Maximum 5.5 %	*4.5 %*
Identifications:		
- Amoxicillin / clavulanic acid: (H.P.L.C.)	The retention times of the major peaks in the chromatograms obtained during the assay of the test sample correspond to those obtained with the reference sample.	*Positive*
- Amoxicillin / clavulanic acid*: (T.L.C. – every fifth batch)	The principle spots in the chromatogram obtained with the reference solution are similar in position and colour to those in the chromatogram obtained with the test solution.	*Positive**
- Erythrosine*: (UV-VIS Spectrometry - every fifth batch)	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**
Assays:		
- Amoxicillin:	400.0 (380.0 – 420.0) mg/tablet	*392.0 mg/tabl.*
- Clavulanic acid:	100.0 (100.0 – 110.0) mg/tablet	*104.4 mg/tabl.*
Related substances/Degradation products:		
Amoxicillin		
- Specified identified:		
- p-OH-phenylglyc. (RRT~0.4)	Max. 1.0 %	*0.0 %*
- Impurity D (RRT~0.7)	Max. 1.0 %	*0.3 %*
- Impurity A (RRT~0.8)	Max. 1.0 %	*0.0 %*
- Impurity B (RRT~0.9)	Max. 1.0 %	*0.0 %*
- Impurity E (RRT~2.6)	Max. 1.0 %	*0.0 %*
- Impurity C;2R (RRT~3.3)	Max. 1.0 %	*0.1 %*
- Impurity C;2S (RRT~3.4)	Max. 1.0 %	*0.1 %*
- Impurity J;n=1 (RRT~4.1)	Max. 1.0 %	*0.1 %*
- Impurity J;n=2 (RRT~5.7)	Max. 1.0 %	*0.0 %*
- Specified unidentified:		
- UI1 (RRT~0.65)	Max. 1.0 %	*0.0 %*
- UI2 (RRT~1.2)	Max. 1.0 %	*0.1 %*
- UI3 (RRT~1.5)	Max. 1.0 %	*0.1 %*
- UI4 (RRT~3.6)	Max. 1.0 %	*0.2 %*
- UI5 (RRT~4.2)	Max. 1.0 %	*0.9 %*
- UI6 (RRT~4.3)	Max. 1.0 %	*0.1 %*
- Any unspecified:	Max. 1.0 %	*0.0 %*
- Total:	Max. 4.0 %	*0.9 %*

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Clavulanic acid		
- Specified unidentified:		
- Impurity 1 (RRT~0.30)	Max. 1.0 %	*0.0 %*
- Impurity 2 (RRT~0.50)	Max. 1.0 %	*0.0 %*
- Impurity 3 (RRT~0.63)	Max. 1.0 %	*0.0 %*
- Impurity 4 (RRT~0.71)	Max. 1.0 %	*0.0 %*
- Impurity 5 (RRT~1.05)	Max. 1.0 %	*0.0 %*
- Impurity 6 (RRT~1.35)	Max. 1.0 %	*0.1 %*
- Any unspecified:	Max. 1.0 %	*0.0 %*
- Total:	Max. 2.0 %	*0.0 %*
Dissolution:		
- Amoxicillin:	Minimum 85.0 % within 15 minutes	*96.1 %*
- Clavulanic acid:	Minimum 85.0 % within 15 minutes	*104.5 %*
Weight:	1800.0 mg ± 5 % (1710.0 – 1890.0)	*1825.8 mg*
Thickness:	5.50 – 6.50 mm	*5.55 mm*
Diameter:	18.20 – 18.50 mm	*18.43 mm*
Uniformity of dosage units:	- 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).	*Complies*
Hardness:	15 – 40 kp	*33 kp*
Friability:	Maximum 1.0 %	*0.0 %*
Disintegration:	≤ 15 minutes	*7.5 min.*
Microbiological quality*:		
- TAMC:	Maximum 10^3 bacteria/g	*Complies**
- TYMC:	Maximum 10^2 yeasts-moulds/g	*Complies**
- Escherichia coli:	Absent in 1 g.	*Absent**

* complies, if tested

Conclusion: The product meets the requirements

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Name and signature of the Qualified Person:
Date: 03/06/2021

L. Aerden
Qualified Person
V.M.D. nv