1295/2016/VET
2016-02-16

NOVARTIS

Novartis Santé Animale S.A.S.
26, rue de la Chapelle
BP 224
68332 HUNINGUE Cedex
Number of manufacturing Authorisation : V 827/87/2

CERTIFICATE OF ANALYSIS

Product	MILBEMAX FC 16/40 MG 5X10 CP '147'	Batch n° :	71097
Product Code	600724147A00	Specification	SPPF00901 - 002
File Number	DS0836641	UC concerned	1 UC/ 1
Manufacturing	02/03/2015		
Expiry Date	03/2018		

Tests	Specification	Results
GENERAL INFORMATION		
Current method version	BE-328.H.3 & BE-328 AUS.1	Complies
CHARACTERS		
Appearance	Reddish to reddish-brown, ovaloid tablet, scored on both sides. One side bears imprint "KK", the other side "NA". Length : approx. 9.1 mm Broadness : approx. 5.3 mm Thickness : approx. 3.9 mm	Complies
Mean mass	126 to 139 mg	132 mg
Divisibility	Tablet halves meet the requirement of Ph. Eur., Procedure 07/2006:0478 "Tablets", Subdivision of Tablets	Complies
Loss on drying	Not more than 6 %	2 %
IDENTIFICATIONS		
Iron	Positive	Complies
Praziquantel by TLC	Corresponds qualitatively to the reference	Complies
Milbemycin oxime by TLC	Corresponds qualitatively to the reference	Complies
Praziquantel by LC	Corresponds qualitatively to the reference	Complies
Milbemycin oxime by LC	Corresponds qualitatively to the reference	Complies
BY PRODUCTS		
Related substances (LC) (detection limit 0.05 %)	Not more than 0.5 % each based on the sum of the declared contents of praziquantel and milbemycin oxime	0.20 %
Total related substances by LC	Not more than 2 % based on the sum of the declared contents of praziquantel and milbemycin oxime	0.2 %
ASSAY		
Dissolution of Praziquantel after 15 min (LC)	Meets the requirements of the Paddle method USP "711" : not less than 30% of the declared content (Q-value)	Complies
Dissolution of Praziquantel after 15 min (LC), lowest value	Not less than Q+5% for n=6 or Not less than Q-15% for n=12 Not more than 2 units are less than Q-15 %, and no unit is less than Q -25 % for n=24 (Q=30%)	82 %
Dissolution of Praziquantel after 15 min (LC), highest value	Not less than Q+5% for n=6 or Not less than Q-15% for n=12 Not more than 2 units are less than Q-15 %, and no unit is less than Q -25 % for n=24 (Q=30%)	84 %

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Dissolution of Praziquantel after 15 min (LC), mean	Not less than Q+5% for n=6 or Average is equal to or greater than Q for n=12 and n=24 (Q=30%)	83 %
Dissolution of Praziquantel after 15 min, with n=	6, 12 or 24	6
Dissolution of Praziquantel after 60 min (LC)	Meets the requirements of the Paddle method USP "711" : not less than 70% of the declared content (Q-value)	Complies
Dissolution of Praziquantel after 60 min (LC), lowest value	Not less than Q+5% for n=6 or Not less than Q-15% for n=12 Not more than 2 units are less than Q-15% and no unit is less than Q-25% for n=24 (Q=70%)	98 %
Dissolution of Praziquantel after 60 min (LC), highest value	Not less than Q+5% for n=6 or Not less than Q-15% for n=12 Not more than 2 units are less than Q-15% and no unit is less than Q-25% for n=24 (Q=70%)	100 %
Dissolution of Praziquantel after 60 min (LC), mean	Not less than Q+5% for n=6 or Average is equal to or greater than Q for n=12 and n=24 (Q=70%)	99 %
Dissolution of Praziquantel after 60 min, with n=	6, 12 or 24	6
Dissolution of Milbemycin oxime after 15 min (LC)	Meets the requirements of the Paddle method USP "711" : not less than 30% of the declared content (Q-value)	Complies
Dissolution Milbemycin oxime after 15 min (LC), lowest value	Not less than Q+5% for n=6 or Not less than Q-15% for n=12 Not more than 2 units are less than Q-15% and no unit is less than Q-25% for n=24 (Q=30%)	67 %
Dissolution Milbemycin oxime after 15 min (LC) highest value	Not less than Q+5% for n=6 or Not less than Q-15% for n=12 Not more than 2 units are less than Q-15% and no unit is less than Q-25% for n=24 (Q=30%)	68 %
Dissolution of Milbemycin oxime after 15 min (LC), mean	Not less than Q+5% for n=6 or Average is equal to or greater than Q for n=12 and n=24 (Q=30%)	68 %
Dissolution of Milbemycin oxime after 15 min, with n=	6, 12 or 24	6
Dissolution of Milbemycin oxime after 60 min (LC)	Meets the requirements of the Paddle method USP "711" : not less than 70% of the declared content (Q-value)	Complies
Dissolution Milbemycin oxime after 60 min (LC), lowest value	Not less than Q+5% for n=6 or Not less than Q-15% for n=12 Not more than 2 units are less than Q-15% and no unit is less than Q-25% for n=24 (Q=70%)	94 %

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Dissolution Milbemycin oxime after 60 min (LC) highest value	Not less than Q+5% for n=6 or Not less than Q-15% for n=12 Not more than 2 units are less than Q-15% and no unit is less than Q-25% for n=24 (Q=70%)	96 %
Dissolution of Milbemycin oxime after 60 min (LC), mean	Not less than Q+5% for n=6 or Average is equal or greater than Q for n =12 and n= 24 (Q=70%)	95 %
Dissolution of Milbemycin oxime after 60 min, with n=	6, 12 or 24	6
Praziquantel, Uniformity of Dosage Units by LC	Meets requirements of Ph. Eur. 2.9.40 "Uniformity of Dosage Units"	Complies
Praziquantel Uniformity of Dosage Units, lowest value	Lowest value	99.3 %
Praziquantel Uniformity of Dosage Units, highest value	Highest value	101.7 %
Praziquantel Uniformity of Dosage Units with n=	10 or 30	10
Praziquantel Uniformity of Dosage Units: Acceptance value VA	Not more than 15.0	2.2
Milbemycin oxime Uniformity of Dosage Units	Meets the requirements of Ph. Eur. 2.9.40 "Uniformity of Dosage Units"	Complies
Milbemycin oxime Uniformity of Dosage Units, lowest value	Lowest value	99.0 %
Milbemycin oxime Uniformity of Dosage Units : highest value	Highest value	101.8 %
Milbemycin oxime Uniformity of Dosage Units with n=	10 or 30	10
Milbemycin oxime Uniformity of Dosage : Acceptance value VA	Not more than 15.0	2.4
Praziquantel assay by LC	95.0 to 105.0 % ot the declared content	100.9 %
Milbemycin oxime assay,LC	95.0 to 105.0 % of the declared content	100.3 %
PACKAGING		
Packaging control	Corresponds to the specification	Complies

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated / manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.
BATCH RELEASED on 27 july 2015 by LEGRAND KEVIN, Deputy, Authorized Person

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