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СЕРТИФИКАТ АНАЛИЗА CERTIFICATE OF ANALYSIS

STOMORGYL 20

ПАРТИЯ ТОВАРА: S1T1531AA
COMMERCIAL LOT: S1T1531AA

ФОРМА ВЫПУСКА: STOMORGYL 20 / BOX 10 TABLETS
PRESENTATION: STOMORGYL 20 / BOX 10 TABLETS

НОМЕР ПАРТИИ ФАСОВКИ: S1T1531A
FILLED PRODUCT LOT NUMBER: S1T1531A

ДАТА ИЗГОТОВЛЕНИЯ: 08-Октябрь-2019
MANUFACTURING DATE:
08-October-2019

СРОК ГОДНОСТИ: 09/2022
EXPIRY DATE: 09/2022

**МЫ ПОДТВЕРЖДАЕМ, ЧТО ДАННЫЙ ПРОДУКТ ОТВЕЧАЕТ
ТРЕБОВАНИЯМ КОМПЕТЕНТНЫХ ОРГАНОВ
WE CERTIFY THIS PRODUCT MEETS THE REQUIREMENTS OF THE
COMPETENT AUTHORITIES**

Подпись / Должность
Signature / Function
Jérôme LORET / Qualified Person

Dr Samuel BARTOLI
Deputy Qualified Person
Boehringer - Ingelheim
Animal Health France





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TESTS	THRESHOLDS	RESULTS
APPEARANCE	PINK CIRCULAR CONVEX SCORED TABLET	PINK CIRCULAR CONVEX SCORED TABLET
UNIFORMITY OF MASS	NOT MORE THAN 2 OF 20 INDIVIDUAL VALUES DEVIATE FROM AVERAGE MASS BY MORE THAN 5 % AND NONE DEVIATES BY MORE THAN 10 %	NOT MORE THAN 2 OF 20 INDIVIDUAL VALUES DEVIATE FROM AVERAGE MASS BY MORE THAN 5 % AND NONE DEVIATES BY MORE THAN 10 %
DISINTEGRATION	R ≤ 30 min	6 min
DISSOLUTION OF SPIRAMYCIN	COMPLIES WITH PH. EUR. 2.9.3 (45 MIN)	COMPLIES WITH PH. EUR. 2.9.3 (45 MIN)
Q	R = 75 %	75 %
AVERAGE (N=6)	R ≥ 80 %	103 %
DISSOLUTION OF METRONIDAZOLE	COMPLIES WITH PH. EUR. 2.9.3 (45 MIN)	COMPLIES WITH PH. EUR. 2.9.3 (45 MIN)
Q	R = 75 %	75 %
AVERAGE (N=6)	R ≥ 80 %	97 %
IDENTIFICATION OF METRONIDAZOLE	RT IDENTICAL TO THE REFERENCE (HPLC)	RT IDENTICAL TO THE REFERENCE (HPLC)
IDENTIFICATION OF SPIRAMYCIN	RF IDENTICAL TO THE REFERENCE (TLC)	RF IDENTICAL TO THE REFERENCE (TLC)
ASSAY OF METRONIDAZOLE (COMBINED HPLC)	225 ≤ R ≤ 275 MG/tab	247.8 MG/tab
ASSAY OF SPIRAMYCIN	1350000 ≤ R ≤ 1650000 IU/tab	1510728 IU/tab
METRONIDAZOLE ANY INDIVIDUAL IMPURITY	R ≤ 1.0 %	<1.0 %
METRONIDAZOLE TOTAL IMPURITIES	R ≤ 2.0 %	<0.3 %
SPIRAMYCIN ANY INDIVIDUAL IMPURITY	R ≤ 2.0 %	<2.0 %
SPIRAMYCIN TOTAL IMPURITIES	R ≤ 10.0 %	4.7 %
IDENT OF COCHINEAL RED A (TLC)	RF IDENTICAL TO THE REFERENCE	RF IDENTICAL TO THE REFERENCE
IDENT OF TITANIUM DIOXIDE (CHEMICAL)	YELLOW COLORATION	YELLOW COLORATION

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