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СЕРТИФИКАТ АНАЛИЗА CERTIFICATE OF ANALYSIS

STOMORGYL 10

ПАРТИЯ ТОВАРА: S1U1601AA
COMMERCIAL LOT: S1U1601AA

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

НОМЕР ПАРТИИ ФАСОВКИ: S1U1601A
FILLED PRODUCT LOT NUMBER: S1U1601A

ДАТА ИЗГОТОВЛЕНИЯ: 28-Май-2020
MANUFACTURING DATE: 28-May-2020

СРОК ГОДНОСТИ: 04/2023
EXPIRY DATE: 04/2023

**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





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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	3 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 %	100 %
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)	112.5 ≤ R ≤ 137.5 MG/tab	125.90 MG/tab
ASSAY OF SPIRAMYCIN	675000 ≤ R ≤ 825000 IU/tab	744344 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 %	4.4 %
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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