



4 chemin du Calquet  
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## CERTIFICATE OF ANALYSIS

### STOMORGYL 2

**COMMERCIAL LOT:** S1T1451DA

**PRESENTATION:** STOMORGYL 2 / BOX 20 TABLETS

**FILLED PRODUCT LOT NUMBER:** S1T1451D

**MANUFACTURING DATE:** 09-Aug-2019

**EXPIRY DATE:** 07/2022

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 7.5 % AND NONE DEVIATES BY MORE THAN 15 %	NOT MORE THAN 2 OF 20 INDIVIDUAL VALUES DEVIATE FROM AVERAGE MASS BY MORE THAN 7.5 % AND NONE DEVIATES BY MORE THAN 15 %
DISINTEGRATION	R ≤ 30 min	5 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 %	99 %
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 %	99 %
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)	22.5 ≤ R ≤ 27.5 MG/tab	24.71 MG/tab
ASSAY OF SPIRAMYCIN	135000 ≤ R ≤ 165000 IU/tab	141855 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

**WE CERTIFY THIS PRODUCT MEETS THE REQUIREMENTS OF THE COMPETENT AUTHORITIES**

**Signature / Function  
Jérôme LORET / Qualified Person**





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**СЕРТИФИКАТ АНАЛИЗА  
CERTIFICATE OF ANALYSIS**

STOMORGYL 2

**ПАРТИЯ ТОВАРА: S1T1451DA  
COMMERCIAL LOT: S1T1451DA**

**ФОРМА ВЫПУСКА: STOMORGYL 2 / BOX 20 TABLETS  
PRESENTATION: STOMORGYL 2 / BOX 20 TABLETS**

**НОМЕР ПАРТИИ ФАСОВКИ: S1T1451D  
FILLED PRODUCT LOT NUMBER: S1T1451D**

**ДАТА ИЗГОТОВЛЕНИЯ: 09-Август-2019  
MANUFACTURING DATE: 09-August-2019**

**СРОК ГОДНОСТИ: 07/2022  
EXPIRY DATE: 07/2022**

**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**

