

**CERTIFICATE OF ANALYSIS**

**STOMORGYL 2**

**COMMERCIAL LOT: S1T1402AA**

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

**FILLED PRODUCT LOT NUMBER: S1T1402A**

**MANUFACTURING DATE: 10-May-2019**

**EXPIRY DATE: 04/2022**

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	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 %	105 %
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)	22.5 ≤ R ≤ 27.5 MG/tab	24.86 MG/tab
ASSAY OF SPIRAMYCIN	135000 ≤ R ≤ 165000 IU/tab	158606 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 %	4.6 %
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  
Bénédicte ESCARPIT / Quality Control Manager**


