



CERTIFICATE OF ANALYSIS

STOMORGYL 2

COMMERCIAL LOT: S1T1402BA

PRESENTATION: STOMORGYL 2 / BOX 20 TABLETS

FILLED PRODUCT LOT NUMBER: S1T1402B

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
Isabelle COUDERT / Quality Control Manager