



4 chemin du Calquet  
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## CERTIFICATE OF ANALYSIS

### STOMORGYL 20

**COMMERCIAL LOT:** S1T1531AA

**PRESENTATION:** STOMORGYL 20 / BOX 10 TABLETS

**FILLED PRODUCT LOT NUMBER:** S1T1531A

**MANUFACTURING DATE:** 08-Oct-2019

**EXPIRY DATE:** 09/2022

| 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 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                                                                                                      |

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

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

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





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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**

