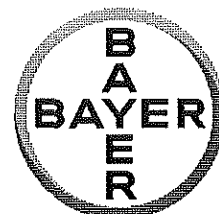




|                                                                                          |  |                                                                                                           |  |                                  |                             |
|------------------------------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------|--|----------------------------------|-----------------------------|
| KVP Pharma+Veterinär<br>Produkte GmbH<br>Projensdorfer Straße 324<br>24106 Kiel, Germany |  | Certificate of Analysis                                                                                   |  | Page: 1 of 3<br>Date: 2020-06-10 |                             |
| Material: 86566672<br>Your material:                                                     |  | DRONTAL PLUS TASTY (DP90) 10 KG 1X2<br>DRONTAL PLUS TASTY (DP90) 10 KG 1X2                                |  |                                  |                             |
| Batch: KP0F344<br>Date of manufacture: 2020-03-19<br>Expiry date: 2025-03-31             |  | Country: Russian Fed.<br>Delivery number: 121949783<br>Order number: 708237127                            |  |                                  |                             |
| From material: 82292861<br>Batch: KP0EZ8X<br>Inspection lot: 040002229417                |  | FEB/PRAZ/PYR 150/50/144MG TREAT 10KG TAB<br>Insp. instruction: T.02.02 - 9<br>Specification: T.02.28 - 11 |  |                                  |                             |
| Inspection                                                                               |  | Acceptance criterion                                                                                      |  | UoM                              | Result                      |
| Material (visual)                                                                        |  | tablet                                                                                                    |  |                                  | tablet                      |
| Colour (visual)                                                                          |  | light-brown to brown                                                                                      |  |                                  | brown                       |
| Markings tablet                                                                          |  | score on both sides                                                                                       |  |                                  | score on both sides         |
| Odour                                                                                    |  | characteristic, liver<br>aroma                                                                            |  |                                  | characteristic, liver aroma |
| Hardness                                                                                 |  | 80 - 170                                                                                                  |  | N                                | 149                         |
| Tablet weight                                                                            |  | 978 - 1196                                                                                                |  | mg                               | 1084                        |
| Identity Praziquantel                                                                    |  | must comply                                                                                               |  |                                  | complies                    |
| Identity Pyrantel embonate                                                               |  | must comply                                                                                               |  |                                  | complies                    |
| Identity Febantel                                                                        |  | must comply                                                                                               |  |                                  | complies                    |
| Identity Praziquantel (UV)                                                               |  | must comply                                                                                               |  |                                  | complies                    |
| Identity Pyrantel embonate (UV)                                                          |  | must comply                                                                                               |  |                                  | complies                    |
| Identity Febantel (UV)                                                                   |  | must comply                                                                                               |  |                                  | complies                    |
| Water                                                                                    |  | max. 7.0                                                                                                  |  | %                                | 5.1                         |
| Dissolution Prazi.after 15 min.(Q=80%)                                                   |  | min. 85                                                                                                   |  | %                                | 95                          |
| Dissolution Pyran.after 15 min.(Q=80%)                                                   |  | min. 85                                                                                                   |  | %                                | 97                          |



|                                                                                          |  |                                                                                |        |                                                               |  |
|------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------------------|--------|---------------------------------------------------------------|--|
| KVP Pharma+Veterinär<br>Produkte GmbH<br>Projensdorfer Straße 324<br>24106 Kiel, Germany |  | Certificate of Analysis                                                        |        | Page: 2 of 3<br>Date: 2020-06-10                              |  |
| Material: 86566672<br>Your material:                                                     |  | DRONTAL PLUS TASTY (DP90) 10 KG 1X2<br>DRONTAL PLUS TASTY (DP90) 10 KG 1X2     |        |                                                               |  |
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| From material: 82292861<br>Batch: KP0EZ8X<br>Inspection lot: 040002229417                |  | FEB/PRAZ/PYR 150/50/144MG TREAT 10KG TAB                                       |        | Insp. instruction: T.02.02 - 9<br>Specification: T.02.28 - 11 |  |
| Inspection                                                                               |  | Acceptance criterion                                                           | UoM    | Result                                                        |  |
| Dissolution Feban.after 15 min.(Q=80%)                                                   |  | min. 85                                                                        | %      | 96                                                            |  |
| Uniformity of dosage units (mass)                                                        |  | must comply                                                                    |        | complies                                                      |  |
| Any unspecified degradation product                                                      |  | max. 0.50                                                                      | %/ACT  | 0.10                                                          |  |
| Sum of all degradation products                                                          |  | max. 1.0                                                                       | %/ACT  | 0.1                                                           |  |
| Assay Praziquantel                                                                       |  | 47.5 - 52.5                                                                    | mg/Tab | 49.3                                                          |  |
| Assay Pyrantelmonat                                                                      |  | 136.0 - 152.0                                                                  | mg/Tab | 141.5                                                         |  |
| Assay Febantel                                                                           |  | 142.0 - 158.0                                                                  | mg/Tab | 150.0                                                         |  |
| Total aerobic microbial count (TAMC)                                                     |  | max. 1000                                                                      | CFU/g  | *)                                                            |  |
| Total combined yeast/mould count (TYMC)                                                  |  | max. 100                                                                       | CFU/g  | *)                                                            |  |
| Escherichia coli                                                                         |  | Absence in 1 g                                                                 |        | *)                                                            |  |

\*) Test is carried out on spot-check basis. However we confirm compliance with the inspection and requirements also for this batch.

This batch complies with the specification and is manufactured in accordance with EC Guide to GMP for Medicinal Products and the requirement laid down in the product license and/or marketing authorisation.

Release Documentation is signed by responsible Person Quality Management.



|                                                                                          |                                                                                |                                  |
|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------|
| KVP Pharma+Veterinär<br>Produkte GmbH<br>Projensdorfer Straße 324<br>24106 Kiel, Germany | Certificate of Analysis                                                        | Page: 3 of 3<br>Date: 2020-06-10 |
| Material: 86566672<br>Your material:                                                     | DRONTAL PLUS TASTY (DP90) 10 KG 1X2<br>DRONTAL PLUS TASTY (DP90) 10 KG 1X2     |                                  |
| Batch: KP0F344<br>Date of manufacture: 2020-03-19<br>Expiry date: 2025-03-31             | Country: Russian Fed.<br>Delivery number: 121949783<br>Order number: 708237127 |                                  |

Batch release electronically signed:

Dr. Robert Reh (KPRRE)

Qualified Person

Date/time:

2020-05-26 03:26:50 p.m. CET ( UTC + 1 hour )

Inspection lot:

040002247979

This Certificate of Analysis was automatically printed.

Bayer Animal Health GmbH  
Kaiser-Wilhelm-Allee 20  
51373 Leverkusen  
Germany