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|--|---|----------------------------------|
| KVP Pharma+Veterinär<br>Produkte GmbH<br>Kiel, Germany                       | <b>Certificate of Analysis</b>  | Page: 1 of 3<br>Date: 2013-10-10 |
| Material: 81616795<br>Your Material:   | DRONTAL PLUS 10 KG FBG 6 TABL<br>BOX X 6 PCE<br>DRONTAL PLUS 10 KG FBG 6 TABL                           |                                  |
| Batch: KP09114<br>Date of manufacture: 2013-07-19<br>Expiry date: 2018-07-31 | Country: Hungary<br>Delivery number: 101234505<br>Order number: 1828379                                 |                                  |
| From Material: 06748635<br>Batch: KP08VX8<br>Inspection lot: 040001170234    | FEB+PRAZ+PYR TAB 150+50+144MG FLAV BONE<br>Insp. instruction: T.02.02 - 1<br>Specification: T.02.01 - 1 |                                  |

| Inspection                                 | Acceptance criterion         | UoM. | Result              |
|--|------------------------------|------|---------------------|
| Material (visual)                          | tablet                       |      | tablet              |
| Colour (visual)                            | light-brown to brown         |      | light brown         |
| Shape (visual)                             | bone shaped                  |      | bone shaped         |
| Markings tablet                            | score on both sides          |      | score on both sides |
| Odour                                      | characteristic               |      | complies            |
| Identity Praziquantel                      | must comply                  |      | complies            |
| Identity Pyranate<br>Embonate              | must comply                  |      | complies            |
| Identity Febantel                          | must comply                  |      | complies            |
| Water                                      | max. 5                       | %    | 3                   |
| Dissolution praziquantel<br>after 30 min.  | min. 75                      | %    | 100                 |
| Dissolution<br>pyranatelembonate aft.30min | min. 70                      | %    | 115                 |
| Dissolution febantel<br>after 30 min       | min. 70                      | %    | 102                 |
| Uniformity of mass min.<br>90%             | min.18 s.u. in 737-815<br>mg |      | complies            |
| Uniformity of mass 100%                    | 20 s.u. in 698-854 mg        |      | complies            |



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| Inspection                              | Acceptance criterion | UoM.   | Result |
|---|----------------------|--------|--------|
| Any unspecified degradation product     | max. 0.5             | %      | < 0.3  |
| Sum of all degradation products         | max. 1.0             | %      | < 0.3  |
| Assay Praziquantel                      | 47.5 - 52.5          | mg/Tab | 50.1   |
| Assay Pyrantelmonat                     | 136 - 152            | mg/Tab | 149    |
| Assay Febantel                          | 142 - 158            | mg/Tab | 152    |
| 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.

Release Documentation is signed by Responsible Person Quality Management - Dr. Fröhlich - QP



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|--|----------------------|---|--------|----------------------------------|--|
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| Date of manufacture:                                   | 2013-07-19           | Order number: 1828379   |        |                                  |  |
| Expiry date:   | 2018-07-31           |   |        |                                  |  |
| From Material:   | 06748635             | FEB+PRAZ+PYR TAB 150+50+144MG FLAV BONE                                       |        |                                  |  |
| Batch:   | KP08VX8              | Insp. instruction:  |        | T.02.02 - 1                      |  |
| Inspection lot:  | 040001170234         | Specification:  |        | T.02.01 - 1                      |  |
| Inspection   | Acceptance criterion | UoM.  | Result |                                  |  |

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