

DRONTAL PLUS 150/144/50MG DOG 102X
 Gysz: KV02KL7 Lej: 2023-10-31
 Kisz: 102X Me: Doboz
 SZÉKELY KFT részére

Szállító:
 Medimpex Gy. Zrt.
 1158 Budapest
 Rákospalotaihatárút2
 Tel: +36-1-414-6477
 e-mail: qa@mpx.hu



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| KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany | Certificate of Analysis | Page: 1 of 3 Date: 2021-01-26 |
|--|--------------------------------|----------------------------------|

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|--------------------------------------|--|
| Material: 84836559 Your material: | DRONTAL TASTY TAB DOG(DP90)10KG 17X6 VTQ DRONTAL TASTY TAB DOG(DP90) 10KG 17X6 - 460944 |
|--------------------------------------|--|

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|--|---|
| Batch: KV02KL7 Date of manufacture: 2020-10-27 Expiry date: 2023-10-31 | Country: France Delivery number: 80392203 Order number: 700363844 |
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|---|---|
| From material: 82292861 Batch: KV02CTE Inspection lot: 040000006580 | FEB/PRAZ/PYR 150/50/144MG TREAT 10KG TAB Insp. instruction: T.02.02 - 9 Specification: T.02.28 - 11 |
|---|---|

| Inspection | Acceptance criterion | UoM | Result |
|--|-----------------------------|-----|-----------------------------|
| Material (visual) | tablet | | tablet |
| Colour (visual) | light-brown to brown | | light brown |
| Markings tablet | score on both sides | | score on both sides |
| Odour | characteristic, liver aroma | | characteristic, liver aroma |
| Hardness | 80 - 170 | N | 164 |
| Tablet weight | 978 - 1196 | mg | 1088 |
| 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 | % | 5.4 |
| Dissolution Prazi.after 15 min.(Q=80%) | min. 85 | % | 99 |

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| Inspection | Acceptance criterion | UoM | Result | |
| Dissolution Pyran.after 15 min.(Q=80%) | min. 85 | % | 97 | |
| Dissolution Feban.after 15 min.(Q=80%) | min. 85 | % | 100 | |
| Uniformity of dosage units (mass) | must comply | | complies | |
| Any unspecified degradation product | max. 0.50 | %/ACT | 0.18 | |
| Sum of all degradation products | max. 1.0 | %/ACT | 0.2 | |
| Assay Praziquantel | 47.5 - 52.5 | mg/Tab | 52.1 | |
| Assay Pyrantelmonat | 136.0 - 152.0 | mg/Tab | 149.4 | |
| Assay Febantel | 142.0 - 158.0 | mg/Tab | 154.6 | |
| 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 | | *) | |

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

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Release Documentation is signed by responsible Person Quality Management.

Batch release electronically signed: Dr. Andreas Engwicht-Lassmann (TGENW)
Qualified Person
Date/time: 2021-01-25 10:43:40 a.m. CET (UTC + 1 hour)
Inspection lot: 040000009771

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