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# BATCH CERTIFICATE

| | |
|---|---|
| Name of the Product: **7D0142 PRINOCATE DOGS 400 mg/100 mg spot on solution for veterinary use** | |
| Batch No. of the Product: **Z97459** | |
| Date of manufacture: **10.2023** | Expiry date: **10.2025** |
| According to Specification: **DPSPEC007985_3** | |

| Characteristic | Specification | Results | |
|---|---|---|---|
| Appearance | Clear, slightly yellow to yellow or to brownish yellow solution. | Complies | |
| Seal integrity | Must comply with the test. | Complies | |
| Density | 1.095 - 1.101 g/ml | 1.099 | |
| Clarity and degree of opalescence of liquids | The solution must be clear | Complies | |
| Degree of coloration of liquids | The solution is not more intensively coloured than reference solution BY4 or Y4. | Complies | |
| Water | Max. 2.0 % | 0.1 | *1 |
| Uniformity of dosage units-mass variation of imidacloprid; AV | Max. 15.0 % | 0.7 | |
| Uniformity of dosage units-mass variation of moxidectin; AV | Max. 15.0 % | 0.7 | |
| Identification of imidacloprid - HPLC | Assay is at the same time identification. | Complies | |
| Identification of imidacloprid - TLC | The lower main spot in the chromatogram of sample solution corresponds in approximate Rf value and approximate size to the main spot in the chromatogram of standard solution 1. | Complies | |
| Identification of moxidectin - HPLC | Assay is at the same time identification. | Complies | |
| Identification of moxidectin - TLC | The higher main spot in the chromatogram of sample solution corresponds in approximate Rf value and approximate size to the main spot in the chromatogram of standard solution 2. | Complies | |
| Identification of butylhydroxytoluene | Assay is at the same time identification. | Complies | |
| Related substances of imidacloprid - individual | Max. 0.5 % | <= 0.30 | |
| Related substances of imidacloprid - total | Max. 1.5 % | <= 0.30 | |
| Related substances of moxidectin - 23-keto-nemadectin | Max. 0.5 % | <= 0.30 | |
| Related substances of moxidectin - other individual | Max. 0.5 % | <= 0.30 | |
| Related substances of moxidectin - total | Max. 2.0 % | <= 0.30 | |
| Content of butylhidroxytoluene | 96 - 126 % of stated amount | 112 | |
| Content of imidacloprid (mg/pipette) (4ml) | 380 - 420 mg/pipette | 403 | |
| Content of moxidectin (mg/pipette) (4ml) | 95 - 105 mg/pipette | 101 | |
| Microbial quality - TAMC | Max. 100 CFU/ml | < 10 | *2 |
| Microbial quality - TYMC | Max. 10 CFU/ml | < 10 | *2 |
| Microbiological quality - Staphylococcus aureus | Absent in 1 ml | Complies | *2 |
| Microbiological quality - Pseudomonas aeruginosa | Absent in 1 ml | Complies | *2 |

*1 Testing not performed on every batch (monitoring programe- at least one batch per year).
*2 First three production batches are tested and than every 10-th batch or at least one batch annually.

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