Marbocyl P 20mg tabletta A.U.V.
Gysz:6C1152MA Lej:19/04/07
Kisz:10x Me.:darab
TOLNAGRO KFT. részére

2151 Fót
Keleti Márton u. 19.
Tel:27/537-100
Fax:27/537-100

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## BATCH CERTIFICATE FOR MEDICINAL PRODUCT

| | |
|---|---|
| Name, strength/potency, dosage form | **MARBOCYL P 20 mg, tablets** |
| Package size | **10 tablets** |
| Batch number of the finished product | **6C1152MA** |
| Name of the destination country / countries of the batch | **Hungary** |
| Certification statement<br><br>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 [when within the EU] with the requirements of the Marketing Authorisation(s) of the destination country/countries. | |
| Name of the Qualified Person certifying the batch | Mariola Kiszewska |
| Signature of Qualified Person certifying the batch | |
| Date of signature | 2016 -11- 02 |

Vetoquinol Biowet Sp. z o.o.
Oddz. ul. Kos. Gdyńskich 13-16, PL 66-400 GORZÓW WLKP
tel. +48/95/ 726 55 90 - 93, fax +48/95/ 735 96 43
Dział Logistyki Sprzedaży tel./fax +48/95/ 728 53 37
Magazyn Zbytów tel./fax +48/95/ 735 55 50
e-mail: info.pl@vetoquinol.com www.vetoquinol.pl
Sąd Rejonowy w Zielonej Górze VI Wydział Gospodarczy KRS o numerze 0000064275
Konto: Bank BGZ BNP Paribas S.A.
EUR PL79 1600 1084 0004 0[illegible]
USD PL53 1600 1084 0004 0[illegible]
CHF PL28 1600 1084 0004 0[illegible]
PL 37 1[illegible]
REGON 2[illegible] NIP 5[illegible]
Wysokość kapitału zakładowego [illegible]

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# CERTIFICATE OF ANALYSIS



## FINISHED PRODUCT

| | | | |
|---|---|---|---|
| **Product name :** | MARBOCYL P 20MG CPRPLQ10 SI PL | **Analytical code :** | 416169 |
| **Pharmaceutical form :** | Not Coated Tablets | **Manufacturing date :** | 07/04/2016 |
| **Batch number :** | 6C1152M | **Expiration date :** | 07/04/2019 |

| TESTS | SPECIFICATIONS | RESULTS |
|---|---|---|
| Appearance of tablets | Beige brown-spotted tablets | Pass |
| Tablet shape and marking | Round tablet and breaking line | Pass |
| Diameter | >= 8.6 <= 9.4 mm | 9.1 mm |
| Average weight and uniformity of weight | | |
| Average weight | >= 273.0 <= 287.0 mg | 283.7 mg |
| Uniformity of weight | Complies with Eur.Ph. | Pass |
| Disintegration test | <= 15 min | <4 min |
| Resistance to crushing | >= 40 N | 60 N |
| Marbofloxacin dissolution | | |
| Average Dissolution | >= 80 % in 30 min | 101.5 %<br>Pass |
| Humidity | <= 3.5 % | 2.5 % |
| TLC identification | Positive | Pass |
| Marbofloxacin assay | | |
| Marbofloxacin identity (HPLC) | Positive | Pass |
| Marbofloxacin content | >= 19.00 <= 21.00 mg/tab | 19.69 mg/tab. |
| Marbofloxacin impurities | | |
| Ro47-3012 | <= 0.5 %w/w | 0.1 % w/w |
| Each unknown impurity | <= 0.1 %area | <0.1 % area |
| Total unknown impurities | <= 0.5 %area | 0.1 % area |

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# CERTIFICATE OF ANALYSIS



## FINISHED PRODUCT

| | | | |
|---|---|---|---|
| **Product name :** | MARBOCYL P 20MG CPRPLQ10 SI PL | **Analytical code :** | 416168 |
| **Pharmaceutical form :** | Not Coated Tablets | **Manufacturing date :** | 07/04/2016 |
| **Batch number :** | 6C1152M | **Expiration date :** | 07/04/2019 |

| TESTS | SPECIFICATIONS | RESULTS |
|---|---|---|
| Total Aerobic Microbial Count (TAMC) | <= 1000 cfu/g | <100 cfu/g |
| Total Yeasts and Moulds Count (TYMC) | <= 100 cfu/g | <10 cfu/g |
| Escherichia coli | No growth | Pass |

I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in the current European Union rules for Good Manufacturing Practice for medicinal products for veterinary use, and that the finished product in all aspects answers the requirements laid down in the marketing authorisation.

| | |
|---|---|
| Released by Qualified Person : | Anne SANTIPERI |
| Date : | 20/09/2016 14:04:59 |
| Decision : | FULL RELEASE |

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