S.C. VIM SPECTRUM S.R.L., Romania
for PHARMA VIM K.F.T., Hungary

CERTIFICATE OF ANALYSIS
No. 260/11.04.2016

FENBENDANIN 5% belsőleges por AUV – oral powder
fenbendazole 50 mg/g

Batch Number: 10 AUV 095
Date of Manufacture: 04 16
Expiry Date: 04 18
Analysis performed by product specification: ST-10AUV-2011-01

Tests	Acceptance criteria	Results
Appearance	Fine-grained, white, odorless powder	Corresponds
Identification	a) in the assay, the retention time of the principal peak in the chromatogram obtained with test solution has to be same as that of the principal peak in the chromatogram obtained with reference solution b) the retention factor of the principal spot optained with test solution has to be same to that of the principal spot optained with reference solution	Corresponds Corresponds
Total mass: 1000 g	950.0 – 1050.0 g (1000 g ± 5%)	999.2
Loss on drying	Not more than 10.0 %	8.47
Related impurities - Impurity A - Impurity B - Impurity 1	 Not more than 0.5% Not more than 0.5% Not more than 0.5%	 ND ND 0.13
Assay - fenbendazole, mg/g	47.5 – 52.5 (50.0 ± 5%)	49.65

Conclusions: The analyzed product – Fenbendanin 5% belsőleges por AUV – oral powder, meets the requirements of product specification ST-10AUV-2011-01

Quality Control Manager
Pharm. Kis Erika Lilla, PhD

Analysis performed by
Pharm. Réti Zenkő Zsuzsanna

SOCIETATEA COMERCIALA VIM SPECTRUM S.R.L. CORUNCA J26/1496/1994 RO6599330 MURES ROMANIA

Quality Manager
Pharm. Gagyi László, PhD