

HUBEI HVSEN BIOTECHNOLOGY CO.,LTD

Certificate of AcetylisovalerylTylosin Tartrate(Tylvalosin Tartrate)

Batch No.	201901004	Packing specification	10kg/drum
Quantity	1150.00kg	Date of manufacture	Jan.19.2019
Expiry date	Jan.18.2021	Date of report	Jan.20.2019
Basis	<Veterinary Drug Quality Standards>(Chemicals Vol.) 2017 Edition		
Items	Standards	Results	Conclusions
Appearance	White powder or pale white powder.	White powder	Complies
Identification	(1) Wave length (nm) Max.Absorbance290nm aqueous solution.	(1) Wavelength (nm) Max. Absorbance 290nm	Complies
	(2) Dissolved in acetone, by addition of hydrochloric acid, the solution gradually turns from light yellow to dark purple.	(2) Positive	Complies
	(3) Dissolved in water, by addition of silver nitrate solution, yield white precipitation; separating the precipitation and which can be dissolved in nitric acid.	(3) Positive	Complies
	(4) By TLC method, the sample should show the same dominant color spot as the reference standard at the same position at 254nm.	(4) Complies	Complies
Solubility	Stir 1.0mg of powder with 300ml water by mechanical stirrer for 10 minutes, then wait for 30 minutes until the solution become completely clear.	Complies	Complies
Acidity	pH value 3.0-5.0	pH value 4.0	Complies
Tyramine	Sample absorbance not more than that of reference substance at 570nm.	Sample absorbance lower than reference substance at 570nm.	Complies
Active constituent	Content of acetylisovaleryl tylosin A is not less than 80%.	85%	Complies
Loss on drying	Weight loss is not more than 4.0%.	1.5%	Complies
Heavy metals	Heavy metal content is not more than 20ppm.	<20ppm	Complies
Potency	The potency of 1 milligram sample is not less than 800U of acetylisovaleryl tylosin on the dried basis.	946U/mg	Complies
Conclusion: the product met all requirements of <Veterinary Drug Quality Standards>(Chemicals Vol.) 2017 Edition			

Analyzer: 宋佳

Checker: 王洁

