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山东鲁抗生物制药有限公司

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## CERTIFICATE OF ANALYSIS

COA No.: 0001

|   |                              |
|---|------------------------------|
| Product name: Tylosin Tartrate            | Issuing Date: 2018 / 03 / 02 |
| Batch No.: T1802027                       | MFG. Date: 2018 / 02 / 24    |
| Packing size: 25kg/drum                   | EXP. Date: 2021 / 02 / 23    |
| Quantity: 173 drums 4325kg / 3974.675 BOU | Workshop: 607                |

Reference: EP 9.3

| Item                   | Specification  | Result                 |
|------------------------|--|------------------------|
| Appearance             | Almost white or slightly yellow powder   | Slightly yellow powder |
| Solubility             | Freely soluble in water, in ethanol (96%) and in methylene chloride, practically insoluble in heptane. | Conform                |
| Identification         | A. IR test: identified with Tylosin tartrate CRS.  | Positive               |
|                        | B. Reaction: a green colour is produced.   | Positive               |
| Appearance of solution | The solution is clear and not more intensely coloured than reference solution Y <sub>3</sub>           | Clear, <Y <sub>3</sub> |
| pH                     | 5.0 ~ 7.2  | 6.0                    |
| Composition            | Tylosin A  | ≥80.0%                 |
|                        | Sum of tylosin A, B, C and D   | ≥95.0%                 |
| Related substances     | Impurity A   | ≤2.0%                  |
|                        | Sum of impurities eluting between impurity A and Tylosin C   | ≤2.0%                  |
|                        | Impurity N   | ≤1.0%                  |
|                        | Impurity O   | ≤1.0%                  |
|                        | Impurity E   | ≤0.5%                  |
|                        | Impurity R   | ≤0.5%                  |
|                        | Impurity S   | ≤0.5%                  |
|                        | Any other impurity   | ≤0.50%                 |
|                        | Total impurities   | ≤5.0%                  |
| Tyramine               | ≤0.35%   | <0.35%                 |
| Loss on drying         | ≤4.5%  | 1.2%                   |
| Sulfated ash           | ≤2.5%  | 0.3%                   |
| Assay (dried basis)    | Not less than 900 IU/mg  | 930 IU/mg              |

Conclusion: The above results comply with EP9.3. ☒

Remarks: \_\_\_\_\_

Reporter: 果宇萍

Reviewer: 石希所

QC Manager: 丁房军

