

Amendments of standards and specifications of Salinomycin sodium

Ministry of Agriculture, Forestry and Fisheries (MAFF) will add standards and specifications to

“Ministerial Ordinance on the Specifications and Standards of Feeds and Feed Additives”

(Ordinance No. 35 of July 24th, 1976 of the Ministry of Agriculture and Forestry).

Major additions are as follows.

Salinomycin sodium No.2

Specifications for feed additives

Product No.2

Compositional specifications

This product comes in the form of pieces, particles or powder and is produced by mixing with excipient substances to the Active Substance No.2 of Salinomycin sodium No.2.

Unit $\leq 200 \mu\text{g}$ (titer) /mg. This product contains the amount of salinomycin sodium corresponding to 85 to 125% of titer shown on the label.

Physical and chemical properties

- (1) It comes in pale yellow-pale brown pieces, particles or powder and has characteristic odor .
- (2) It passes through a 2.00 mm standard mesh sieve.
- (3) It grows no mouldy.

Confirmation test:

- (1) Confirmation test No.1 of Product No.1 of Salinomycin sodium No.2
- (2) Confirmation test No.2 of Product No.1 of Salinomycin sodium No.2
- (3) Confirmation test No.3 of Product No.1 of Salinomycin sodium No.2

Loss on drying: $\leq 10.0\%$ (1 g, 105°C, 3 hours)

Titer test

Agar plate: Same as the titer test for Active Substance of Salinomycin sodium No.1

Test bacteria: Same as the titer test for Active Substance of Salinomycin sodium No.1

Preparation of Standard diluent: Same as the titer test for Active Substance of Salinomycin sodium No.1

Preparation of Sample solution: Same as the titer test for Product No.1 of Salinomycin sodium No.2

Standard for method of manufacture

It is produced by mixing with excipient substances to the Active Substance No.2 of Salinomycin sodium No.2.

Standard for method of storage

Same as the standard for method of storage for Active substance of Salinomycin sodium No.2

Standard for method of labelling

Same as the standard for method of labelling for Product No.1 of Salinomycin sodium No.2