IN USE MONENSIN 150g/L TROUGH TREATMENT FOR CATTLE 100 DAY STUDY

Protocol for the testing of Monensin Oral Drench 15%

Aim

The aim of the study is to collect information that will confirm that when Monensin Drench 15% is used as advised on the label it will produce a stable suspension of Monensin in the trough that contains the same levels of the active ingredient as are provided by the reference product. Similarly, the behaviour of the new product when mixed and used through a power doser is to be evaluated. The study also aims to provide evidence of the physicochemical similarities between the test and the reference product after dilution into the water trough.

Materials and Methods

The study will consist of testing relating to the use of the test product in troughs a 200L trough alongside the reference product.

Trough treatment

The first series of studies will involve side by side comparisons of the physicochemical properties of the "trough water" following the dispensing of the test and the reference products using an inline Dosatron or equivalent system that feeds into a 100L trough. The Monensin suspension in the trough will not be agitated or stirred during the period of the study. Ideally the study should evaluate the behaviour of the monensin suspension in both plastic and concrete troughs. However, it is expected to be acceptable to use a plastic trough for the main studies and maybe one small scale short term confirmatory study could be carried out in a concrete trough. The main comparisons will be carried out between the test and one reference product (Rumensin Max – A10731). These evaluations will involve the testing of the following physicochemical properties from samples collected at the bottom, middle and top of the trough:

1. Monensin concentration
2. pH
3. Water temperature

Samples will be collected for testing at the following times after the adding of the products to the trough: immediately after mixing, daily for seven days and then at weekly intervals for a period of 100 days. It can be noted that the trough is not to be agitated or mixed at any time after the products have been added to the trough.

Summary of Trough Treatment Study

The study report summarizes the testing performed according to the attached protocol for the testing of Monensin 15%. The study shows that the new product, Monensin 15% produces a stable suspension of monensin in the trough for 100 days when compared with the reference product.
Rumension Max was used as a reference product.

1. Location of study: Jaychem Industries Ltd, 3 Kordel Pl, East Tamaki, Auckland.
2. Sampling Start Date: 03 June 2014
3. Sampling End Date: 11 September 2014
4. Quantities of test and reference products used:

   Monensin 15% and Rumensin Max as a reference product were dispersed in two separate 200L troughs with identical dilutions using the Dosatron machine to dispense the product into the trough (See Appendix A).

   0.4L of Monensin 15% and Rumension Max products were diluted separately to 10L with water to make Monensin 0.6%.
   2.5L of these diluted solutions were dispersed in to the 200L water troughs by using the Dosatron.
   The final 200L water troughs contain 0.0075% monensin.

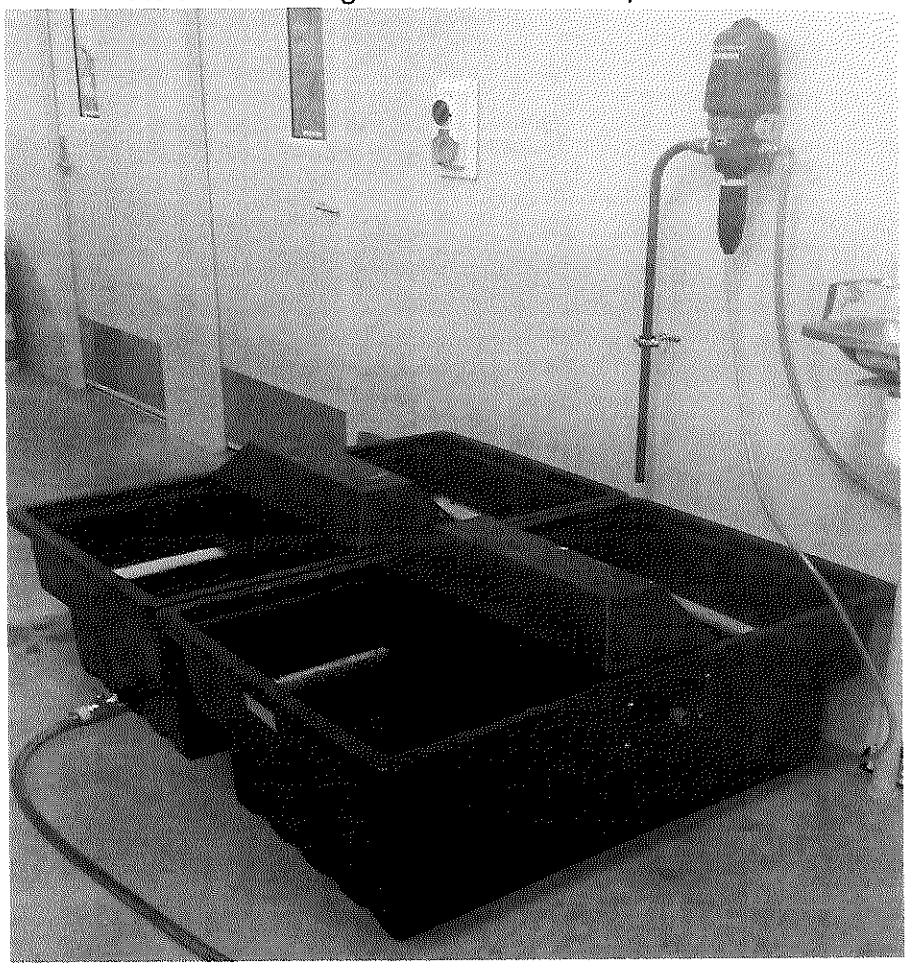
5. Sampling: Dark brown 100mL plastic bottles were used to store collected samples from top, middle and bottom of the troughs. For collecting top, middle and bottom samples a sampling stick was used.
   The samples were collected immediately after the addition of the product to the trough then daily for seven days and then at weekly intervals for a period of 100 days.
   The troughs were not agitated throughout 100 days.

6. pH and Temperature measurements were carried out inhouse at Jaychem Industries Ltd and then were sent to Labtec, 357 Great south Rd, Auckland for Monensin testing.

The study shows that the Monensin content is in comparable concentrations in the trough when compared to Rumension Max.

Appendix A

Photo of 200 L Troughs and Dosatron Setup



Appendix B – Lab Results

Monensin 15% Trough Drench Test results

Date			Top Temp (°C)	Top pH	Top Monensin%	Middle Temp (°C)	Middle pH	Middle Monensin %	Bottom Temp (°C)	Bottom pH	Bottom Monensin%
	Week	Day									
03.06.2014	Day 0	0	15	7.8	0.006	15	7.8	0.005	15	7.8	0.006
04.06.2014	Day 1	1	15	7.7	0.006	15	7.8	0.006	15	7.8	0.006
05.06.2014	Day 2	2	15	7.7	0.006	15	7.7	0.006	15	7.7	0.006
06.06.2014	Day 3	3	15	7.3	0.006	15	7.3	0.006	15	7.3	0.006
07.06.2014	Day 4	4	15	7.2	0.005	15	7.2	0.005	15	7.2	0.006
Sunday	Day 5	5	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
09.06.2014	Day 6	6	15	7.0	0.005	15	6.9	0.006	15	6.9	0.005
10.06.2014	Day 7	7	15	6.8	0.006	15	6.9	0.006	15	6.9	0.006
17.06.2014	Week 2	14	16	7.0	0.006	16	7.0	0.006	16	7.0	0.007
24.06.2014	Week 3	21	16	7.1	0.006	16	7.0	0.007	16	7.0	0.006
01.07.2014	Week 4	28	16	7.2	0.006	16	7.2	0.006	16	7.2	0.006
08.07.2014	Week 5	35	14	7.0	0.006	14	7.1	0.007	14	7.2	0.007
15.07.2014	Week 6	42	11	6.9	0.006	11	6.9	0.006	11	6.9	0.006
22.07.2014	Week 7	49	10	7.0	0.007	10	7.0	0.006	10	7.0	0.006
29.07.2014	Week 8	56	12	7.1	0.007	12	7.1	0.007	12	7.1	0.007
05.08.2014	Week 9	63	12	7.2	0.007	12	7.2	0.006	12	7.2	0.007
12.08.2014	Week 10	70	12	7.1	0.008	12	7.1	0.008	12	7.1	0.008
19.08.2014	Week 11	77	15	7.1	0.008	15	7.1	0.007	15	7.1	0.008
26.08.2014	Week 12	84	13	7.0	0.008	13	7.1	0.009	13	7.1	0.009
02.09.2014	Week 13	91	15	7.1	0.009	15	7.1	0.009	15	7.1	0.008
09.09.2014		98	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
10.09.2014		99	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
11.09.2014		100	16	7.1	0.008	16	7.1	0.009	16	7.1	0.008

Appendix C – Lab results

Rumensin Max 15% Trough Test results

			Top			Middle			Bottom		
			Temp (°C)	pH	Monensin %	Temp (°C)	pH	Monensin %	Temp (°C)	pH	Monensin %
Date	**Week**	**Days**									
03.06.2014	**Day 0**	**0**	15	7.57	0.004	15	7.57	0.003	15	7.57	0.004
04.06.2014	**Day 1**	**1**	15	7.57	0.004	15	7.57	0.004	15	7.57	0.004
05.06.2014	**Day 2**	**2**	15	7.46	0.004	15	7.45	0.004	15	7.52	0.004
06.06.2014	**Day 3**	**3**	15	7.64	0.004	15	7.67	0.003	15	7.64	0.004
07.06.2014	**Day 4**	**4**	15	7.02	0.003	15	7.06	0.003	15	7.00	0.003
Sunday	**Day 5**	**5**	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
09.06.2014	**Day 6**	**6**	15	6.9	0.003	15	6.9	0.003	15	6.9	0.003
10.06.2014	**Day 7**	**7**	15	7.0	0.003	15	7.0	0.003	15	6.9	0.003
17.06.2014	**Week 2**	**14**	16	6.8	0.004	16	6.8	0.004	16	6.8	0.004
24.06.2014	**Week 3**	**21**	16	6.8	0.004	16	6.7	0.004	16	6.6	0.004
01.07.2014	**Week 4**	**28**	16	6.5	0.003	16	6.5	0.004	16	6.5	0.004
08.07.2014	**Week 5**	**35**	14	6.6	0.004	14	6.6	0.004	14	6.6	0.004
15.07.2014	**Week 6**	**42**	11	6.4	0.004	11	6.4	0.004	11	6.4	0.003
22.07.2014	**Week 7**	**49**	10	6.6	0.004	10	6.5	0.004	10	6.5	0.004
29.07.2014	**Week 8**	**56**	12	6.7	0.004	12	6.7	0.003	12	6.7	0.004
05.08.2014	**Week 9**	**63**	12	6.7	0.004	12	6.7	0.003	12	6.7	0.003
12.08.2014	**Week 10**	**70**	12	6.7	0.004	12	6.7	0.004	12	6.7	0.004
19.08.2014	**Week 11**	**77**	15	6.7	0.004	15	6.7	0.005	15	6.7	0.004
26.08.2014	**Week 12**	**84**	13	6.7	0.005	13	6.7	0.005	13	6.7	0.005
02.09.2014	**Week 13**	**91**	15	6.7	0.007	15	6.7	0.007	15	6.7	0.007
09.09.2014		**98**	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
10.09.2014		**99**	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
11.09.2014		**100**	16	6.7	0.007	16	6.7	0.004	16	6.7	0.005

Appendix D – Labtec Results