



# SAFETY AND EFFICACY OF A NEXT GENERATION IMMUNE COMPLEX VACCINE IN LAYERS

## OBJECTIVE

The present farm follow-up trial was performed with the aim of evaluating the safety and efficacy of GUMBOHATCH® when administered in layers via the subcutaneous route under field conditions within a company in Indonesia.

## MATERIAL & METHODS

During the period from 28/12 to 29/12/2020, a total of 10,000 day-old layer chicks were vaccinated via the subcutaneous route with GUMBOHATCH®, following the manufacturer's instructions. The chicks belonged to the same parent stock and were contained in 1 house. The flock was monitored up to 7 weeks old. Several safety and efficacy parameters were evaluated during this period. Blood sampling of 20 chicks was performed at different time points, from week 0 until 7 weeks of age. Necropsy of 8 chicks was performed at 33 and 44 days of age. Antibody titres to the IBD virus were determined using the ELISA kit IDEXX IBD. During necropsies, bursal imprints on FTA cards were collected for PCR analysis.

ELISA titres and productive parameters of the GUMBOHATCH® flock were compared with parameters of two flocks vaccinated with a standard-formulated immune complex vaccine on the same farm during the same period. A t-test was used to examine the effect of the vaccine in each week on the different productive parameters, using the statistical program package R v4.0. A probability level of  $p < 0.05$  was chosen as the limit for statistical significance in all tests.

## RESULTS

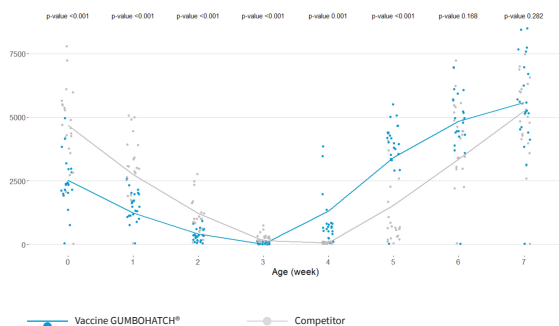
### SAFETY

No adverse reactions to GUMBOHATCH® were observed.

Bursa size scores at 33 and 44 days ranged from 6 to 3 as expected. Expected macroscopic signs of vaccine virus replication were observed in some of the bursas evaluated.

### EFFICACY

PCR results from bursal imprints evidenced replication of the vaccine virus from day 33 onwards in the GUMBOHATCH® flock. The evolution of antibody titres to the IBD virus after vaccination followed a similar pattern in all individuals, showing a rapid increase in vaccine-induced antibodies from day 21 onwards up to 7 weeks of age. (Figure 1).



**Figure 1.** Evolution of serum antibody titres to the IBD Virus by vaccine group (ELISA titre mean; cut-off value = 357) until the end of rearing (7 weeks of life).

A comparison of productive parameters from the same period is shown in Tables 1, 2, 3, 4 and 5. From week 1 to week 5, a trend was observed towards a higher body weight (BW), feed intake and uniformity in the flock vaccinated with GUMBOHATCH® compared with the standard-formulated immune complex vaccine. However, all these differences disappeared at weeks 6 and 7. A lower mortality was also observed in the last two weeks in the flock vaccinated with GUMBOHATCH®.

Body weight (gr)	Standard immune complex vaccine	GUMBOHATCH®	P-value
Week 1	75.5	81.0	<0.001
Week 2	137.0	148.0	<0.001
Week 3	227.5	229.0	0.604
Week 4	323.5	320.0	0.182
Week 5	417.0	436.0	<0.001
Week 6	545.0	551.0	NV
Week 7	637.0	646.0	NV

**Table 1.** Comparison of body weights between GUMBOHATCH® and the standard immune complex vaccine within the same period. NV indicates no variability within the flocks to estimate the effect of the vaccine.

Feed intake	Standard immune complex vaccine	GUMBOHATCH®	P-value
Week 1	11.6	12.8	<0.001
Week 2	15.0	18.3	0.001
Week 3	22.5	24.1	0.008
Week 4	31.2	31.9	NV
Week 5	35.2	36.9	0.001
Week 6	40.0	44.0	NV
Week 7	44.7	44.8	NV

**Table 2.** Comparison of feed intake between GUMBOHATCH® and the standard immune complex vaccine within the same period. NV indicates no variability within the flocks to estimate the effect of the vaccine.

Feed conversion ratio	Standard immune complex vaccine	GUMBOHATCH®	P-value
Week 1	1.07	1.10	0.001
Week 2	1.36	1.47	0.011
Week 3	1.51	1.69	0.01
Week 4	1.73	1.90	0.005
Week 5	1.94	1.99	0.032
Week 6	1.98	2.13	NV
Week 7	2.18	2.30	NV

**Table 3.** Comparison of feed conversion ratio between GUMBOHATCH® and the standard immune complex vaccine within the same period. NV indicates no variability within the flocks to estimate the effect of the vaccine.

Mortality	Standard immune complex vaccine	GUMBOHATCH®	P-value
Week 1	0.19	0.66	<0.001
Week 2	0.10	0.17	0.111
Week 3	0.04	0.04	0.999
Week 4	0.06	0.08	0.57
Week 5	0.03	0.14	<0.001
Week 6	0.92	0.42	<0.001
Week 7	0.19	0.02	<0.001

**Table 4.** Comparison of mortality between GUMBOHATCH® and the standard immune complex vaccine within the same period.

Uniformity	Standard immune complex vaccine	GUMBOHATCH®	P-value
Week 1	70.0	91.0	0.059
Week 2	68.5	74.0	0.643
Week 3	72.5	77.0	0.721
Week 4	78.5	87.0	0.481
Week 5	91.0	94.0	0.847
Week 6	90.0	92.0	0.941
Week 7	93.0	97.0	0.827

**Table 5.** Comparison of uniformity between GUMBOHATCH® and the standard immune complex vaccine within the same period.

## CONCLUSIONS

The results obtained in this study allow the conclusion to be drawn that vaccination with GUMBOHATCH® is safe and confers good protection to layer chicks against IBD when administered via the subcutaneous route under field conditions. A higher humoral response was observed with GUMBOHATCH® throughout the period evaluated when compared with the standard immune complex vaccine. Comparison of productive parameters with flocks vaccinated with a standard-formulated immune complex vaccine showed a similar growth curve to that in the flock vaccinated with GUMBOHATCH®.