

DESCRIPTION:

Inactivated emulsified vaccine against avian influenza (H5N1) and Newcastle disease
 Dosage form: emulsion for injections. The vaccine is produced from the avian influenza virus (H5N1 strain) (A/chicken/Primorsky/85/08/H5N1) with Newcastle disease virus (LaSota strain) supplemented with Montanide ISA 70 G oil adjuvant at ratio of 30:70.

BIOLOGICAL PROPERTIES

The vaccine induces immune response in chickens against H5 avian influenza and Newcastle disease agents 21 days after single administration. The immunity lasts for at least 5 months.

INDICATIONS:

ARRIAH H5N1+ND vaccine is intended for prevention of H5 avian influenza and Newcastle disease in chickens kept on backyards or in zones at high risk.

DOSAGE:

The vaccine is administered once S/C or intramuscularly in the breast muscle.
 Poultry of 1–30 days old, Inoculation dose is 0.25 cm³ of the vaccine.
 Chickens at the age of 30 days or older, Inoculation dose is 0.5 cm³ of the vaccine.

ADMINISTRATION:

- All clinically healthy poultry irrespective of the age is subject to immunization with revaccination in 30–40 days. Poultry from which eggs are derived are revaccinated one month prior to egg laying. Poultry of 1–30 days old are vaccinated with a half of the immunizing dose.
- Clinically diseased and/or emaciated poultry as well as chickens less than one month before egg-laying stage shall not be vaccinated.
- Before administration the vaccine shall be kept at temperature of 20–25°C for 6–9 hours. (The heating of the vaccine in water bath or on heating devices is not allowed).
- The bottle with vaccine shall be periodically shaken before and during use to reconstitute the emulsion homogeneity.

SAFETY:

- The vaccine overdosing does not induce any symptoms of avian influenza and Newcastle disease or other pathological signs.
- The vaccine does not induce any clinically apparent post vaccinal reactions. In some cases, slight swelling can occur at the site of injection that disappears in 2–3 weeks.
- It is recommended to avoid violating vaccination scheme as it may result in decreased effectiveness of avian influenza and Newcastle disease prevention.
- No adverse events and complications are generally observed when the vaccine is used according to the given instructions.
- The vaccine shall not be used in combination with other live immunobiologicals and drugs (antibiotics, sulfonamides, etc.).
- The birds shall not be vaccinated with other vaccines within 5 days after vaccination.
- The birds shall not be slaughtered for meat earlier than 40 days after vaccine administration.
- Eggs derived from vaccinated birds can be used without any restrictions.

PRESENTATION:

The vaccine is filled in plastic bottles of 500 cm³ (1000 doses) per bottle,

SHELF LIFE:

The vaccine shelf-life is 24 months from the date of its production provided that its storage and transportation conditions are complied. The expired vaccine shall not be used.

STORAGE & TRANSPORTATION:

The vaccine shall be stored and transported in a dry dark place at a temperature of 2°C–8°C. (Vaccine freezing is not allowed).

MANUFACTURER:

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FGBI (ARRIAH)



ARRIAH H5N1+ND

Safe to be used in chickens (S/C or I/M)

High immunogenic and protective activity for chickens against Avian Influenza and Newcastle Diseases

High Quality Adjuvant (Montanide ISA 70 G mineral oil)
 - Stable emulsion with low viscosity.
 - Long-term Protective Immune Response.
 - Stimulate both Humoral and Cell-mediated Immune Response.
 - Compatible with Inactivated Antigen.

ARRIAH H5N1+ND

Inactivated emulsified vaccine against avian influenza (H5N1) and Newcastle disease

Highly pathogenic avian influenza and Newcastle disease are the most common diseases for poultry industry in many countries. Damage caused by these diseases includes direct losses (poultry deaths, for AI H5, death ~100%) as well as indirect losses such as material costs for quarantine measures, vaccination. Due to viral nature of the said diseases, antibiotics cannot be used for their control. That's why vaccine prevention is the main method for their control.

ARRIAH H5N1+ND has a high immunogenic and protective activity for chickens against Avian Influenza and Newcastle Diseases

STUDY: Efficacy of Inactivated emulsified vaccine against avian influenza and Newcastle disease (ARRIAH H5N1+ND) for commercial poultry. Department for Biological and Technological Control, FGBI ARRIAH

Poultry: commercial chickens from poultry farms free from acute infectious diseases. Methods: 30 commercial chickens at the age of 80–120 days are used for testing of each vaccine batch (90 chickens per 3 batches). One dose was administered to one chicken intramuscularly, 30 chickens are left unvaccinated as controls for each vaccine batch (90 chickens per 3 batches). The chickens were observed during 360 days

Table 3
Efficacy of Inactivated emulsified vaccine against avian influenza and Newcastle disease (ARRIAH H5N1+ND) (Batch No. 1 of 01.2012)

Days	AIV antibody titers (log2)	NDV antibody titers (log2)	Control
0	0	6,00±0,25	6,10±0,33
28	5,60±0,16	10,2±0,14	5,19±0,23
60	6,52±0,29	11,84±0,15	5,80±0,36
90	6,28±0,98	11,43±0,27	6,23±0,45
120	6,15±0,29	11,23±0,21	6,02±0,37
150	5,83±0,85	11,19±0,19	5,83±0,87
180	5,86±0,82	10,83±0,14	4,97±0,92
210	5,42±0,14	10,75±0,22	5,32±0,75
240	5,89±0,28	10,54±0,27	4,89±0,45
270	4,64±0,96	10,17±0,23	5,12±0,63
300	4,19±0,12	9,85±0,18	5,34±0,83
330	4,11±0,97	9,74±0,16	6,00±0,98
360	4,19±0,82	9,34±0,19	6,16±0,87

Table 4
Efficacy of Inactivated emulsified vaccine against avian influenza and Newcastle disease (ARRIAH H5N1+ND) (Batch No. 2 of 03.2012).

Days	AIV antibody titers (log2)	NDV antibody titers (log2)	Control
0	0	6,10±0,87	6,12±0,73
28	4,90±0,43	9,22±0,44	5,35±0,76
60	5,98±0,49	10,36±0,65	5,48±0,39
90	6,08±0,77	10,47±0,37	6,76±0,95
120	6,50±0,13	10,29±0,28	6,57±0,68
150	6,20±0,25	10,39±0,59	5,93±0,63
180	5,99±0,84	9,25±0,17	4,58±0,84
210	5,62±0,19	9,56±0,62	5,03±0,60
240	5,19±0,45	10,93±0,87	4,59±0,36
270	4,87±0,90	9,57±0,81	5,34±0,78
300	4,34±0,19	9,39±0,33	5,32±0,29
330	4,11±0,97	9,86±0,76	5,98±0,93
360	3,65±0,79	8,34±0,46	6,06±0,57

Table 5
Efficacy of Inactivated emulsified vaccine against avian influenza and Newcastle disease (ARRIAH H5N1+ND) (batch 3 of 05.2012)

Days	AIV antibody titers (log2)	NDV antibody titers (log2)	Control
0	0	6,33±0,25	6,32±0,89
28	5,75±0,76	10,34±0,57	5,86±0,46
60	6,23±0,48	11,46±0,34	5,84±0,55
90	6,29±0,95	11,33±0,85	6,36±0,74
120	6,45±0,68	11,49±0,68	6,45±0,85
150	5,44±0,83	11,58±0,92	5,84±0,28
180	5,38±0,74	10,76±0,75	4,93±0,39
210	5,62±0,36	10,36±0,48	5,49±0,24
240	5,30±0,28	10,75±0,37	4,76±0,67
270	4,75±0,46	10,24±0,96	5,39±0,74
300	4,18±0,45	9,86±0,49	5,48±0,62
330	4,07±0,74	9,03±0,12	6,19±0,39
360	4,36±0,12	9,36±0,37	6,34±0,48

Conclusion:

The testing results demonstrate a high level of efficacy of Inactivated emulsified vaccine against avian influenza and Newcastle disease (ARRIAH H5N1+ND)

ARRIAH H5N1+ND is safe to be used in chickens (S/C or I/M)

STUDY: Vaccine over dosage safety (2 doses) at intramuscular administration

Test venue: Department for Biological and Technological Control, FGBI

Vaccine: Inactivated emulsified vaccine against AI and ND disease (ARRIAH H5N1+ND)

Ten 80–120 days-old commercial chickens were used for testing each vaccine batch (30 chickens for 3 batches). Each chicken was administered two vaccine doses intramuscularly. Ten chickens were kept as controls. All chickens were observed for 21 days. Within 21 days chicken should demonstrate no disease clinical signs or inflammation signs.

Results

During the observation period neither vaccinated nor control chickens demonstrated any ND or avian influenza signs or any signs of inflammation

Conclusion:

Intramuscular administration of double dose of Inactivated emulsified vaccine against AI and ND (ARRIAH H5N1+ND) induced no avian influenza (AI) or ND clinical signs and no inflammation at the administration site.

STUDY: Vaccine over dosage safety (2 doses) at subcutaneous administration

Test venue: Department for Biological and Technological Control, FGBI

Vaccine: Inactivated emulsified vaccine against AI and ND disease (ARRIAH H5N1+ND)

Ten 80–120 days-old commercial chickens were used for testing each vaccine batch (30 chickens for 3 batches). Each chicken was administered two vaccine doses subcutaneously. Ten chickens were kept as controls. All chickens were observed for 21 days. Within 21 days chicken should demonstrate no disease clinical signs or inflammation signs.

Results

During the observation period neither vaccinated nor control chickens demonstrated any ND or avian influenza signs or any signs of inflammation

Conclusion:

Subcutaneous administration of double dose of Inactivated emulsified vaccine against AI and ND (ARRIAH H5N1+ND) induced no avian influenza (AI) or ND clinical signs and no inflammation at the administration site.

High Quality Adjuvant (Montanide ISA 70 G mineral oil)

- Stable emulsion with low viscosity.
- Long-term Protective Immune Response.
- Stimulate both Humoral and Cell-mediated Immune Response.
- Compatible with Inactivated Antigen.