DESCRIPTION:

Live, freeze-dried Vaccine against infectious chicken bronchitis and Newcastle disease.

Medicinal form – a lyophilized mass. The vaccine is produced from the attenuated virus of chicken infectious bronchitis (strain "H-120" serotype Massachusetts) and Newcastle disease virus ("La-Sota" strain).

BIOLOGICAL PROPERTIES:

The vaccine causes the creation in birds of an immune response to chicken infectious bronchitis and Newcastle disease agents in 21 days following two-fold use and it lasts within not less than 3 months.

The vaccine induces immune response to IB and ND agents on day 21 after revaccination which lasts for 3 months.

One immunizing vaccine dose contains not less than 3,5 \lg EID₅₀ of IBV (H-120 strain) and not less than 6,5 \lg EID₅₀ of NDV (LaSota strain).

ADMINISTRATION:

- The vaccine is administered twice with interval of 10–14 days enterally (with drinking water), intranasal (ocularly) or with a large drop spraying (spray method).
- It is prohibited to vaccinate clinically diseased and/or injured birds.
- The method and the terms of vaccination are determined for a certain farm depending on the epizootic situation on chicken infectious bronchitis and Newcastle disease.

SAFETY:

- No symptoms of Newcastle disease and infectious chicken bronchitis or other pathological findings are detected
- At high dustiness of air in bird-houses and at excess of norms of ammonia content in 5-10% of vaccinated poultry, there can be noted a postvaccinal reaction in birds in the form of slight depression, slight rhinitis or conjunctivitis that disappear in 2-3 days.
- The violation of a schedule (dates) for carrying out vaccination shall be avoided as it can lead to the decrease in the efficacy of Newcastle disease and infectious chicken bronchitis prevention. In case of missing a regular administration of the vaccine the immunization shall be carried out as soon as possible.
- If the vaccine is used in accordance with the Instruction, side effects and complications are not observed as a rule in adult birds.
- It is prohibited to use the vaccine within 3-5 days before and 5-7 days after poultry treatment with chemotherapeutical means.
- · There are no restrictions in the use of meat, slaughter products and eggs from poultry immunized by vaccine against Newcastle disease and infectious chicken bronchitis.

SHELF LIFE:

The vaccine shelf life is 18 months from a date of manufacture subject to storage and transportation conditions. It is prohibited to use vaccine after an expiration date.

PRESENTATION:

The vaccine is filled per 1000 – 3000 doses (2.0–4.0 cm3) in vials of corresponding capacity.

STORAGE & TRANSPORTATION:

The vaccine is stored and transported in a dry dark place between +2°C and +8°C. Do not freeze.

MANUFACTURER:

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Highly **Immunogenic** Vaccine

Specific, **Effective & Safe** Vaccine

ARRIAH IB+ND

Live, freeze-dried vaccine for use against infectious chicken bronchitis and Newcastle disease

Highly Immunogenic Vaccine

Immunogenicity study

Vaccine immunogenicity i.e., its ability to protect poultry from infection is a key factor to assess the vaccine quality. During tests minimal immunizing vaccine dose was determined; antibody production dynamics to IBV in chicks after single and double vaccination was studied. The obtained data made it possible to estimate the vaccine as **highly immunogenic drug**.

Vaccine immunogenicity (ND component) was assessed by challenge of vaccinated poultry with NDV virulent strain "Tomilinsky". The results demonstrate **high immunogenicity of the tested drug.**

Obtained results demonstrate that live dry vaccine against IB and ND (ARRIAH IB+ND) is:

- Safe as after the injection of ten-fold vaccination dose all the chicks remained alive for ten days and no specific clinical signs of IB and ND were observed;
- Highly protective for birds as it induces strong immunity.

Specific, Effective & Safe Vaccine

Study of vaccine specific efficacy:

- Specific efficacy of the vaccine was studied both in the laboratory and under the production conditions. Intensity of antibody response and immunity level in chicks immunized with **ARRIAH IB+ND** live dry vaccine against IB and ND viruses was determined.
- Field tests of the vaccine have been carried out for many years in different regions of the country.
- Farms that used **ARRIAH IB+ND** live dry vaccine against IB and ND viruses remained free from infectious bronchitis and Newcastle disease.
- The use of **ARRIAH IB+ND** live dry vaccine against IB and ND during the monitoring period from 2006 to 2013 showed that the vaccine is an effective means of ND and IB specific prevention and poses no risk of serious adverse reactions, unexpected adverse reaction and side effects. (Individual clinical studies protocol)

Study of antibody production dynamics in chicks vaccinated with ARRIAH IB+ND live dry vaccine against IB and ND viruses (Single and Double Vaccination)

Antibody production dynamics observed during vaccination were studied in fifty 14 days old SPF chicks. Vaccination was carried out via drinking water at the dose of 10 000 EID50/cm3 of H-120 IBV strain and 106.5 EID50 of LaSota NDV strain. Sera samples were tested using ELISA and HI test on days 14, 28, 60, 90, 120, 150 and 180 post vaccinations. Half of chicks were revaccinated on day 10. Sera were tested using ELISA and HI test. Obtained results are given in the Table 12.

Table 12
Antigenicity of live dry vaccine against IB and ND during single or double vaccination

IB and ND	Groups					
antibody titers (days)	Single vac	ccination ND	Double va	ccination ND	Cor	itrol
Before vaccination	32±6	1:2	46±9	1:2	26±5	1:2
14	964±192	1:16	1073±214	1:16	38±7	1:2
21	1875±375	1:64	2124±424	1:64	52±10	1:2
60	1624±324	1:64	2247±449	1:128	67±13	1:2
90	1487±297	1:64	2035±407	1:64	63±12	1:2
120	925±185	1:32	1978±395	1:64	78±15	1:2
150	836±167	1:16	1347±269	1:32	85±17	1:2
180	785±157	1:8	922±184	1:16	71±14	1:2

Data in the Table 12 suggest that:

- Humoral antibody titers against IB and ND viruses after double vaccination were higher than after the single one. It was also established that humoral antibodies after double immunization with ARRIAH IB+ND vaccine remain at protection titers for a longer period.
- Young poultry is more susceptible to IB and ND viruses, that's why early vaccination seems reasonable.
- Revaccination is necessary if antibody titer is lower than two minimum positive values for IB and lower than 4,0 log2 for ND, that will help to maintain a sufficient immunity level in chicks for IB and ND prevention.
- Taking into account the abovementioned information, a single vaccination of chicks with live ARRIAH IB+ND vaccine ensures complete protection at early stages of poultry keeping.
- Later on, if antibody titer decreases to a level lower than two minimal positive values in ELISA for IB and lower than 4,0 log2 in HI-test for ND, revaccination is required that will intensify immune response and preserve high antibody titers for 120 days post revaccination. (Individual clinical studies protocol)

Influence of vaccine dose on immunity development in chicks

In order to determine an optimal vaccine dose, 7 days old chicks reared on farms free from infectious diseases were divided into 5 groups (15 birds per group).

The vaccine was administered at doses of 100, 1 000, 10 000 and 100 000 EID_{50} in reference to IB virus and at $10^{4.5}$, $10^{5.5}$, $10^{6.5}$, $10^{7.5}$ EID_{50} in reference to ND virus.

Group 5 served as control. Antibody titers were determined on day 21 using ELISA in reference to IB virus and HI test in reference to ND virus.Results are shown in the Table 10.

Average antibody titers in sera from chicks prior to vaccination and 3, 6 and 9 months post inoculation

Virus dose,

Titers of antibodies to IB virus in blood se

Virus dose,	Titers of antibodies to IB virus in blood sera (ELISA)				
lg EID₅₀	Before vaccination	Day 21			
100	35±7	452±90			
1000	22±4	1132±226			
10 000	43±8	1849±369			
100 000	28±5	1893±378			
Control	37±7	63±12			
Virus dose,	Titers of antibodies to ND virus in blood sera (HI test)				
Virus dose,	Titers of antibodies to ND	virus in blood sera (HI test)			
Virus dose, Ig EID ₅₀	Titers of antibodies to ND Before vaccination	virus in blood sera (HI test) Day 21			
lg EID ₅₀	Before vaccination	Day 21			
Ig EID ₅₀	Before vaccination	Day 21			
104.5 105.5	Before vaccination 1:2 1:2	1:16 1:32			

The data in the Table 10 suggest that:

- The humoral immune response of chicks to ARRIAH IB+ND vaccine doses of 10 000 and 100 000 $\rm EID_{50}$ in reference to IB virus on day 21 was much higher as compared with vaccine doses 100 and 1 000 $\rm EID_{50}$ in reference to ND virus. As for vaccination against ND vaccine doses of $10^{6.5}$ and $10^{7.5}$ caused more intensive antibody creation as compared with vaccine doses of $10^{4.5}$ and $10^{5.5}$.
- Thus, 10 000 EID_{50} dose can be recommended for vaccination against IB virus and $10^{6.5}$ dose can be recommended for vaccination against ND virus. A higher dose does not result in a further increase of humoral antibody titers in reference to IBV and ND viruses.

References:

- 1. State Pharmacopoeia.
- 2. State standards (GOST) and specifications (TU).
- 3. Internal documents of FGBI "ARRIAH":
- FGBI "ARRIAH" standard "Live dry vaccine against infectious bronchitis and Newcastle disease" (STO 00495527-0053-2012) (approved on 06.06.2012);
- Manufacturing specification for production of live dry vaccine against infectious bronchitis and Newcastle disease (approved on 11.11.2009);
- Instruction for use of live dry vaccine against infectious bronchitis and Newcastle disease (approved on 06.06.2012);
- Results of the pre-clinical tests for live dry vaccine against infectious bronchitis and Newcastle disease