

## Laboratories

All laboratory procedures and tests are conducted in compliance with international standards such as Good Laboratory Practice (GLP) and Good Clinical Practice (GCP).

### 1. Research and development (R&D) laboratory:

The lab consists of several units including Cell Culture, Virus, Molecular Analysis and Serology.

**Cell Culture Unit:** Culturing verity of cells is possible in Cell Culture unit.

**Virus Unit:** Virus isolations from contaminated tissues, virus inoculation and attenuation of pathogen virus can be done in Virus Unit.

**Molecular Analysis Unit:** Bacterial and viral DNA/RNA extraction, isolation and amplification of specific genes and recombinant proteins production are done in Molecular Analysis Unit.

**Serology Unit:** Antibody concentration in serum samples can be measured in Serology Unit.



### 2. In-Process Quality Control (IPQC) laboratory:

Demonstrate the quality of intermediate and final bulk.



### 3. Quality Control laboratory:

Demonstrate the quality of final products. Sterility, Mycoplasma, Virus titration, Potency, Karl. Fischer, Solubility, Extraneous Agent, Leak tests on final products and also Environmental Monitoring, Filter Integrity and Row Material Analysis can be done.

### 4. Animal laboratory

Animal laboratory is consist of mice keeping room, guinea pigs keeping room and autopsy room with the area of 36 m<sup>2</sup>. Environmental conditions monitor continuously. In this laboratory, Safety test is carried out on rodents (Mice and guinea pigs).



### Production Site

Production site is designed based on modern facilities with 400 m<sup>2</sup> clean room area for vaccine production in accordance with the European standards of GMP. Not to mention that it is equipped with the water treatment system for providing Water for Injection (WFI) and Pure Water (PW) in order to use in cell culture performances. Production site consists of variety units including Washing-Sterile, Storage, In-Process Quality Control (IPQC), Media, Cell Culture, Virus, Filling and Lyophilizing Room.

### Packaging

Externally final products survey in Eye Inspection (amount, shape and color) and transfer to Labeling and then Packaging room. Finally, it will be kept in Cold room.



### 5. Farm

Farm is consist of individual animal keeping rooms and autopsy room with the area of 100 m<sup>2</sup>. To evaluate vaccine quality, Essential tests such as safety and efficacy have done on target host (sheep and goat).



LIVE ATTENUATED PPR VACCINE



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Produced By: Vira vaccine Shaya Co.  
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Under supervision of IRAN Veterinary Organization





#### Peste des Petits Ruminants (PPR)

Peste des Petits Ruminants (PPR), also known as 'goat plague', is an acute, highly contagious and fatal viral disease of small ruminants and camels characterized by fever, oculonasal discharges, stomatitis, diarrhea, pneumonia with foul offensive breath and sometimes death. It is caused by a morbillivirus which belongs to the Paramyxoviridae family. PPR is a disease listed in the OIE Terrestrial Animal Health Code, and countries are obligated to report the disease to the OIE according to the criteria (OIE Terrestrial Animal Health Code).

#### Prevention and Control of PPR

Control of PPR outbreaks routinely is based on movement control combined with proper disposal of carcass and the use of vaccine. However, the most efficient way to control disease is vaccination. Vaccination should be carried out before the start of the rainy season and annually in endemic areas. Currently, live attenuated vaccines are used to immunize the susceptible small ruminant population.

#### Opportunities to eradicate PPR

- Vaccine induces a strong life-long immunity.
- Vaccine induces protective immunity against all known serotypes.
- Virus is transmitted by direct contact and does not persist in the environment.
- Infected animals are infectious for a short period of time and there is no carrier state.
- An effective, robust, safe and affordable vaccine is available.
- A thermo-stable vaccine has been developed.
- Sensitive and specific diagnostic tests are available.



#### Important Requirements for a Vaccine

- **Efficacy:** must give strong protection against disease following proper administration.
- **Safety:** no side effect whatever the physiological status of the host (in particular: no abortion).
- **Cost:** Affordable cost.
- **Availability:** must be easy to produce.

#### Characteristics of Vira-Peste® Vaccine

- Nigeria 75/1 vaccine strain developed by CIRAD (Origin: Nigeria 75/1 strain attenuated by 74 successive passages on Vero cells).
- Efficient, potent, safe and no residual side effects.
- Protective antibodies after a single injection in twenty-one days.
- Clinical protection against all lineages of PPRV.
- Passive immunity in young animals for 2-4 months after birth.

#### Vira-Peste® PPR Vaccine

Vira-Peste Vaccine is the first product produced by Vira Vaccine Shaya Company. It is packed in 15 vials per box. Each lyophilized vaccine vial reconstituted with 1 ml diluent contains 100 doses which is composed of the following material:

Constituent parts	Constituent value per vaccine
PPR virus Antigen Type Nigeria 75/1	$\geq 10^{2.5}$ TCID <sub>50</sub> /Dose
Sucrose	2.5%
Lactalbumin	1.25%
L-glutamine	0.5%



#### Thermostable Vira-Peste Vaccine (1 ml/vial Freeze-dried Vaccine)

One of the key issues in effective implementation of the existing live attenuated PPR vaccines is their limited thermo tolerance. Freeze-dried by use of lactalbumin, sucrose and L-glutamine as stabilizers increase the persistence of the vaccine. In accordance with stability tests, this technology has been applied to Vira-Peste Vaccine, resulting in proper stabilization. For instance, Vira-Peste Vaccine is stable for 5 days at +40 °C.

#### Vira Vaccine Shaya Company

Vira Vaccine Shaya Company was established in 2016 with the presence of competent authorities in the field of vaccine. The main goal is joining OIE in order to control and eradicate many animal diseases in Iran and the Middle East countries. This company obtained the GMP certification for production site and export license by the Iranian veterinary organization in 2018.

