Summary of product characteristics As per Annexure C

ANNEXURE C to MODULE I

SUMMARY OF PRODUCT CHARACTERISTICS
Doc. No. SPC/71108 Ver.1

1. NAME OF THE MEDICINAL PRODUCT.

- Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Inactivated Tetravalent Influenza Vaccine (Split Virion) for intramuscular injection is a sterile, opalescent suspension. Inactivated Tetravalent Influenza Vaccine (Split Virion) is prepared from influenza virus propagated in the fertilized hen's eggs. Following harvest, the virus is purified in a sucrose density gradient using a continuous flow ultra-centrifuge. The purified virus is spitted by Triton-X 100 and Purified with Tangential Flow Filtration & inactivated. The inactivated bulk is further diluted in a phosphate buffered isotonic solution for final formulation to prepare final bulk.

Name of ingredient	Spec.	Target Conc. Qty / Dose	Used as
A/California/7/2009 (H1N1) Like Virus	I.P.	≥ 15 µg HA	Antigen/Immunogen
A/Switzerland/9715293/2013/H3N2 Like Virus	I.P.	≥ 15 µg HA	Antigen/Immunogen
B/Phuket/3073/2013 Like Virus	I.P	≥ 15 µg HA	Antigen/Immunogen
B/Brisbane/60/2008 Like Virus	I.P	≥ 15 µg HA	Antigen/Immunogen
Phosphate Buffer Saline	I.H	q.s	Excipient

Propagated in fertilized hens eggs from healthy chicken flocks Inactivated by Betapropiolactone. Vaccine may contain traces of antibiotics, egg protein.

3. PHARMACEUTICAL FORM

Drug Substance(s)

- Inactivated bulk (Split vaccine) of H1N1, H3N2, Type B Phuket & Type B Brisbane has been developed as per WHO TRS 927 & 941 and Indian pharmacopoeia 2010 / 2014

Drug Product

- Inactivated Tetravalent Influenza Vaccine (Split Virion) – Single dose has been developed as per WHO TRS 927 & 941 and Indian pharmacopoeia 2010 / 2014.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. is indicated in adults (≥18 years of age) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.

4.2 Posology and method of administration

The recommended dose for adults (≥ 18 years of age) is 0.5ml single dose.

Shake well before administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

The preferred site for intramuscular injection is the deltoid muscle of the upper arm. Do not inject in the gluteal area or areas where there may be a major nerve trunk. Do not administer this product intravenously, intradermally, or subcutaneously.

4.3 Contraindications

Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. is contraindicated in person with history of severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or following a previous dose of any influenza vaccine. Immunization shall be postponed in patients with acute febrile illness

4.4 Special warnings and precautions for use

The vaccine should under no circumstances be administered intravascularly.

In rare cases anaphylactic shock may occur in susceptible individual and for such emergency 1:1000 adrenaline injection should be kept ready to be injected intramuscularly or subcutaneously. For treatment of severe anaphylaxis the initial dose of adrenaline is 0.1-0.5 mg (0.1-0.5ml of 1:1000 injections) given s/c or i/m. Single dose should not exceed 1 mg (1ml). For infants and children the recommended dose of adrenaline is 0.01mg/kg (0.01ml/kg of 1:1000 injections). Single paediatric dose should not exceed 0.5mg (0.5ml).

The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It should be used at the first suspicion of anaphylaxis. As with the use of all vaccines the vaccines should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions. Antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.

- If Guillain-Barre syndrome (GBS) has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. should be based on careful consideration of the potential benefits and risks.

- Syncope (fainting) can occur in association with administration of injectable vaccines, including Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P.. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

- If Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immuno competent persons

- As with other intramuscular injections, Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. should be given with caution in individuals with bleeding disorders such as hemophilia or on anticoagulant therapy, to avoid the risk of hematoma following the injection.

- Vaccination with Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. may not protect all susceptible individuals.

- Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1, have been observed. The Western Blot technique disproves the results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.5 Interaction with other medicinal products and other forms of interaction

Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. should not be mixed with any other vaccine in the same syringe or vial. There are insufficient data to assess the concurrent administration of Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. with other vaccines. When concomitant administration of other vaccines is required, the vaccines should be administered at different injection sites.

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune response to Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P.

4.6 Pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women. Data from worldwide use of influenza vaccine during pregnancy do not indicate any adverse Foetal or maternal outcomes attributable to the vaccine. Inactivated influenza vaccines can be used in all stages of pregnancy and lactation

4.7 Effects on ability to drive and use machines

Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. is unlikely to produce an effect on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions that have been observed during clinical trial with Inactivated Tetravalent Influenza Vaccine (Split Virion) I.P. include (irrespective of causal association): injection site pain, headache, fever, cold, vertigo, nausea, body ache, myalgia, fatigue and vomiting.

4.9 Overdose

Over dosage is unlikely to have any untoward effect

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

- Not applicable

5.2 Pharmacokinetic properties

- Not applicable

5.3 Preclinical safety data

- Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Phosphate Buffer Saline

6.2 Incompatibilities

- This product must not be mixed with other medicinal products.

6.3 Shelf life

- 1 Year

6.4 Special precautions for storage

The Vaccine should be stored at a temperature between 2 to 8°C. Transportation should also be at 2 to 8 °C.

Storage Condition: Store at 2 to 8 °C
Do not Freeze.
Discard Vaccine if Frozen
Shake well before use

6.5 Nature and contents of container

- 2R clear tubular glass Vial - USP Type I with 13 mm Grey Bromo butyl rubber stoppers with 2.70 mm flange thickness and 13 mm Aluminium flip off seals.

6.6 Special precautions for disposal

- Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION

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8. MARKETING AUTHORISATION NUMBER(S)

- **G/28D/VAC/03** (Manufacturing License Form 28-D)

9. DATE OF FIRST AUTHORISATION

- License No. G/28D/VAC/03 in Form 28D issued dated on 05/08/2015 & Valid up to dated 04/08/2020