

**Annexure-I(b)**

**Details of Manufacturing Permissions of Human Vaccines**

<b>Year 2025</b>					
<b>S.no</b>	<b>Name of Firm</b>	<b>Name of Vaccine</b>	<b>Composition</b>	<b>Indication</b>	<b>Permission No. &amp; Date</b>
9	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47,49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village: Changodar, Taluka: Sanand, Dist.: Ahmedabad-382213, Gujarat, India	Inactivated Influenza Vaccine (Split Virion) I.P (Trivalent) - Single dose (0.5 ml)	Each dose of Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) contains: <b>Ingredients</b> A/California/7/2009 (H1N1) like virus : $\geq 15 \mu\text{g}$ HA A/Switzerland/9715293/2013/H3N2 like virus : $\geq 15 \mu\text{g}$ HA B/Phuket/3073/2013 like virus : $\geq 15 \mu\text{g}$ HA	The vaccine indicated in adults ( $\geq 18$ 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.	24-04-2025

10	M/s Serum Institute of India Pvt. Ltd.,212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) - 411028	Influenza Vaccine (Human, Live Attenuated), Seasonal, Trivalent (Liquid) (NASOVAC S3)	Each dose of 0.5 mL after reconstitution contains: <b>Active Ingredients:</b> A(H1N1) Strain @* : Not less than 107 EID50 A(H3N2) Strain @* : Not less than 107 EID50 <b>Inactive Ingredients:</b> Partially hydrolyzed gelatin (IP/BP/EP/IH) : 1 % : 0.005 Sorbitol (IP/BP/EP) : 5.0 % : 0.025 L-Alanine (BP/EP) : 0.1 % : 0.0005 L-Histidine (BP/EP) : 0.21 % : 0.00105 Tricine (IH) : 0.3 % : 0.0015 L-Arginine Hydrochloride (BP/EP) : 1.6 % : 0.008 Phosphate buffered saline (IH) : Q. S. Q. S.: Quantity Sufficient @Propagated in Embryonated SPF Hen eggs. Strain names are as per WHO recommendation for a particular influenza season	For active Immunization against influenza disease caused by two influenza A subtype viruses and one influenza Type B virus in the age group of 2 years and above,	MF/BIO/25/00080 30-05-2025
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11	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram, Gachibowli, Hyderabad, Telangana (India) – 500032	Inactivated Hepatitis A vaccine (Adsorbed), I.P.” (0.5 ml) in pre-filled syringes (PFS)	<p>Each single dose of 1 mL contains:</p> <p><b>Ingredients</b></p> <p>Hepatitis A antigen : NLT 25 IU</p> <p>Aluminium content as Al(OH)<sub>3</sub> : NMT 1.25 mg</p> <p>Tween 20 : ≤ 0.0060 % w/v</p> <p>Phosphate buffered saline : q.s.</p> <p><b>Each single dose of 0.5 mL contains:</b></p> <p>Hepatitis A antigen : NLT 12.5 IU</p> <p>Aluminium content as Al(OH)<sub>3</sub> : NMT 0.625 mg</p> <p>Tween 20 : ≤ 0.0060 % w/v</p> <p>Phosphate buffered saline : q.s.</p>	For prevention of Hepatitis A infection for 0.5 mL dose of children (above 1 year) & adolescents and 1mL in adults (age 19 years to 49 years).	12-06-2025
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