

## VACCINES - INTERNATIONAL

### WHO PREQUALIFIED

1. Product	:	<b>DTwP–rHepB–Hib (Liquid) Pentavalent</b> Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and <i>Haemophilus influenzae</i> Type b conjugate Vaccine (Adsorbed)
Brand	:	<b>ComBE Five</b>
Label Composition	:	Each Dose of 0.5 mL contains : <ul style="list-style-type: none"> <li>◆ Diphtheria Toxoid ..... 25 Lf (≥ 30 IU)</li> <li>◆ Tetanus Toxoid ..... 5.5 Lf (≥ 60 IU)</li> <li>◆ B. Pertussis (Whole cell) ..... 16 IOU (≥ 4 IU)</li> <li>◆ r-HBsAg ..... 12.5 µg</li> <li>◆ Purified Capsular Polysaccharide of Hib (PRP) covalently linked to 20 to 36.7 µg of Tetanus Toxoid ..... 11 µg</li> <li>◆ Al<sup>+++</sup>(as AlPO<sub>4</sub>) ..... ≤ 1.25 mg</li> <li>◆ Preservative: Thiomersal BP/ Ph.Eur ..... 0.01% w/v</li> </ul>
Pack	:	0.5 mL Vial, 1.0 mL Vial, 2.5 mL Vial, 5.0 mL Vial, 0.5 mL Prefilled Syringe
Indication	:	Active Immunization against Diphtheria, Tetanus, Pertussis, Hepatitis B and <i>Haemophilus influenzae</i> type b diseases.

2. Product	:	<b>TT</b> Adsorbed Tetanus Vaccine BP
Brand	:	<b>BETT</b>
Label Composition	:	Each Dose of 0.5 mL contains : <ul style="list-style-type: none"> <li>◆ Tetanus Toxoid ..... ≥ 40 IU</li> <li>◆ Adsorbed on Aluminium Phosphate AlPO<sub>4</sub> ..... ≥ 1.5 mg</li> <li>◆ Preservative: Thiomersal BP ..... 0.01% w/v</li> </ul>
Pack	:	0.5 mL Vial, 5 mL Vial, 10 mL Vial
Indication	:	Active Immunization against Tetanus disease.

3. Product	:	<b>Td</b> Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content)
Brand	:	<b>BETd</b>
Label Composition	:	Each Dose of 0.5 mL contains : <ul style="list-style-type: none"> <li>◆ Diphtheria Toxoid ..... 2 Lf (≥ 2 IU)</li> <li>◆ Tetanus Toxoid ..... 8.8 Lf (≥ 20 IU)</li> <li>◆ Adsorbed on Aluminium Phosphate (AlPO<sub>4</sub>) ..... ≥ 1.5 mg</li> <li>◆ Preservative : Thiomersal BP ..... 0.01% w/v</li> </ul>
Pack	:	0.5 mL Vial, 5 mL Vial
Indication	:	Active Immunization against Tetanus and Diphtheria diseases in adults and adolescents.

4. Product	:	<b>JE</b> Japanese Encephalitis Inactivated Vaccine (Human) (Purified Inactivated Vaccine (Adsorbed))
Brand	:	<b>JEEV</b>
Label Composition	:	Each Dose of 0.5 mL contains : <ul style="list-style-type: none"> <li>◆ Purified Inactivated Japanese Encephalitis Virus Vaccine Strain (SA<sub>14</sub>-14-2)<sup>1</sup> ..... 3 µg</li> <li>◆ Aluminium as Aluminium Hydroxide ..... 0.1% w/v</li> <li>◆ Phosphate Buffer Saline ..... q.s</li> </ul> <sup>1</sup> Produced in Vero Cells
Pack	:	0.5 mL Vial*, 0.5 mL Prefilled Syringe * The product is also available as 2.5 mL - 5 Doses Vial with Thiomersal as preservative at a concentration of 0.005% w/v
Indication	:	Active Immunization against Japanese Encephalitis in 1-3 Years Aged Children

5. Product	:	<b>JE</b> Japanese Encephalitis Inactivated Vaccine (Human) (Purified Inactivated Vaccine (Adsorbed))
Brand	:	<b>JEEV</b>
Label Composition	:	Each Dose of 0.5 mL contains : <ul style="list-style-type: none"> <li>• Purified Inactivated Japanese Encephalitis Virus Vaccine Strain (SA<sub>14</sub>-14-2)<sup>1</sup> ..... 6 µg</li> <li>• Aluminium as Aluminium Hydroxide ..... 0.1% w/v</li> <li>• Phosphate Buffer Saline ..... q.s</li> </ul> <sup>1</sup> Produced in Vero Cells
Pack	:	0.5 mL Vial*, 0.5 mL Prefilled Syringe * The product is also available as 2.5 mL - 5 Doses Vial with Thiomersal as preservative at a concentration of 0.005% w/v
Indication	:	Active Immunization against Japanese Encephalitis in 3 - 49 years Aged Individuals

6. Product	:	<b>DTwP</b> Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed)
Brand	:	<b>TRIPVAC</b>
Label Composition	:	Each Dose of 0.5 mL contains : <ul style="list-style-type: none"> <li>• Diphtheria Toxoid ..... 25 Lf (≥ 30 IU)</li> <li>• Tetanus Toxoid ..... 5.5 Lf (≥ 60 IU)</li> <li>• B. Pertussis ..... 16 IOU (≥ 4.0 IU)</li> <li>• Adsorbed on Aluminium Phosphate AIPO<sub>4</sub> ..... ≥ 1.5 mg</li> <li>• Preservative: Thiomersal ..... 0.01 % w/v</li> </ul>
Pack	:	0.5 mL Vial, 5 mL Vial
Indication	:	Active Immunization against Diphtheria, Tetanus and pertussis diseases.

7. Product	:	<b>MR</b> Measles and Rubella Vaccine (Live) (Attenuated, Freeze Dried)
Brand	:	<b>MRBEV</b>
Label Composition	:	Each Reconstituted Dose of 0.5 mL contains : <ul style="list-style-type: none"> <li>◆ Measles Virus (CAM-70 Strain), Propagated in Chicken Embryo Fibroblast cells ..... ≥ 1000 CCID<sub>50</sub></li> <li>◆ Rubella Virus (Wistar RA 27/3 Strain), propagated in MRC 5 Cells ..... ≥ 1000 CCID<sub>50</sub></li> </ul> Reconstitute the vaccine vial with diluent (0.9% w/v Sodium Chloride Injection IP)
Pack	:	1 dose, 5 dose and 10 dose presentations in vials  The vaccine is supplied along with diluent (0.9% w/v Sodium Chloride for Injection). Only the diluent supplied with the vaccine shall be used for reconstitution.
Indication	:	Active Immunization against Measles and Rubella viruses.

8. Product	:	<b>TCV Typhoid Conjugate Vaccine</b> (Monovalent)
Brand	:	<b>TYPHIBEV</b>
Label Composition	:	Each Dose of 0.5 mL contains : <ul style="list-style-type: none"> <li>◆ Typhoid Vi Polysaccharide<sup>1</sup> conjugated to 16.7 µg to 100 µg of CRM<sub>197</sub> ..... 25 µg</li> <li>◆ Sodium chloride and phosphate buffer ..... q.s</li> <li>◆ 2-Phenoxyethanol (as Preservative) ..... 5 mg</li> </ul> <sup>1</sup> Produced from <i>C. freundii sensu lato</i> 3056
Pack	:	Single dose vial of 0.5 mL & Five dose vial of 2.5 mL  Single dose vial of 0.5 mL supplied along with 2 mL syringe and two 25 G needles (One 5/8" length & One 1" length)
Indication	:	Active Immunization against Typhoid

**OTHERS**

1. Product : **Hep B**  
Hepatitis B Vaccine (rDNA) BP (Paediatric)
- Brand : **BEVAC**
- Label Composition : Each Dose of 0.5 mL contains :
- ◆ Purified HBsAg ..... 10 µg
  - ◆ Aluminium Hydroxide gel equivalent to Al<sup>+++</sup> ..... 0.25 mg
  - ◆ Preservative: Thiomersal BP ..... 0.025 mg
- Recombinant HBs antigen produced in *Pichia pastoris* (Yeast)
- Pack : 0.5 mL Vial, 1 mL Vial, 2.5 mL Vial , 5 mL Vial
- Indication : Active Immunization against infection caused by Hepatitis B.
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2. Product : **Hep B**  
Hepatitis B Vaccine (rDNA) BP (Adult)
- Brand : **BEVAC**
- Label Composition : Each Dose of 1 mL contains :
- ◆ Purified HBsAg ..... 20 µg
  - ◆ Aluminium Hydroxide gel equivalent to Al<sup>+++</sup> ..... 0.5 mg
  - ◆ Preservative: Thiomersal BP ..... 0.05 mg
- Recombinant HBs antigen produced in *Pichia pastoris* (Yeast)
- Pack : 1 mL Vial, 10 mL Vial
- Indication : Active Immunization against infection caused by Hepatitis B.
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3. Product : **DT**  
Adsorbed Diphtheria and Tetanus Vaccine
- Label Composition : Each Dose of 0.5 mL contains :
- ◆ Diphtheria Toxoid ..... ≥ 30 IU
  - ◆ Tetanus Toxoid ..... ≥ 40 IU
  - ◆ Adsorbed on Aluminium Phosphate  $AlPO_4$  ..... ≥ 1.5 mg
  - ◆ Preservative: Thiomersal BP ..... 0.01 %w/v
- Pack : 0.5 mL Vial, 5 mL Vial, 10 mL Vial
- Indication : Active Immunization against Diphtheria and Tetanus diseases.
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**PIPELINE**

1. Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) ..... **PCV**
2. Inactivated Polio Vaccine ..... **IPV**
3. DTwP-rHepB-Hib-IPV ..... **Hexavalent**