WHO PREQUALIFIED

1. **Product**: DTwP–rHepB–Hib (Liquid) Pentavalent
   Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus Inuenzae Type b conjugate Vaccine (Adsorbed)
   
   **Brand**: ComBE Five
   
   **Label Composition**: Each Dose of 0.5 mL contains:
   - Diphtheria Toxoid ........................................... 25 Lf (≥ 30 IU)
   - Tetanus Toxoid ............................................... 5.5 Lf (≥ 60 IU)
   - B. Pertussis (Whole cell) ................................. 16 IOU (≥ 4 IU)
   - r-HBsAg ......................................................... 12.5 µg
   - Puried Capsular Polysaccharide of Hib (PRP) covalently linked to 20 to 36.7 µg of Tetanus Toxoid ........................................... 11 µg
   - AI*** (as AlPO₄) .............................................. ≤ 1.25 mg
   - Preservative: Thiomersal BP/ Ph.Eur ................... 0.01% w/v
   
   **Pack**: 0.5 mL Vial, 1.0 mL Vial, 2.5 mL Vial, 5.0 mL Vial, 0.5 mL Prefilled Syringe
   
   **Therapeutic Use**: Active Immunization against Diphtheria, Tetanus, Pertussis, Hepatitis B and Haemophilus Inuenzae type b

2. **Product**: TT Adsorbed Tetanus Vaccine BP
   
   **Brand**: BEtt
   
   **Label Composition**: Each Dose of 0.5 mL contains:
   - Tetanus Toxoid ............................................... ≥ 40IU
   - Adsorbed on Aluminium Phosphate AlPO₄ .................. ≥ 1.5 mg
   - Preservative: Thiomersal BP .............................. 0.01% w/v
   
   **Pack**: 0.5 mL Vial, 5 mL Vial, 10 mL Vial
   
   **Therapeutic Use**: Active Immunization against Tetanus

3. **Product**: Td Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content)
   
   **Brand**: BE Td
   
   **Label Composition**: Each Dose of 0.5 mL contains:
   - Diphtheria Toxoid ........................................... 2 Lf (≥ 2 IU)
   - Tetanus Toxoid ................................................ 8.8Lf (≥ 20 IU)
   - Adsorbed on Aluminium Phosphate (AlPO₄) ........... ≥ 1.5 mg
   - Preservative: Thiomersal BP .............................. 0.01% w/v
   
   **Pack**: 0.5 mL Vial, 5 mL Vial
   
   **Therapeutic Use**: Active Immunization against Tetanus and Diphtheria for Adults and Adolescents
4. Product : **JE**
Japanese Encephalitis Inactivated Vaccine (Human)
(Purified Inactivated Vaccine (Adsorbed))

Brand : **JEEV**

Label Composition : Each Dose of 0.5 mL contains:
- Purified Inactivated Japanese Encephalitis Virus Strain (SA_{14}-14-2) \( 1 \) \( 3 \) µg
- Aluminium as Aluminium Hydroxide \( 0.1 \) % w/v
- Phosphate Buffer Saline \( q.s \)

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

Therapeutic Use : Active Immunization against Japanese Encephalitis in 1-3 Years Aged Children

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5. Product : **JE**
Japanese Encephalitis Inactivated Vaccine (Human)
(Purified Inactivated Vaccine (Adsorbed))

Brand : **JEEV**

Label Composition : Each Dose of 0.5 mL contains:
- Purified Inactivated Japanese Encephalitis Virus Strain (SA_{14}-14-2) \( 1 \) \( 6 \) µg
- Aluminium as Aluminium Hydroxide \( 0.1 \) % w/v
- Phosphate Buffer Saline \( q.s \)

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

Therapeutic Use : Active Immunization against Japanese Encephalitis in 3-49 years Aged Individuals

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6. Product : **DTwP**
Diphtheria, Tetanus and Whole cell Pertussis Vaccine (Adsorbed)

Brand : **TRIPVAC**

Label Composition : Each Dose of 0.5 mL contains:
- Diphtheria Toxoid \( 25 \)Lf (≥ 30 IU)
- Tetanus Toxoid \( 5.5 \)Lf (≥ 60IU)
- B. Pertussis \( 16 \) IOU (≥ 4.0IU)
- Adsorbed on Aluminium Phosphate AIPO_{4} \( \geq 1.5 \) mg
- Preservative: Thiomersal \( 0.01 \) % w/v

Pack : 0.5 mL Vial, 5 mL Vial

Therapeutic Use : Active Immunization for Diphtheria, Pertussis and Tetanus
**PRODUCT LIST**

**VACCINES**

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**OTHERS**

7. **Product**: 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+++ ........................................ 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  
**Therapeutic Use**: Active Immunization against Hepatitis B

8. **Product**: 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+++ ........................................ 0.5 mg  
- Preservative: Thiomersal BP ................................................................. 0.05 mg  
  Recombinant HBs antigen produced in Pichia Pastoris (Yeast)  
**Pack**: 1 mL Vial, 10 mL Vial  
**Therapeutic Use**: Active Immunization against Hepatitis B

9. **Product**: MR  
**Measles and Rubella Vaccine (Live) (Attenuated, Freeze Dried)**  
**Brand**: MRBEV  
**Label Composition**: Each Reconstituted Dose of 0.5 mL contains:  
- Measles Virus (CAM-70 Strain), Propagated in Chicken Embryo Fibroblast cells .......................................................... ≥ 1000 CCID$_{50}$  
- Rubella Virus (Wistar RA 27/3 Strain), propagated in MRC 5 Cells .................................................. ≥ 1000 CCID$_{50}$  
  Reconstitute the vaccine with diluent  
  (0.9% w/v Sodium Chloride Injection IP)  
**Pack**: 0.5 mL Vial, 2.5 mL Vial, 5 mL Vial  
**Therapeutic Use**: Active Immunization against Measles and Rubella
PRODUCT LIST

VACCINES

10. 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 AlPO4 ≥ 1.5 mg
   - Preservative: Thiomersal BP 0.01 %w/v

   **Pack** : 0.5 mL Vial, 5 mL Vial, 10 mL Vial
   **Therapeutic Use** : Active Immunization against Diphtheria and Tetanus in Children

11. Product : **Hib**
   Haemophilus Type b Conjugate Vaccine (Lyophilized)

   **Brand** : **HiBE**

   **Label Composition** : Each Reconstituted Dose of 0.5 mL contains :
   - Purified Capsular Polysaccharide (PRP) 10 µg
   - Tetanus Toxoid (Carrier Protein) 19 to 33 µg
   - Sucrose BP 42 mg

   Reconstitute the Vaccine with Diluent (0.4% w/v Sodium Chloride Injection BP)

   **Pack** : 0.5 mL Vial, 5 mL Vial
   **Therapeutic Use** : Active Immunization against *Haemophilus Influenzae* type b infection in children of age group 6 weeks to 5 years

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**PIPELINE**

1. Typhoid Conjugate Vaccine – **TCV**
2. Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14) – **PCV**
3. Inactivated Polio Vaccine – **IPV**
4. DTwP-rHepB-Hib-IPV – **Hexavalent**
5. Hepatitis A Vaccine