Annexure 4 The committee deliberated on the technical specification of the drugs/ immunoglobulin to be used under the NVHCP and finalized the following specifications

1) Tenofovir 300 mg (TDF)
2) Entecavir 0.5 mg
3) Entecavir 1mg
4) Hepatitis B Immunoglobulin (HBIG)

1) **Tenofovir 300 mg (TDF)**

Technical specifications:

1. Each tablet contains TenofovirDisoproxilFumarate 300mg
2. Number of tablets /capsules per container: 30 tablets/package
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4. The product insert must indicate dosage form (tablet/capsule) and the drug content. The product should conform to standards of IP or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry dates

General specifications:

1. Standard Shelf Life: at least 18 months at the place of dispatch to the consignee
2. Primary Container: Suitable , Opaque Plastic Bottle to contain 30 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap**OR** any other packaging subject to the approvals of the concerned authority based on which the license has been granted under the provisions of Drug and Cosmetic Act & Rules
3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by NVHCP should be used. Each label should have clearly marked as "Government of India Supply, Not for sale" on primary packaging. The packaging and labelling requirements must meet the GMP practices
4. Each lot shall be tested in compliance with thepharmacopeia specifications by a designated laboratory before supply.

The committee approved the specification of Tenofovir 300 mg (TDF)

2) Entecavir 0.5 mg

1) Each tablet contains : Entecavir 0.5mg
2) Number of tablets per container: 30 tablets/package
3) Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4) The product insert must indicate dosage form (tablet) and the drug content. The product should conform to standards of IP or any other pharmacopeia
5) The label must indicate clearly the manufacturing and the expiry dates

General specifications

1. Standard Shelf Life: atleast 18 months at the place of dispatch to the consignee
2. Primary Container: Suitable , Opaque Plastic Bottle to contain 30 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap**OR** any other packaging subject to the approvals of the concerned authority based on which the license has been granted under the provisions of Drug and Cosmetic Act & Rules
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4. Each lot shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply.

The committee approved the specification of Entecavir 0.5 mg

3) Entecavir 1 mg

Technical specifications

1. Each tablet contains : Entecavir1mg
2. Number of tablets per container: 30 tablets/package
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4. The product insert must indicate dosage form (tablet) and the drug content. The product should conform to standards of IP or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry dates

General specifications

1. Standard Shelf Life: atleast 18 months at the place of dispatch to the consignee
2. Primary Container: Suitable , Opaque Plastic Bottle to contain 30 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap**OR** any other packaging subject to the approvals of the concerned authority based on which the license has been granted under the provisions of Drug and Cosmetic Act & Rules
3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by NVHCP should be used. Each label should have clearly marked as " Government of India Supply, Not for sale" on primary packaging. The packaging and labelling requirements must meet the GMP practices
4. Each lot shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply.

The committee approved the specification of Entecavir 1 mg