1.3.1 SPC – Summary of the Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Poliomyelitis Vaccine (Oral) Bivalent Type 1 and 3 – 20 dose

2. QUALITATIVE AND QUANTATIVE COMPOSITION

Each dose of 2 drops (0.1 ml) contains Polio virus (Sabin), grown on Primary Monkey Kidney Culture:

Contents	Quantity per 0.1 ml [Each dose of 2 drops]	Active / Non active	Specification	Reason for inclusion
Polio virus (Sabin) Type 1	$\geq 10^{6.0}$ $CCID_{50}$	Active	WHO TRS 904, Annex 1, 2002	Immunizing agent
Polio virus (Sabin) Type 3	$\geq 10^{5.8}$ $CCID_{50}$			
Neomycin sulphate	15 mcg	Non active	In-house/ IP/BP/Ph.Eur	Preservative
Magnesium chloride	1M	Non active	IP/BP/Ph.Eur	Stabilizer

3. PHARMACEUTICAL FORM

Solution for Oral administration. Pale pink to pink clear liquid in clear glass vial.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Bivalent OPV (Type 1 and 3) is indicated for active Immunization against Type 1 & 3 Polioviruses.

4.2 Posology and method of administration

Bivalent OPV must only be administered orally. Two drops are delivered directly into the mouth from the multi dose vial by dropper. For older children it may be preferred to avoid

possible bitter taste by first placing the drops on a sugar lump or in syrup. Care should be taken not to contaminate a multi dose dropper with saliva of the vaccinee.Overdose if any, will not result in ill effect.
Once opened, multi dose vials should be kept between +2°C and +8°C.Multi dose vials of bOPV from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for upto a maximum of 4 weeks, provided that all of the following conditions are met (as described by WHO policy statement. The use of opened multidose vials in subsequent immunization sessions WHO/V& B/00.09):

- The expiry date has not passed.
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water;
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point (see figure).

4.3 Contraindication

No adverse effects are produced by giving OPV to a sick child. In case of Diarrhea or vomiting (including gastrointestinal infection) the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.
Individuals infected with Human Immune Deficiency Virus (HIV) both symptomatic and asymptomatic should be immunized with OPV according to standard schedules. However the vaccine is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukaemia, lymphoma or generalized malignancy.

4.4 Special Warning and Precaution

The possibility of allergic reactions in individuals sensitive to the components of the vaccine should be evaluated. OPV bivalent should not be used for routine immunization.

4.5 Interaction With other Medicinal Products, Other Interactions

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4.6 Pregnancy and Lactation

Not Applicable.

4.7 Effects On Ability To Drive And Use Machines

Not Applicable.

4.8 Adverse Reactions

Adverse Reactions

In the vast majority of cases there are no side effects. Very rarely, there may be vaccine associated paralysis (one case per one million doses administered).Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine associated paralytic poliomyelitis.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Vaccines

ATC code J07BF

5.2 Pharmacokinetics Properties

Pharmacokinetic studies are not required for vaccines.

5.3 Preclinical Safety Data

No data available.

6.0 PHARMACEUTICAL PROPERTIES

6.1 List of Excipients

List of Excipients

(a) List of excipients

S. No.	Name	Specification	SOP No	Used for
1	Magnesium Chloride	IP/BP/Ph.Eur	035 6299	Stabilizer preparation
2	Tween 80 (Polysorbate 80)	IP	035 6433	To avoid aggregation of virus particles
3	Neomycin sulphate	In-house based on IP/BP/Ph.Eur	035 6229	Preservative
4	Water for Injections q.s.	IP/BP/Ph.Eur/ USP	035 0088	Solvent

6.2 Incompatibilities

Stability studies have demonstrated compatibility of the container closure system with the drug product. No decrease in potency of the final vaccine as a result of sorption to the primary packaging materials during storage has been found.

6.3 Shelf Life

24 Months .Vaccine is potent if stored at not higher than -20°C until the expiry date indicated on the vial. It can be stored for up to 6 months between +2°C and +8°C.

6.4 Special Precautions for storage

Vaccine is potent if stored at not higher than -20°C until the expiry date indicated on the vial. It can be stored for up to 6 months between +2°C and +8°C.

6.5 Nature and Contents of Packaging

4 ml clear tubular USP type I glass Vial, body diameter 16.5 mm and height 40 mm.

6.6 Instructions regarding the preparation of medicinal products for its use and handling

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1.7 MARKETING AUTHORISATION HOLDER

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1.8 NUMBER IN THE REGISTER OF MEDICINAL PRODUCTS

1.9 DATE OF AUTHORISATION OR LAST RENEWAL OF AUTHORISATION

1.10 DATE OF REVISION OF TEXT
