PUBLIC ASSESSMENT SUMMARY REPORT – Poliomyelitis Vaccine (Oral) bivalent types 1 & 3– Serum Institute of India Limited (SIIL)

What is Poliomyelitis Vaccine (Oral) bivalent types 1 & 3 (bOPV)?

Poliomyelitis Vaccine (Oral) bivalent types 1 & 3 (bOPV) is a vaccine filled by SIIL from monovalent bulks supplied by Bio Farma, Indonesia with the following composition:

Name of ingredients	Unit and/or percentage formula
Active ingredients :	
Polio virus (Sabin) Type 1 Polio virus (Sabin) Type 3 Grown in Primary Monkey Kidney Cells	6.0 $CCID_{50}$/0.1ml =2drops 5.8 $CCID_{50}$/0.1ml =2drops
Excipients :	
Neomycin sulphate Magnesium chloride Tween 80 (Polysorbate 80) Water for injection q.s.	15mcg/0.1ml 1M 10µg 0.10ml

Phenol red and traces of antibiotics (kanamycin and erythromycin) are not added during formulation but can be present as traces from the monovalent bulks.
Source of the prequalified monovalent bulk is Bio Farma, Indonesia.

The vaccine is supplied in transparent glass vials of 4 mL capacity, in 10 & 20 doses.

Real time and accelerated stability data reviewed support the use of a VVM type 2, that is affixed on the label.

What is Poliomyelitis Vaccine (Oral) bivalent types 1 & 3 (bOPV) used for?

Bivalent OPV (Type 1 and 3) is indicated for active immunization against Type 1 and 3 polioviruses.

How is Poliomyelitis Vaccine (Oral) bivalent used?

Bivalent OPV (type 1 and 3) is indicated for routine and supplementary immunization activities (SIAs) against type 1 and 3 poliovirus in all age groups. The use of this vaccine should be in accordance with official recommendations. bOPV can be given safely and effectively at the same time as IPV, measles,

rubella, mumps, DTP, DT, TT, Td, BCG, hepatitis B, Haemophilus influenzae type b, yellow fever vaccine and Vitamin A supplementation.

Precautions for use:

bOPV must be administered by oral route only, by using an oral dropper supplied with the vaccine vial.
2 drops will deliver 0.1 mL directly into the mouth from the multi dose vial by dropper. For older children it may be preferred to avoid the 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.

What are the vaccine characteristics?

Vaccine is potent if stored at not higher than -20º C until the expiry date indicated on the vial. It can be stored for up to six months between +2º C and +8º C.
The vaccine may present a colour varying from light yellow to dark pink due to a slight variation of pH, however this does not affect the quality of vaccine.

Who is the regulatory authority responsible for its oversight vis a vis WHO?

bOPV was licensed in India on 9 January 2013. The NRA of Record for this vaccine is the Central Drugs Standard Control Organization in India, www.cdsco.nic.in

How has bOPV been studied from the clinical point of view?

No specific clinical data was required before licensing of SIIL bOPV and prequalification by WHO. The monovalent bulks produced by Bio Farma in Indonesia and filled by several manufacturers have been extensively used and epidemiological and clinical data have clearly demonstrated the good seroprotection acquired in the target population with those different bOPVs.

Other information about evaluation of bOPV:

The vaccine was accepted for review under the special considerations for fast track procedure as described in the Procedure for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies WHO/BS/10.2155. Evaluation of the pharmaceutical dossier was performed in collaboration with the NRA of record. In addition, WHO specific requirements were evaluated for compliance with the tender issued by the UN procurement agencies. On the basis of the satisfactory (i) assessment of the quality data, (ii) independent testing in WHO contracted laboratories, and (iii) outcome of a site audit conducted by WHO, the prequalification was granted by WHO.

The vaccine meets WHO requirements of WHO TRS 980, annex 2 published at:
http://www.who.int/immunization_standards/en/

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