PUBLIC ASSESSMENT SUMMARY REPORT – POLIO VACCINE - ORAL (OPV) BIVALENT TYPES 1 AND 3

Bivalent type 1&3 Oral Poliomyelitis vaccine, IP (bOPV)

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What is bivalent type 1&3 oral poliomyelitis vaccine, IP (bOPV)?

Bivalent type 1&3 oral poliomyelitis vaccine, IP (bOPV) is a vaccine produced by Haffkine Bio Pharmaceutical Corporation Ltd, India 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 LSc, 2ab (Live, attenuated)	Not less than $10^{6.0}$ $CCID_{50}$*
Polio virus (Sabin) Type 3 Leon 12a, 1b (Live, attenuated)	Not less than $10^{5.8}$ $CCID_{50}$
Grown in primary monkey kidney cells	For each 0.1mL dose (2 drops)
Excipients:	
Erythromycin and Kanamycin (from bulks)	Trace amounts
Hanks balanced salt solution with $MgCl_2$ 1M and phenol red	Qs 0.1mL

* $CCID_{50}$: 50% Cell Culture Infective Doses (viral infectious units)

Source of the prequalified monovalent bulk is Bio Farma, Indonesia.

The vaccine is presented in glass vials (multi-dose vials containing 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 bivalent type 1&3 oral poliomyelitis vaccine, IP (bOPV) used for?

Bivalent type 1&3 oral poliomyelitis vaccine, IP (bOPV) is indicated for poliomyelitis routine immunization in addition to Supplementary Immunization Activities (SIAs) in children from 0 to 5 years

of age, to interrupt types 1 & 3 poliovirus transmission in remaining polio endemic areas. The routine poliomyelitis vaccination program should continue according to national policy and WHO recommendations.

How is bivalent type 1&3 oral poliomyelitis vaccine, IP (bOPV) used?

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.

Warnings and precautions for use

In case of diarrhoea, the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

bOPV must be administered by oral route only, by using a multi-dose 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 young 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.

Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, in compliance with WHO Multi-Dose Vial Policy.

What are the vaccine characteristics?

The 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 six months between +2°C and +8°C.

Due to minor variation of its pH, OPV may vary in colour from light yellow to light red. However this does not affect the quality of the vaccine.

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

bOPV was licensed in India on 25th February, 2010. 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 for the licensing of Haffkine Bio Pharmaceutical Corporation Ltd bOPV by CDSCO and prequalification by WHO. A randomized controlled trial study of bivalent oral

polio vaccine manufactured by Indian filler using monovalent bulk procured from PT. Bio Farma (Persero) was conducted in India, in 2008.
It was assessed the superiority of bOPV types 1 and 3, monovalent type 2 OPV (mOPV2), monovalent type 3 OPV (mOPV3) over trivalent OPV (tOPV) and the non-inferiority of bivalent vaccine compared with mOPV1 and mOPV3.

The findings demonstrated the superiority of bOPV compared with tOPV, and the non-inferiority of bOPV compared with mOPV1 and mOPV3. Epidemiological and clinical data have clearly showed the good seroprotection acquired in the target population with bOPV types 1 and 3.
The study was published by Roland W Sutter et al in Lancet, 2010; 376, 1682-88 and served the purposes of licensing and prequalification.

Other information about evaluation of bOPV:

Assessment of the product was based on appropriate review of the submitted Product Summary File, evaluation of the consistency of final product characteristics and follow up of implementation of recommendations made by WHO reviewers during the evaluation.

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

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