Annexure – 9

Bharat Immunologicals & Biologicals Corporation Limited

Annexure C to Module I

Doc. No. SPC/71108 Ver.1

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Bivalent Oral Polio Vaccine containing not less than $10^{6.0}$ $CCID_{50}$ of Type - 1 and $10^{5.8}$ $CCID_{50}$ of Type – 3

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

COMPOSITION	EACH DOSE (2 DROPS=0.1 ml.) CONTAINS NOT LESS THAN		
	POLIOVIRUS TYPE 1	:	$10^{6.0}$ $CCID_{50}$
	POLIOVIRUS TYPE 3	:	$10^{5.8}$ $CCID_{50}$
	1M $MgCl_2$ AS STABILIZER	:	20.33 mg
	KANAMYCIN ACID SULPHATE	:	0.015 MG.
	TWEEN-80	:	0.010 MG.
	WATER FOR INJECTION	:	Q.S. 0.1ml

3. PHARMACEUTICAL FORM

*Liquid doses form (**2 DROPS = 0.1 ml. (ONE HUMAN DOSE))***

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vaccine

4.2 Posology and method of administration

To be delivered orally for children of the age of 5 years or below.

4.3 Contraindications

No adverse effect are produce by giving OPV to a sick child.

4.4 Special warnings and precautions for use

1. *Vaccine is for oral route only. It should not be given parenterally.*
2. *Vaccine should not be used if turbidity noted on thawing.*

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4.5 Interaction with other medicinal products and other forms of interaction

Not applicable

4.6 Pregnancy and lactation

Not applicable

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Not applicable

4.9 Overdose

Not side effect of overdose is known.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1M $MgCl_2$ AS STABILIZER	:	*20.33 mg*
KANAMYCIN ACID SULPHATE	:	*0.015 MG.*
TWEEN-80	:	*0.010 MG.*
WATER FOR INJECTION	:	*Q.S. 0.1ml*

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

i. 2 years at -20^{0}C or below
ii. Six months at 2-8^{0}C

6.4 Special precautions for storage

Vaccine should be stored at -20^{0}C or below

6.5 Nature and contents of container

Vaccine will be stored in 3ml. USP Type-1 glass container. Volume of vaccine will be 2.2 ml equipvalent to 20 doses.

6.6 Special precautions for disposal

Unused product for waste materials could be disposed after decontamination and as per Regulatory provision in this regard.

7. MARKETING AUTHORISATION> <PREQUALIFICATION> HOLDER

BIBCOL has marketing authorization for tOPV and mOPV 1, 2 and 3.

8. <MARKETING> AUTHORISATION NUMBER(S)

BIBCOL has marketing authorization for tOPV and mOPV 1, 2 and 3 – (Four numbers)

9. DATE OF FIRST < AUTHORISATION> / RENEWAL OF THE <AUTHORISATION>

It is fresh application to obtain license for bOPV production.

<{DD/MM/YYYY}> <{DD month YYYY}> {MM/YYYY}