



Haffkine Bio-Pharmaceutical Corporation Limited.
(A Govt. of Maharashtra Undertaking)
Acharya Donde Marg, Parel, Mumbai 4000 12.

EXPRESSION OF INTEREST

HBPCL invites expression of Interest from manufacturer of :

1. 20mm Grey Butyl Rubber stopper (Ready for Sterilization) Plain & slotted.
2. 20mm Aluminium seals for vials plain & Laquer coated or pre-sterilized (Gama irradiated) clean Aluminium seals.
3. Pre-sterilized (Gama irradiated) Plastic dropper for Polio Vaccine.

You may send your company's profile by courier or on our e-mail. For details visit our website.

E-mail: haffkine_mm@yahoo.co.in

website: www.vaccinehaffkine.com

Material Manager

A. GREY BUTYL RUBBER STOPPERS

Sr. Code Specification of Grey Butyl Rubber Stopper

**1. GBR20 'GREY BUTYL' RUBBER STOPPER–20mm (Non Popping)
Ready for sterilization (RFS) of ISO 8362 - 2 B Type**

(030341) N.B.:- Specification for measurements given must be strictly adhered to.

- (A)
- | | | |
|------|--|--------------------|
| i. | Diameter of the top ring | - 18.6 to 19.00 mm |
| ii. | Bung diameter below N.P ring | - 12.9 to 13.1 mm |
| iii. | Plunger diameter at notch | - 13.1 to 13.5 mm |
| iv. | Total Height (without astrick) | - 8.5 to 9.1 mm |
| v. | Height of the collar (without astrick) | - 3.05 to 3.55 mm |
| vi. | Weight of the stopper | - NLT 1.4 gm. |
| vii. | Performance test satisfactory to Production Dept | |
- (B)
- Complies all other chemical test as per ISO 8362 - 2B type and Annexure to it.
- | | | |
|-------|------------------------|---|
| i. | Turbidity | - Not exceeding 3 annex- G |
| ii. | Acidity or Alkalinity | - NMT 1.0 ml of Hcl or
NaoH (5mmol/litre/ 20ml) Annex-G |
| iii. | Ammonia | - NMT 20 microgm NH ₄ /10 ml
Annex - E |
| iv. | Reducing substance | - Diff. NMT 7.0 ml of KMnO ₄ of
2 mmol/ litre per 20 ml Annex- C |
| v. | Heavy Metals | - NMT 10 micro gm of pb ² /20 ml
Annex - D |
| vi. | Residue on evaporation | - NMT 4.0 mg//100 ml annex-H |
| vii. | Conductivity | - NMT 40 microsiemens/cm ² / 20 ml
Annex- D |
| viii. | Volatile sulphides | - Discoloration of lead acetate paper.
- NMT 50 microgram
sodiumsulphide/ 20cm ² of
- Rubber surface Annex- I |
| ix. | Zinc | - NMT 30 microgm/10ml Annex- K |
- (C)
- Additional Test
- | | | |
|----|---------------|--------------------------------------|
| 1. | Toxicity Test | - Complies Toxicity test as per I.P. |
|----|---------------|--------------------------------------|

Note:- Packing stile

- 1) 2500 or 1000 stoppers packed in double bags with inner steri bags.
- 2) Each box contain 10000 stopper in poly bags of 4x2500 nos. each or 10x1000 nos. each
- 3) Rubber stopper should be preferably moulded from vacuum molding or injection molding press for precision in physical dimension.

1) Proved clean Index (PCI) - Limit NMT 3.4

Specification may change as per I-P 2010

2. GBRS20 (030060) GREY BUTYL SLOTTED GROOVE RUBBER STOPPER(20mm) (RFS)

- | | | |
|------|----------------------------|-------------------|
| i. | Diameter of the top ring | 18.5 to 19.1 mm |
| ii. | Diameter of the bung | 12.75 to 13.25 mm |
| iii. | Height of the rubber bungs | 12.5 to 14.0 mm |
| iv. | Height of the collar | 2.8 to 3.5 mm. |
- For ASVS Pimpri or Mumbai Approx. Quantity: 2,00,000

Notes:-

- I. Important additional specifications of rubber stopper
 1. a) Grey bromo butyl or gray butyl rubber stopper should pass all I.P. 2007 test & latest specification of ISO 8362.2.
 2. Measurements of Individual rubber stopper must be within specification.
 3. These rubber stopper being used for automatic filling machine need to move freely without any resistance allowing filling process uninterrupted i.e proper siliconisation, homogeneous, devoid of any physical defect practically free from flash, and adventitious materials such as fibers, foreign particles and adhering rubber pieces. Colour should be uniform.
 4. Sterilization- should not soften or make rubber stopper tacky and their should not be any visual change in the size, shape and appearance of rubber stopper.
- II. Other parameters
 - a) While washing in distilled water and sterilization, any chemicals or oily sticky substance should not be released.
 - b) After steam sterilization rubber stopper should not clump together or stick to each other and should allow free flow of individual rubber stopper.
 - c) The absorption of preservative by rubber stopper should be nil or the rubber stopper should withstand the treatment for saturation with permitted preservative solution.
 - d) Testing report should accompany with each supply.
 - e) % Ash content at 800°C, 25 - 30 % (in-house specification).

Sr. No. 3

A. ALUMINIUM SEALS

Code	Specifications
1	ASTD20 20 mm CENTRAL RING TEAR DOWN HAFFKINE EMBOSSED (PLAIN FOR topv)
(030089)	ALUMINIUM SEALS
i)	Outer diameter - 20.45 mm to 20.75mm
ii)	Inner diameter - 20.0 mm to 20.2 mm
iii)	Height of the Cap - 7.5 mm to 8.1 mm
iv)	Thickness - 0.19 mm to 0.21 mm
v)	Trimming - Duly evenly trimmed
(For OPV Dept)	

Code	Specifications
2	ASTD20 20 mm CENTRAL RING TEAR DOWN HAFFKINE EMBOSSED (BLUE and GREEN LAQUAR COATED)
(030348)	ALUMINIUM SEALS
i)	Outer diameter - 20.45 mm to 20.75mm
ii)	Inner diameter - 20.0 mm to 20.2 mm
iii)	Height of the Cap - 7.5 mm to 8.1 mm
iv)	Thickness - 0.19 mm to 0.21 mm
v)	Trimming - Duly evenly trimmed
(For OPV Dept)	

Provide 3 deep tear down impression lines to make two halves of cap easily while opening the cap. Embossing should be clear. Seals should be free from oil.

- 2) Provide 3 deep tear down impression lines to make two halves of cap easily while opening the cap. Embossing should be clear. Seals should be free from oil. After autoclaving at 121 C for 30 minutes there should not be any change in colour and reaction on aluminum and no peeling off.
- 3) The cap should be supplied evenly trimmed, washed dried, pack 5 x 5000 nos. carefully, not to cause deformity conditioned as we are feeding it to our fully automatic machine.

Aluminum cap should be clean, dust free, oil free, any particle free. Preferably packed in clean room and sturdy 5 ply virgin corrugated box. Box should have label containing lot number/challan number/quantity and name of manufacture.

- Note:
1. Central ring tear off, evenly trimmed, Aluminum seals must be washed dried, cleaned and packed in sturdy 5 ply corrugated box of 5 x 5000 nos. carefully not to cause deformity.
 2. Colour should not change or fade after sterilization at 121⁰ C for 30 minute. Rejected embossed seals will not be returned.
 4. Aluminum cap should be clean, dust free, oil free, any particle free. Preferably packed in clean room. Box should have label containing lot number/challan Number/quantity and name of manufacture.

Sr. No. 6

C. ORAL POLIO VACCINE DROPPER

Sr. Code Specification of O.P.V. Droppers

H1. OPVD (030181)

A) Dropper body

1.	Bottom I.D.	-	20.0 mm to 20.4mm
2.	Bottom 2nd ring I.D.	-	18.8 mm to 19.0mm
3.	Total Height	-	(NLT) 38.00 mm
4.	Nozzle I.D.	-	0.95 to 1.05mm
5.	Weight with cap	-	0.9 to 1.5gm
6.	Weight of cap	-	0.18 to 0.22 gm

B) Accuracy 0.05 ml per drop at 5-10 c
(40-44 drops per 2.2 ml Oral Polio Vaccine)

C) Chemical Tests

Plastic containers for Non Parenteral Preparation.

- 1) Leakage test : NA
- 2) Collapsibility test : NA
- 3) Clarity of aqueous extract : To comply IP 2010
- 4) Non volatile residue (at 105 c) : NMT 12.5 mg.

D) Sterility and Toxicity Test as per I.P. 2010

E) Material: L.D.P.E (Low density Polyethylene) Grade:- 16 MA400

(IPCL) No equivalent imported material should be used.

Non toxic and without any addition of heavy metals

Notes

1. Droppers should be ISOMED (BARC) sterilized, labeled and certificate should be given with each supply.
2. GMP should be followed for manufacturing, packing and storage of raw materials and for finished goods also. Clean dropper individually packed in LDP bags and 50 such droppers will be packed in HDP Bags. Bulk packing to suit the Bags size and box size for ISOMED. Body should not have any visual, physical and marking type of defect.
3. Each dropper should show Company identity mark & number of mould.
4. Approval must be taken for pilot batch before commencing bulk supply.
5. The price will be inclusive of packing forwarding sterilization and all other incidental charges.
6. Delivery will be at our factory at Parel, Mumbai - 400 012.
7. Preference will be given to party who can supply dropper in blister pack.

Specification may change as per IP-2010