REQUEST FOR QUOTATION FOR GOODS AND SERVICES

PM

ONDERSTEPOORT BIOLOGICAL PRODUCTS LTD
PRIVATE BAG X7, ONDERSTEPOORT 0110

From: Supply Chain Department Date: Oct 05 2026 Tel: 012 522 1500 Fax: N/A Email: purchasing@obpvaccines.co.za	To: Supplier: Tel: Fax: Email:

Kindly provide the quotation for the following: RFQ/OBP251/2026/27

Compulsory Document Requirements	Yes/No
- Distributors to provide a letter that they have the authority/rights to distribute the vials from their suppliers. - Manufacturers provide CIPC registration documents that there are manufacturers.	
Provide samples for all items being requested in the RFQ, before the closing date and time. (new supplier and unapproved suppliers to provide samples only)	

Evaluation of Price and Preference

All Bids will be evaluated on a points system based on weighted average score for Price and Preference as per Preferential Procurement Framework Act of 2000 (Act 5 of 2000).

Preference Point allocation – 80/20	
Price / Preference	**Weighting percentage**
Preference:	**20%**
Price:	**80 %**
Total must equal:	**100%**

OBP Onderstepoort Biological Products will award preference points as follows: Specific Goal	**Points**	**Evidence required**	**Yes/No**
Historically disadvantaged by unfair discrimination on the basis of Race	10	A valid BBBEE Certificate showing at least 51% black ownership	
Historically disadvantaged by unfair discrimination on the basis of Gender (women)	8	A valid BBBEE Certificate showing at least 30% women ownership	
Historically disadvantaged by unfair discrimination on the basis of disability	2	A doctor's note confirming disability, confirmation of disability from the Department of Labour, BEE certificate or equivalent confirmation.	
Total points	**20**		

NB: Please note that if any of the above requirements is not submitted with the quote it will be an immediate disqualification.

TO APPOINT A SUPPLIERTO PROVIDE THE FOLLOWING ITEM/S OR SERVICE AS PER SCOPE BELOW.

Quantity	Product/Item Code	Specification
3600 EACH	BOTTLES VACCINE 10ML X3600	See attached specification
847 each	50 ML Sterile Plastic Bottles for Diluent	see attached specifications
972 Units	100 ML Sterile Plastic Bottles for Diluent	See attached specifications
6048 EACH	BOTTLES VACCINE 5ML X6048	See specifications below.

Requirements from the supplier (To be used to select the contractor)

- - - Kindly note that OBP is establishing a panel for Sterile plastic vails, which will commence once the test for vails provided is completed which will take a year (The pane be for 5-year period).

- - OBP will conduct a audit on supplier premises/QMS on those whose samples have pass OBP tests, an audit plan will be sent to the recommended bidder/s before the audit; A successful audit outcome will be required for the supplier to be part of the panel.

- - New suppliers must submit sterile samples for each item as indicated in the RFQ, samples must be packed as per the specifications.

- - The rules of the panel for those who qualify will be as follow: OBP will send a request the quantities needed, the evaluation will be based on estimated time of delivery and PPPFA total scores.

SCM Administration requirements:

- - SBD4 Bidders Disclosure - All suppliers MUST Complete, sign & submit the SBD4 declaration with their bid application

- - Bidder must submit CSD report and must be register on CSD

Government Procurement: all quotations of goods and services are subject to the General conditions of Contract July 2010

Requirements from SCM department:

- All bidders MUST register their company (in advance) on the NEW OBP's E-Procurement portal, the link can be found on the official OBP website under supply chain.
- Once bidders account registration is approved by the OBP Supply Chain, login credentials will be supplied, whereby bidders will be able to login and apply for opportunities.
- All open opportunities will reflect on the portal for bidders to part take in.

- All required company documents, proposed submissions or additional requirements MUST be uploaded wit you bid application.
- Any additional questions or Queries can be directed via email (purchasing@obpvaccines.co.za) or telephone (012 522 1500), note NO SUBMISSIONS WILL BE ACCEPTED via EMAIL.
- OBP reserves the right to cancel or re-advertise RFQ's (Request for quotes).

SBD 4

BIDDER'S DISCLOSURE

1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

2. Bidder's declaration

2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest1 in the enterprise, employed by the state? **YES/NO**

2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

Full Name	**dentity Number**	**Name of State institution**

2.2 Do you, or any person connected with the bidder, have a relationship with any person who is employed by the procuring institution? **YES/NO**

2.2.1 If so, furnish particulars:

……

……

1 the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.

2.3 Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract?

YES/NO

2.3.1 If so, furnish particulars:

…….

…….

3. DECLARATION

I, the undersigned, (name)……. in submitting the accompanying bid, do hereby make the following statements that I certify to be true and complete in every respect:

3.1 I have read, and I understand the contents of this disclosure.

3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect.

3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement, or arrangement with any competitor. However, communication between partners in a joint venture or consortium2 will not be construed as collusive bidding.

3.4 In addition, there have been no consultations, communications, agreements, or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.

3.5 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.

3.6 There have been no consultations, communications, agreements, or arrangements made by the bidder with any official of the procuring institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.

3.7 I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.
I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH

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2 Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

……..	..……
Signature	Date
…….	…….
Position	Name of bidder

Terms and Conditions:

- Submission should be no later than (**Dec 04 2026 16:00:00**)
- Please indicate your offer validity and lead time: _____
- All prices must be VAT exclusive,(Vat vendor please indicate as such) if no indication, prices will be evaluated as exclusive.
- Quotation must be on a company letter head and ***strictly*** on a PDF format ***(Quotations sent on Word or Excel format will not be accepted***.)
- Supplier must register on or before any submission can be done , supplier number will be allocated to supplier.
- Submission and Quotations must be done online with all attachments required to be uploaded : any queries can be send to purchasing@obpvaccines.co.za
- **If no reply after 14 days of closing date your RFQ was unsuccessfully.**
- Please indicate if you are unable to quote and state the reason why
- Please note that fluctuations in the exchange rate (where applicable) will not be for the account of OBP.
- *Payment terms: 30 days after statement*
- *Bidders must be registered on CSD (Central Supplier Data Base National Treasury) and be tax complaint*
- **Government Procurement: all quotations of goods and services are subject to the General conditions of Contract July 2010**

I agree that the offer herein shall remain binding upon me and open for acceptance by OBP during the validity period indicated.

_____	_____
Signature	Date

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2022

This preference form must form part of all tenders invited. It contains general information and serves as a claim form for preference points for specific goals.

NB: BEFORE COMPLETING THIS FORM, TENDERERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF THE TENDER AND PREFERENTIAL PROCUREMENT REGULATIONS, 2022

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1. GENERAL CONDITIONS

1.1 The following preference point systems are applicable to invitations to tender:

- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included); and
- the 90/10 system for requirements with a Rand value above R50 000 000 (all applicable taxes included).

1.2 **To be completed by the organ of state**

(*delete whichever is not applicable for this tender*).

a) The applicable preference point system for this tender is the 90/10 preference point system.

b) The applicable preference point system for this tender is the 80/20 preference point system.

c) Either the 90/10 or 80/20 preference point system will be applicable in this tender. The lowest/ highest acceptable tender will be used to determine the accurate system once tenders are received.

1.3 Points for this tender (even in the case of a tender for income-generating contracts) shall be awarded for:

(a) Price; and

(b) Specific Goals.

1.4 **To be completed by the organ of state:**

The maximum points for this tender are allocated as follows:

	POINTS
PRICE	**80**
SPECIFIC GOALS	**20**
Total points for Price and SPECIFIC GOALS	**100**

1.5 Failure on the part of a tenderer to submit proof or documentation required in terms of this tender to claim points for specific goals with the tender, will be interpreted to mean that preference points for specific goals are not claimed.

1.6 The organ of state reserves the right to require of a tenderer, either before a tender is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the organ of state.

2. DEFINITIONS

(a) **"tender"** means a written offer in the form determined by an organ of state in response to an invitation to provide goods or services through price quotations, competitive tendering process or any other method envisaged in legislation;

(b) **"price"** means an amount of money tendered for goods or services, and includes all applicable taxes less all unconditional discounts;

(c) **"rand value"** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;

(d) **"tender for income-generating contracts"** means a written offer in the form determined by an organ of state in response to an invitation for the origination of income-generating contracts through any method envisaged in legislation that will result in a legal agreement between the organ of state and a third party that produces revenue for the organ of state, and includes, but is not limited to, leasing and disposal of assets and concession contracts, excluding direct sales and disposal of assets through public auctions; and

(e) **"the Act"** means the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000).

3. FORMULAE FOR PROCUREMENT OF GOODS AND SERVICES

3.1. POINTS AWARDED FOR PRICE

3.1.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 - \frac{Pt - P\,min}{P\,min}\right) \quad \text{or} \quad Ps = 90\left(1 - \frac{Pt - P\,min}{P\,min}\right)$$

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

3.2. FORMULAE FOR DISPOSAL OR LEASING OF STATE ASSETS AND INCOME GENERATING PROCUREMENT

3.2.1. **POINTS AWARDED FOR PRICE**

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 + \frac{Pt - P\,max}{P\,max}\right) \quad \text{or} \quad Ps = 90\left(1 + \frac{Pt - P\,max}{Pmax}\right)$$

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmax = Price of highest acceptable tender

4. POINTS AWARDED FOR SPECIFIC GOALS

4.1. In terms of Regulation 4(2); 5(2); 6(2) and 7(2) of the Preferential Procurement Regulations, preference points must be awarded for specific goals stated in the tender. For the purposes of this tender the tenderer will be allocated points based on the goals stated in table 1 below as may be supported by proof/ documentation stated in the conditions of this tender:

4.2. In cases where organs of state intend to use Regulation 3(2) of the Regulations, which states that, if it is unclear whether the 80/20 or 90/10 preference point system applies, an organ of state must, in the tender documents, stipulate in the case of—

(a) an invitation for tender for income-generating contracts, that either the 80/20 or 90/10 preference point system will apply and that the highest acceptable tender will be used to determine the applicable preference point system; or

(b) any other invitation for tender, that either the 80/20 or 90/10 preference point system will apply and that the lowest acceptable tender will be used to determine the applicable preference point system,

then the organ of state must indicate the points allocated for specific goals for both the 90/10 and 80/20 preference point system.

Table 1: Specific goals for the tender and points claimed are indicated per the table below.

(Note to organs of state: Where either the 90/10 or 80/20 preference point system is applicable, corresponding points must also be indicated as such.

***Note to tenderers: The tenderer must indicate how they claim points for each preference point system.*)**

The specific goals allocated points in terms of this tender	Number of points allocated (90/10 system) (To be completed by the organ of state)	Number of points allocated (80/20 system) (To be completed by the organ of state)	Number of points claimed (90/10 system) (To be completed by the tenderer)	Number of points claimed (80/20 system) (To be completed by the tenderer)
A valid BBBEE Certificate showing at least 51% black ownership		10		
A valid BBBEE Certificate showing at least 30% women ownership		8		
A doctor's note confirming disability, confirmation of disability from the Department of Labour, BEE certificate or equivalent confirmation.		2		

DECLARATION WITH REGARD TO COMPANY/FIRM

4.3. Name of company/firm…….

4.4. Company registration number: ……...

4.5. TYPE OF COMPANY/ FIRM

- ☐ Partnership/Joint Venture / Consortium
- ☐ One-person business/sole propriety
- ☐ Close corporation
- ☐ Public Company
- ☐ Personal Liability Company
- ☐ (Pty) Limited
- ☐ Non-Profit Company
- ☐ State Owned Company

[TICK APPLICABLE BOX]

4.6. I, the undersigned, who is duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the specific goals as advised in the tender, qualifies the company/ firm for the preference(s) shown and I acknowledge that:

i) The information furnished is true and correct;

ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;

iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 1.4 and 4.2, the contractor may be required to furnish documentary proof to the satisfaction of the organ of state that the claims are correct;

iv) If the specific goals have been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the organ of state may, in addition to any other remedy it may have –

(a) disqualify the person from the tendering process;

(b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;

(c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;

(d) recommend that the tenderer or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and

(e) forward the matter for criminal prosecution, if deemed necessary.

.....

SIGNATURE(S) OF TENDERER(S)

SURNAME AND NAME: .....

DATE: .....

ADDRESS: .....

.....

.....

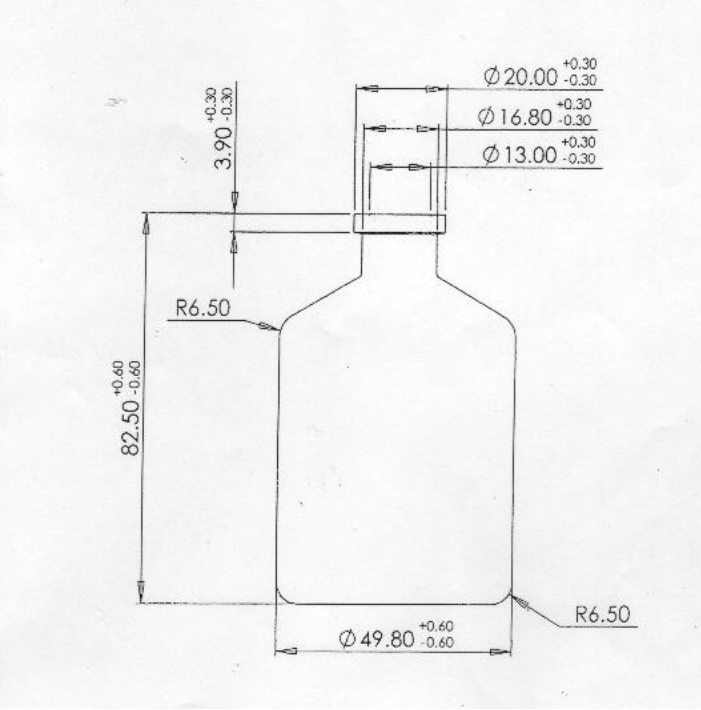
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ONDERSTEPOORT BIOLOGICAL PRODUCTS	**SPECIFICATION** **PLASTIC VACCINE BOTTLES** **PACKAGING SPECIFICATIONS** **100 ML BOTTLES** ITEM CODE : PM 0140 Document no. Version01	Department: Packaging Effective date: Review date: Extended review date: Copy number: Page **1** of **1**

REQUIREMENTS	SPECIFICATIONS
1. Material of construction	100 % virgin High Density Polyethylene (HDPE) that is odourless and transparent.
2. Brimful capacity	112.3 mℓ
3. Dimensions:	Please refer to drawing as per Appendix 1
3a: Total Height of the bottle	82.4mm ± 0.50mm (81.90 – 82.90 mm)
3b: Bottom Width of the bottle	50.3mm ± 0.50mm (49.80 -50.80 mm)
3c: Internal diameter of the bottle neck rim	13.0mm ± 0.20mm (12.80 - 13.20 mm)
3d: Outside diameter of the bottle neck rim	***20.0mm ± 0.20mm (19.80 – 20.20 mm)***
3e: Thickness of the bottle brim	***3.70mm ± 0.20mm (3.50 – 3.90 mm)***
3f: Outer diameter of the neck of the Bottle	***15.8mm ± 0.25mm (15.55 – 16.0 5mm)***
3g: Shape of the bottle	As per attached diagram with the bottom of the bottle being concave(“B”) and the surface smooth. The rim circumference must be Flat and not round and free from inwards or outwards projections. (Refer to appendix 1 for Brim angle, bottom curve and R degrees)
4. Mass one bottle	***14.15 – 14.40g***
5. Quality Control samples for testing purposes at OBP	Samples to be drawn from the beginning, middle and end of the production line over a 12 hour period. The samples must be labelled with the product name, Date ,Time ,batch number and signature of operator.
6. Gamma Irradiation requirements	Minimum dose NLT 8 kGy Certificate must be attached.
7. Stores acceptance criteria	81 bottles must be packed onto a cardboard tray (460mm x 460mm x 60mm). 12 trays must be sealed against dust penetration in 2 plastic bags of at least 35g. The12 trays sealed in the plastic bag must be packed in a firm cardboard box (940x470x546)that is strong enough to stack 4 boxes on top of each other.The individual boxes must be sealed in a plastic shroud to prevent entry of dust.
8. Certificate of conformance / analysis	Each consignment of bottles must have a certificate of conformance/analysis attached when it arrives at stores. The certificate must be signed by the supplier on a company’s letterhead.

Author: Samuel Tshabangu	Reviewer: Raynard Mcdonald	Approver: Soveena Harriepersadh
Role : Packaging manager	Role : QC manager	Role : QA Manager
Signature	Signature	Signature
Date	Date	Date

Appendix 1

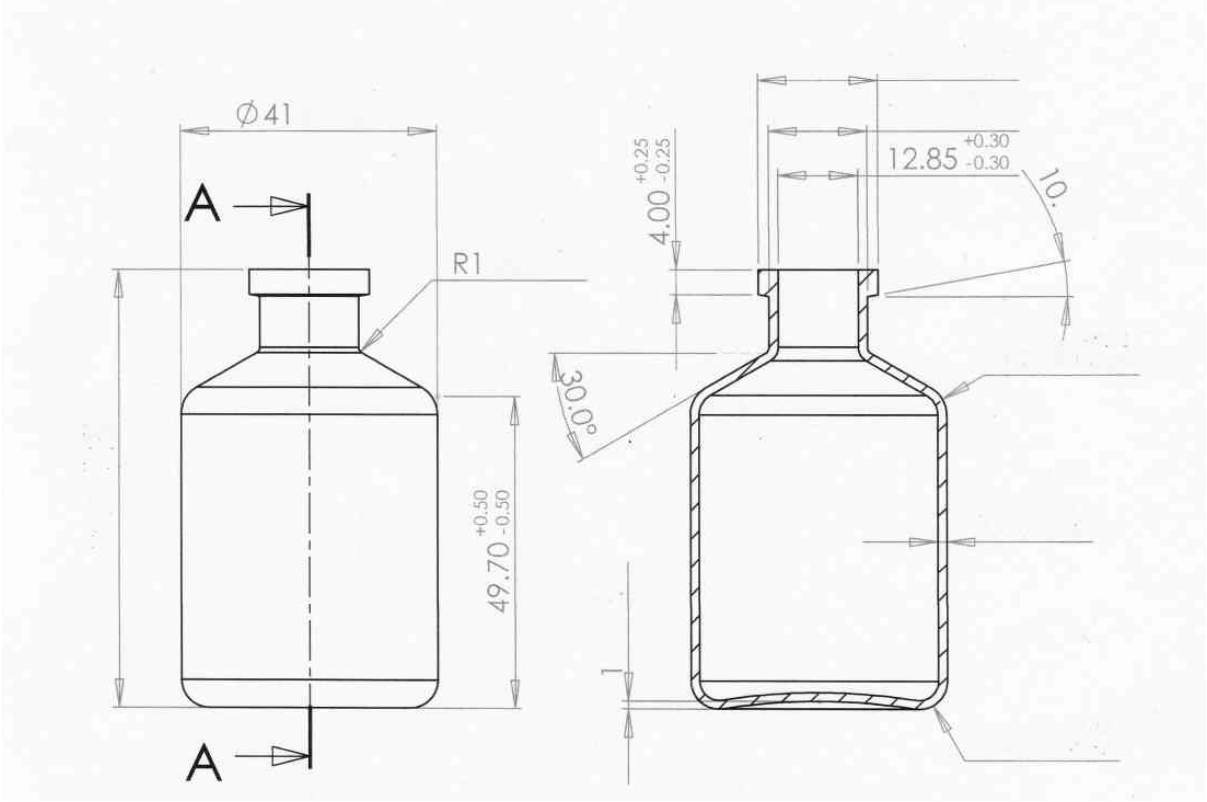

Ø20.00 +0.30 -0.30
Ø16.80 +0.30 -0.30
Ø13.00 +0.30 -0.30
3.90 +0.30 -0.30
R6.50
82.50 +0.60 -0.60
R6.50
Ø49.80 +0.60 -0.60

ONDERSTEPOORT BIOLOGICAL PRODUCTS	**SPECIFICATION** **PLASTIC VACCINE BOTTLES** **PACKAGING SPECIFICATIONS** **50 ML BOTTLES** ITEM CODE: PM 0155 Document no. Version01	Department: Packaging Effective date: Review date: Extended review date: Copy number: Page **1** of **1**

REQUIREMENTS	SPECIFICATIONS
1. Material of construction	100 % virgin High Density Polyethylene (HDPE) that is odourless and transparent.
2. Brimful capacity	60 mℓ
3. Dimensions:	Please refer to drawing as per Appendix 1
3a: Total Height of the bottle	70.0mm ± 0.50mm (69.50 – 70.50 mm)
3b: Bottom Width of the bottle	41mm ± 0.50mm (40.50 - 41.50mm)
3c: Internal diameter of the bottle neck rim	13.0mm ± 0.20mm (12.80 - 13.20 mm)
3d: Outside diameter of the bottle neck rim	20.0mm ± 0.20mm (19.80 – 20.20mm)
3e: Thickness of the bottle brim	3.70mm ± 0.20mm (3.50 – 3.90 mm)
3f: Outer diameter of the neck of the Bottle	**15.8mm ± 0.25mm (15.55 – 16.05mm)**
3g: Shape of the bottle	As per attached diagram with the bottom of the bottle being concave(“B”) and the surface smooth. The rim circumference must be Flat and not round and free from inwards or outwards projections. (Refer to appendix 1 for Brim angle, bottom curve and R degrees)
4. Mass one bottle	**8.00 – 9.00 g**
5. Quality Control samples for testing purposes at OBP	Samples to be drawn from the beginning, middle and end of the production line over a 12 hour period. The samples must be labelled with the product name, Date ,Time ,batch number and signature of operator.
6. Gamma Irradiation requirements	Minimum dose NLT 8 kGy Certificate must be attached.
7. Stores acceptance criteria	847 bottles must be packed onto a cardboard tray (460mm x 460mm x 50mm). 12 trays must be sealed against dust penetration in 2 plastic bags of at least 35g. The 12 trays sealed in the plastic bags must then be packed in a firm cardboard box (470x470x546)that is strong enough to stack 4 boxes on top of each other.The Individual boxes must be sealed in a plastic shroud to prevent entry of dust.
8. Certificate of conformance / analysis	Each consignment of bottles must have a certificate of conformance/analysis attached when it arrives at stores. The certificate must be signed by the supplier on a company’s letterhead.

Author: Samuel Tshabangu	Reviewer: Raynard Mcdonald	Approver: Soveena Harriepersadh
Role : Packaging manager	Role : QC manager	Role : QA Manager
Signature	Signature	Signature
Date	Date	Date

Appendix 1

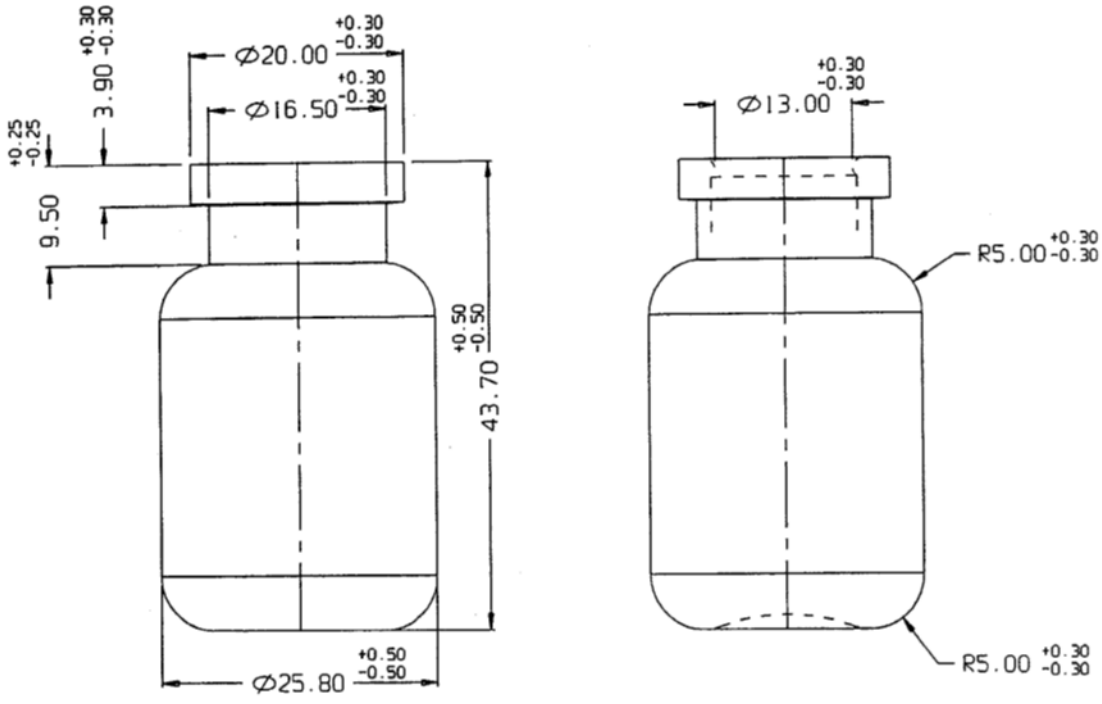


ONDERSTEPOORT BIOLOGICAL PRODUCTS	**SPECIFICATION** **PLASTIC VACCINE BOTTLES** **PACKAGING SPECIFICATIONS** **10 ML BOTTLES** ITEM CODE : PM 0150 Document no. Version01	Department: Packaging Effective date: Review date: Extended review date: Copy number: Page **1** of **1**

REQUIREMENTS	SPECIFICATIONS
1. Material of construction	100 % virgin High Density Polyethylene (HDPE) that is odourless and transparent.
2. Brimful capacity	15.0 mℓ
3. Dimensions:	Please refer to drawing as per Appendix 1
3a: Total Height of the bottle	44.0mm ± 0.50mm (43.50 – 44.50 mm)
3b: Bottom Width of the bottle	26.30mm ± 0.40mm (25.90 - 26.70 mm)
3c: Internal diameter of the bottle neck rim	13.0mm ± 0.20mm (12.80 - 13.20 mm)
3d: Outside diameter of the bottle neck rim	***20.0 mm ± 0.25 mm (19.75 – 20.25 mm)***
3e: Thickness of the bottle brim	***4.0 mm ± 0.25 mm (3.75 –4.25 mm)***
3f: Outer diameter of the neck of the Bottle	***16.5mm ± 0.20mm (16.30 – 16.70 mm)***
3g: Shape of the bottle	As per attached diagram with the bottom of the bottle being concave and the surface smooth. The rim circumference must be flat and not round and free from inwards or outwards projections. (Refer to appendix 1 for Brim angle, bottom curve and R degrees)
4. Mass one bottle	***4.0 g ± 0.4 g (3.60 g – 4.40 g)***
5. Quality Control samples for testing purposes at OBP	Samples to be drawn from the beginning, middle and end of the production line over a 12 hour period. The samples must be labelled with the product name, Date, Time, batch number and signature of operator.
6. Gamma Irradiation requirements	Minimum dose NLT 8 kGy Certificate must be attached.
7. Stores acceptance criteria	330 bottles must be packed onto a cardboard tray (460mm x 460mm x 35mm). 11 trays must be sealed against dust penetration in 2 plastic bags of at least 35g. The 11 trays sealed in plastic bags must then be packed in a firm cardboard box (470x470x546) that is strong enough to stack 4 boxes on top of each other.The individual boxes must be sealed in a plastic shroud to prevent entry of dust.
8. Certificate of conformance / analysis	Each consignment of bottles must have a certificate of conformance / analysis attached when it arrives at stores. The certificate must be signed by the supplier's on a company's letterhead.

Author: Samuel Tshabangu	Reviewer: Raynard Mcdonald	Approver: Soveena Harriepersadh
Role : Packaging manager	Role : QC manager	Role : QA Manager
Signature	Signature	Signature
Date	Date	Date

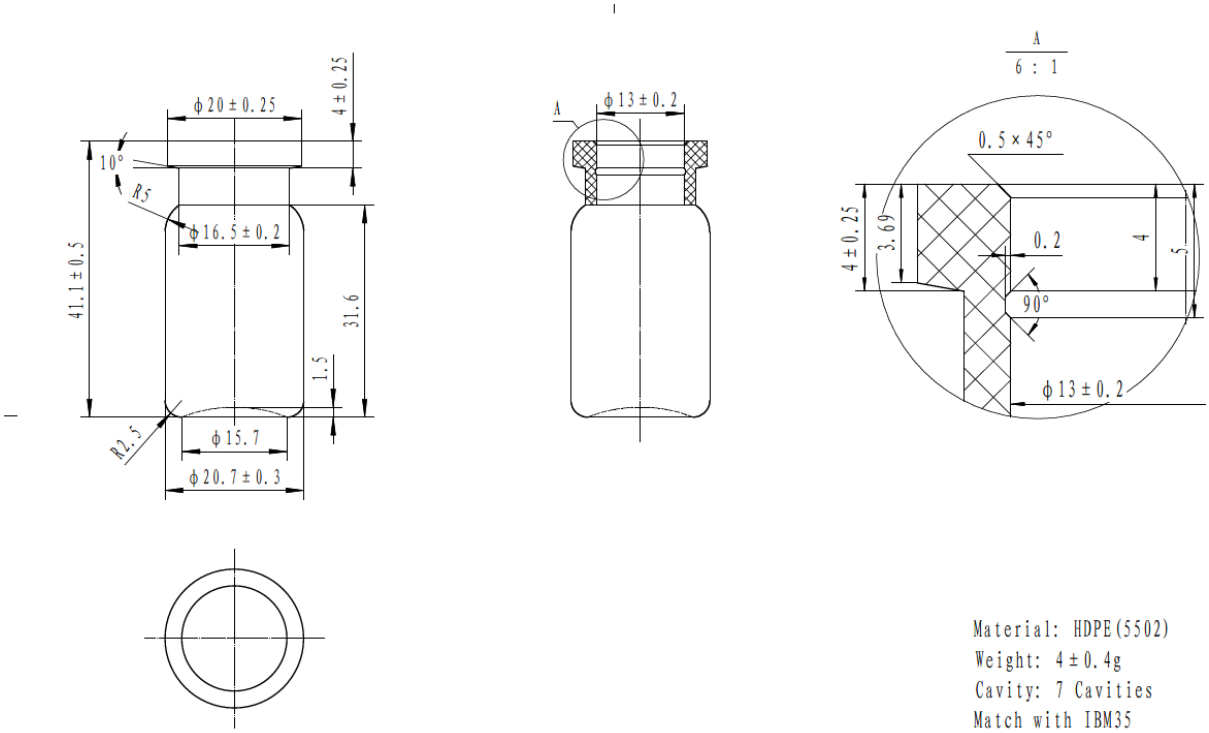
Appendix 1


Ø20.00 +0.30 -0.30
Ø16.50 +0.30 -0.30
3.90 +0.30 -0.30
+0.25 -0.25
9.50
43.70 +0.50 -0.50
Ø25.80 +0.50 -0.50
Ø13.00 +0.30 -0.30
R5.00 +0.30 -0.30
R5.00 +0.30 -0.30

ONDERSTEPOORT BIOLOGICAL PRODUCTS	**SPECIFICATION** **PLASTIC VACCINE BOTTLES** **PACKAGING SPECIFICATIONS** **5ML BOTTLES** ITEM CODE : PM 0170 Document no. Version01	Department: Packaging Effective date: Review date: Extended review date: Copy number: Page **1** of **1**

REQUIREMENTS	SPECIFICATIONS
1. Material of construction	100 % virgin High Density Polyethylene (HDPE) that is odourless and transparent.
2. Brimful capacity	8.0 mℓ
3. Dimensions:	Please refer to drawing as per Appendix 1
3a: Total Height of the bottle	41.1 mm ± 0.50mm (40.60 – 41.60 mm)
3b: Bottom Width of the bottle	20.70 mm ± 0.30mm (20.40 - 21.00 mm)
3c: Internal diameter of the bottle neck rim	13.0 mm ± 0.20 mm (12.80 - 13.20 mm)
3d: Outside diameter of the bottle neck rim	***20.0 mm ± 0.25 mm (19.75 – 20.25 mm)***
3e: Thickness of the bottle brim	***4.0 mm ± 0.25 mm (3.75 –4.25 mm)***
3f: Outer diameter of the neck of the Bottle	***16.5 mm ± 0.20 mm (16.30 - 16.70 mm)***
3g: Shape of the bottle	As per attached diagram with the bottom of the bottle being concave and the surface smooth. The rim circumference must be flat and not round and free from inwards or outwards projections. (Refer to appendix 1 for Brim angle, bottom curve and R degrees).
4. Mass one bottle	***4 g ± 0.4 g (3.60 – 4.40g)***
5. Quality Control samples for testing purposes at OBP	Samples to be drawn from the beginning, middle and end of the production line over a 12 hour period. The samples must be labelled with the product name, Date, Time, batch number and signature of operator.
6. Gamma Irradiation requirements	Minimum dose NLT 8 kGy Certificate must be attached.
7. Stores acceptance criteria	504 bottles must be packed onto a cardboard tray(460mm x 460mm x 35mm) 12 trays must be sealed against dust penetration in 2 plastic bags of at least 35g. The 12 trays sealed in the plastic bags must then be packed in a firm cardboard box (470 x 470 x 546) that is strong enough to stack 4 boxes on top of each other.The Individual boxes must be sealed in a plastic shroud to prevent entry of dust.
8. Certificate of conformance / analysis	Each consignment of bottles must have a certificate of conformance / analysis attached when it arrives at stores. The certificate must be signed by the supplier on a company's letterhead.

Author: Samuel Tshabangu	Reviewer: Raynard Mcdonald	Approver: Soveena Harriepersadh
Role : Packaging manager	Role : QC manager	Role : QA Manager
Signature	Signature	Signature
Date	Date	Date



Material: HDPE(5502)
Weight: 4±0.4g
Cavity: 7 Cavities
Match with IBM35

5ml bottle

2015.11.16