

बी.सी.जी. वैक्सीन प्रयोगशाला / B C G VACCINE LABORATORY
(cGMP Compliant Facility)
110, 33 फीट रोड, माउंट रोड, गिंडी, चेन्नई 600032
110,33 FEET ROAD, MOUNT ROAD, GUINDY, CHENNAI 600 032 TAMILNADU

भारत सरकार / GOVERNMENT OF INDIA

स्वास्थ्य सेवा महानिदेशालय / DIRECTORATE GENERAL OF HEALTH SERVICES
स्वास्थ्य और परिवार कल्याण मंत्रालय/ MINISTRY OF HEALTH & FAMILY WELFARE

Office : 044-22500476
Stores : 044-22500172

website : www.dirbcglab.gov.in
e-mail : bcgvl.tnchn@nic.in

TENDER NOTICE

No. D -21010/04/2021-22 (Stores)

09.03.2022

Sealed tenders are invited from the Manufacturers / Dealers in the prescribed form, for supply of High Speed Diesel for a period of 03 years :

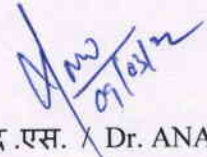
Sl. No	Description of the item	Quantity Required
1	Supply of High-Speed Diesel (to be supplied, as and when required, during a period of 03 years from the date of award of order)	1,50,000 Litres per year (approx) 4,50,000 Litres for 3 years (approx) • The requirement is approximate only and may increase or decrease by 25%

Specification, Tender Forms and Vendor Qualification forms can be downloaded from the CPP Portal / BCGVL website - www.dirbcglab.gov.in

Last Date & Time for submission of Tender : 05.04.2022 at 02.00 PM

Date & Time for Opening of Technical Bid : 05.04.2022 at 03.00 PM

The date and time of opening of Financial Bid will be informed to the bidders who are qualified in the Technical Bid.


(डॉ. आनंद .एस. / Dr. ANAND S.)
पशुचिकित्सक / VETERINARIAN
कृते निदेशक / FOR DIRECTOR

बी.सी.जी. वैक्सीन प्रयोगशाला / B C G VACCINE LABORATORY

(cGMP Compliant Facility)

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Office : 044-22500476

Stores : 044-22500172

website : www.dirbcglab.gov.in

e-mail : bcgvl.tnchn@nic.in

Tender No. D -21010 / 04 / 2021-22 (Stores) dated 09.03.2022


**Tender Document for Supply of HIGH SPEED DIESEL
at BCGVL, Chennai**

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Last Date & Time for Bid Submission : Till 02.00 p.m. on 05.04.2022

Date & Time of Technical Bid Opening : At 03.00 p.m. on 05.04.2022


(डॉ. आनंद .एस. / Dr. ANAND S.)
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बी.सी.जी. वैक्सीन प्रयोगशाला / B C G VACCINE LABORATORY
चेन्नई CHENNAI 600 032

To

M/s.....

.....

.....

Dear Sir(s),

Sub. : Inviting Quotations for Supply of HIGH SPEED DIESEL at BCGVL, Guindy, Chennai

BCG Vaccine Laboratory invites sealed bids under Two Bid System (Technical and Price Bid) for **Supply of HIGH SPEED DIESEL for a period of THREE YEARS (03 years)** at BCGVL, Guindy, Chennai

a.	Bid Reference	Tender No: D-21010/ 04/2021-22 (Stores)
b.	Date and time of receipt of Tender	Till 02.00 p.m.on 05.04.2022
C.	Date and time for Opening of technical Bid	At 03.00 p.m. on 05.04.2022
d.	Date and time for Opening of Financial Bid	To be intimated to successful bidders, who qualify in Technical Bid.
e.	Type of Tender	Two Bid System
f.	Validity of Tender	120 days
g.	GeM Registration	Successful Tenderer should provide GeM Seller ID for award of Contract / placement of order.

The Tender document comprises of the following sections:

Part I (Technical Bid)

- | | |
|-------------|---|
| Section I | : Bidder's Qualification Criteria (BQC), Bid Evaluation Criteria (BEC) and Bid Rejection Criteria (BRC) |
| Section II | : General conditions of the contract (GCC) |
| Section III | : Special Condition of Contract - Scope of work |
| Section IV | : Formats for Technical Bid |

Part II (Price Bid)

Bidders shall submit their Price Bid.

Part-I: Technical Bid

Technical Bid includes all documents that are called for as per Bid Qualification Criteria of this Tender Document. All the pages of this tender document should be duly signed and affixed with seal of the firm towards acceptance of all terms and conditions of all sections of the tender document.

Part-II: Price Bid

Price Bid shall be submitted in the same format as attached along with this Tender document duly signed and affixed with seal of the firm. The quoted value in Rupees in digits should also be written in words. In case of discrepancy between value in digits and value in words, BCGVL shall consider the value written in words ONLY.

The details of Bidder Qualification Criteria (BQC) are given in the Section I. Bidders are advised to refer to the same. If required, Bidders should get clarified of their doubts in understanding the tender documents with BCGVL and subsequently submit their quotes/tenders to BCGVL. **In order to familiarize with nature and quantum of job, it is suggested to all Bidders / Tenderers to visit the location of operations before submission of their quotes and should get clarified all their doubts.**

Price bid envelope Contains price bid format to be quoted by the Bidders as per their choice depending on their experience of work handled. After mentioning their quotes against the items in the format, the document shall be signed, stamped with firm name and the price bid document shall be kept inside the Price Bid envelope and the envelope to be sealed with gum properly.

Technical and Price Bids sent should be sealed separately and enclosed in a single sealed big size envelope and to be mailed to BCGVL writing the Tender No. and Due date on top of the envelope. The Bidder should ensure that his quotation reaches BCGVL on or before the Due date as mentioned in BCGVL Tender Document for consideration. The bid envelop can be sent to BCGVL on address:

**The Director,
BCG Vaccine Laboratory,
33 Feet Road, off Mount Road,
Guindy, Chennai – 600 032**

or could be dropped in Tender Box kept at BCGVL, Chennai.

BCGVL reserves the right to reject any or all bidder's quotes/tenders or to accept in part of offers given by Bidders/Tenderers without assigning any reason thereof. Decision of BCGVL in this regard will be final and binding on all the Bidders/Tenderers.

Thanking you,

(डॉ. आनंद एस. / Dr. ANAND S.)
पशुचिकित्सक / VETERINARIAN
कृते निदेशक / FOR DIRECTOR

SECTION - I

1. BIDDERS QUALIFICATION CRITERIA

- a) The bidder should have average annual turnover of not less than Rs. 75 Lakhs during the last 3 years, ending 31st March of the previous financial year. Relevant documentary evidence, i.e., Profit and loss account for turnover details certified by Chartered Accountant to be submitted in the prescribed format attached herewith (Annexure I)
- b) The bidder shall have experience in supply of similar items successfully to any Central Govt. /State Govt. / PSUs / Public Listed Company. Bidders should furnish copies of work orders / agreement issued by respective organizations to this effect. Details of Experience to be submitted in the prescribed format enclosed. (Annexure II)
 - Bidder must have successfully executed / completed at least one single order of 80% of the Estimated Bid Value or 2 orders each of 50% of the Estimated Bid Value or 3 orders each of 40% of the Estimated Bid Value for similar products in last 02 years to any Central / State Govt. Organisation / PSU / Public Listed Company. Copies of contracts / work orders and documentary evidence of successful execution / completion in support of Past Experience of similar item along with name, address and contact details of clients shall be uploaded with the bid for verification by the Buyer.
- c) Only those firms are eligible to participate which falls in surrounding area of 30 Kms from BCGVL, Guindy, Chennai and who are the manufacturer / Authorized dealers for supply of High-Speed Diesel. However, authorized dealers shall submit documentary evidence to this effect with the Technical Bid.
- d) The bidders who are blacklisted by BCGVL /Central Govt. /State Govt. /Public sector undertaking are ineligible to participate in this tender. Bidder should attach notarized declaration to confirm his eligibility to this effect.

2. BID EVALUATION CRITERIA

- a) The bidder should accept to the technical specification & scope of work given in the tender.
- b) Technically acceptable bids will be evaluated on overall L1 basis (i.e. lowest landed cost to BCGVL).

3. REJECTION CRITERIA:

1. Offers received after the due date / time will be rejected.
2. Non-compliance to any of BQC will be liable for rejection.
3. Non adherence to technical / commercial terms and incomplete bids and bids in deviation to tender conditions will be liable for rejection.

Important notes

- a) BCGVL reserves the right to accept or reject unworkable rates of any or all tenderer at any stage of the tender evaluation process at sole discretion of BCGVL without assigning any reason thereof.
- b) Successful Tenderer should provide GeM Seller ID for award of contract / placement of order.

SECTION – II

GENERAL CONDITIONS OF CONTRACT (GCC)

1. GENERAL GUIDELINES

- a) Bidders shall submit tender in the prescribed format supplied by BCGVL only.
- b) Bidder shall strictly adhere to the terms & conditions and specifications prescribed by BCGVL. Any deviations from the terms and conditions of the Tender Enquiry will not be accepted by BCGVL and will lead to technical disqualification.
- c) All entries in the tender must be written in permanent ink or typewritten without use of eraser or overwriting. Corrections, if any, should be attested under the full signature of the Bidder.
- d) All the Rates given in the Tender must be expressed both in words and in figures and in case of difference between the two, the rates given in words would be final and considered correct.
- e) All Bidders are required to read the terms & conditions of this Tender document carefully and return one set duly signed on each page by them as token of having read, understood and accepted the terms & conditions along with information called for by BCGVL.
- f) All Bidders are required to give complete details in the Proforma attached.
- g) The conditions of contract, which will govern any contract made, are contained in the:
 - (i) The conditions of contract which will govern any contract made are contained in the GFR 2017, Manual of Ministry of Finance for Procurement of Goods 2017 & all orders issued by MHA, CVC and other relevant departments of Government of India from time to time till date of issue of this tender.
 - (ii) Public Procurement order (preference to Make in India, 2017) issued by Department of Industrial Policy and Promotion, Ministry of Commerce & Industry, Govt. of India, vide their letter dated 15.06.2017 and notification issued by Ministry of MSME under section 11 of Micro, Small and Medium Enterprises Development Act 2006 shall also be taken into consideration in procurement of Goods & services.
 - (iii) Any special conditions attached to this invitation to tender will also form part of the conditions of contract and will supersede any general conditions.
 - (iv) The amendment made by Central Government from time to time in policy and instructions will be adhered to.

2. ACCEPTANCE OF TENDER

BCGVL reserves the right to accept or reject in part or whole, any or all the tenders received without assigning any reason, whatsoever. BCGVL is not bound to accept the lowest tender. The decision of BCGVL in this regard shall be final and binding on all bidders.

3. COMMERCIAL TERMS

3.1 SECURITY DEPOSIT / PERFORMANCE SECURITY

- a) Successful Bidders shall be required to furnish security deposit / performance security within 15 days of issuance of Work order by BCGVL and before commencement of work. Amount of Security deposit / performance security (SD) shall be 3% of the work order value. The Security Deposit shall be deposited by successful bidder in the form of Bank Guarantee / Demand Draft. The Bank Guarantee shall be drawn on any Nationalized / Scheduled Bank as per standard Proforma provided by BCGVL and shall remain valid for a period of sixty days beyond maximum possible validity period of the contract work order.
- b) BCGVL shall not pay any interest on Security Deposit / Performance Security under this contract.
- c) BCGVL is entitled without being bound to adjust the whole or any portion of this Security Deposit / performance security towards the recovery of any amount due from the successful bidder under this or any other contract with BCGVL.
- d) BCGVL is entitled to recover any loss / claim and / or any non-compliance of the agreement, against the SD deposited of the successful bidder. Any loss / claims / damages higher than SD amount will be recovered from payments to be made by BCGVL to the successful bidder under this contract or deposits made and / or payments due to the successful bidder under any other contract with BCGVL.
- e) The security deposit / performance security (SD) shall be refunded to the successful bidder after completion of this contract satisfactorily.

3.2 TERMS OF PAYMENT:

As per Rules laid down under Government of India, General Financial Rules, 2017.

BCGVL is a Central Government Organisation and advance payment is not permissible.

Payment will be made on monthly basis based on actual quantity received against submission of Tax Invoice.

4. FORCE MAJEURECLAUSE

If, at any item during the continuance of the contract the performance in whole or part by either party of any obligation under the contract shall be prevented or delayed by reasons of war, hostility acts of public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes, lockouts or acts of God (hereinafter referred to as events) then provided notice of the happenings of any such events if given by either party or the other within twenty one days from the date of occurrence thereof, neither party shall by reasons of such event, be entitled to terminate the contract nor shall either party have any claim for damage against the other whether in respect of such non- performance or delay in performance.

Deliveries or acceptance of deliveries under the contract shall be resumed as soon as practicable after such event has come to an end or ceased to exist and the decision of BCGVL as to whether the deliveries or acceptance of deliveries have to be so resumed or not shall be final and conclusive provided further if the performance in whole or part or any obligation under the contract is prevented or delayed by reasons of any such event for period exceeding 60 days either party may at its option terminate the contract.

6. ARBITRATION CLAUSE

Except, as otherwise provided elsewhere in the contract, if any dispute, difference, question, or disagreement arises between the parties hereto or their respective representatives or assignees, at any time, in connection with, meaning, operation, effect, interpretation or out of the contract or breach thereof, the same shall be referred to decide by an Arbitration Tribunal consisting of three arbitrators. Each party shall appoint one arbitrator and arbitrators so appointed shall appoint third arbitrator who will act as Presiding arbitrator. Subject as aforesaid the Indian Arbitration and Conciliation Act, 1996 shall apply to the arbitration proceedings under the Contract.

7. JURISDICTION

The successful bidder, hereby, agrees that the Courts situated in Chennai / Tamilnadu alone shall have the jurisdiction to hear and determine all actions and proceedings arising out of this contract. This agreement is subject to the special conditions stipulated in our schedule and issued work Order and subsequent amendments, if any, notified from time to time.

8. TERMINATION OF CONTRACT:

BCGVL reserves the right to terminate / cancel the contract by giving written notice of 30 days in advance.

SECTION - III

SPECIFICATION:

HIGH SPEED DIESEL

- Approximate Quantity - 1,50,000 Litres per year &
- Total Approximate Quantity for a period of 03 years - 4,50,000 Litres

SCHEDULE OF REQUIREMENT:

The quantities shown are "Approximate" which may increase or decrease by 25 % based upon requirement.

NOTE:

- (a) Maximum 2500 Litres HSD can be purchased at a time by BCGVL due to storage limitation.
- (b) The supply shall be strictly delivery at BCGVL, Guindy, Chennai
- (c) Discount offered must be very clear.
- (d) The quantity and quality of diesel shall be checked at the Laboratory premises.
- (e) The time of supply shall be within working hours, i.e. between 10.00 am to 05.00 pm
- (f) The supply should be made only in tankers which shall either have a meter or a calibrated dip stick.

SECTION – IV
TECHNICAL BID

Tenderers should fill their technical offer by providing all information as follows. (If not applicable- Please mention as 'N/A'):

1. Name of the Firm
2. Nature of the Firm
(State whether Limited Company, partnership Firm, Co-op. Society or Sole Proprietor, Photocopies of documents Confirming constitution of the firm to be enclosed)
3. Year of Establishment
4. Registration Number
5. Registered Postal Address
6. Telephone No(s).
7. E-mail ID
8. Address of Branches, if any
9. Name of Directors / Partners /Proprietor (as the case may be)
with address & Telephone No.(s).
10. PAN No.
11. Indian Income Tax Return Acknowledgement for the previous year (Attach Photocopy)
12. GST Registration No.
13. Name of Bankers & Branch with full address
14. Type of Account & A/C No.
15. Were you associated with BCGVL in any other contract in the past?
16. Are you currently having any contract with BCGVL?
17. Are you on the approved list of other Pharma / Vaccine companies/ Public Sector Undertakings / Govt. Dept. etc. If so, furnish copies of Certificates certifying your performance
18. Confirmed that Bank Guarantee will be provided for the Security deposit / performance security.
19. Certified that the firm has not been debarred / blacklisted by Department of Commerce or Ministry / Department concerned or any other Government organization.

20. There is no vigilance/CBI case or court case pending against me/us/my firm.

21. This is to declare & certify that the neither myself nor my firm have ever been blacklisted / banned by any Govt./Semi Govt./Public/Private Institution.

22. I/We hereby certify that the firm poses all the required license/certification to perform the work.

Note: The Bidder has to fill up the above and enclose supporting documents along with Technical Bid.

Signature of the Bidder with seal

CHECK LIST
(to be submitted alongwith Technical Bid)

Sl. No.	Description	Indicate Yes / No	Page No.
1.	Tender submitted in Two Bid Technical Bid cover shall be superscribed with TECHNICAL BID & Price Bid cover shall be superscribed with PRICE BID and put in a single large cover superscribed with Tender No. & Date		NA
2.	Copy of Registration No. / PAN No. / GST No. enclosed		
3.	Proof for Annual Turnover (Annexure - I) (ITR Acknowledgement)		
4.	Documents in support of Experience enclosed (Annexure-II)		
5.	Tender Validity for 120 days given.		
6.	Sealed & Signed copy of complete Tender Document along with Technical Bid as a token of acceptance of all Terms & Conditions enclosed.		
7.	All documents enclosed with Technical Bid should be clearly numbered and indexed		NA

Note:

1. The above check list must be submitted in the letter head, along with Technical Bid.
2. No price component should be mentioned in above checklist, otherwise tender will be rejected.

Signature & Seal of Tenderer.

ANNUAL TURNOVER CERTIFICATE

Certified that Turnover of M/s. during the following consequent three (03) Financial Years is as given below:

Financial Year	Assessment Year	Amount
		Rs.
2018-19	2019-20	
2019-20	2020-21	
2020-21	2021-22	
TOTAL		
Total (in figure)		

OR

Financial Year	Assessment Year	Amount
		Rs.
2017-18	2018-19	
2018-19	2019-20	
2019-20	2020-21	
TOTAL		
Total (in figure)		

This certificate is given on the basis of audited financial records of M/s.

Place

CHARTERED ACCOUNTANT

Date

STAMP TO BE AFFIXED

This certificate must be duly signed & stamped by Practicing Chartered Accountant containing Member Registration Number as well as Firm Registration Number.

ANNEXURE-II

EXPERIENCE DETAILS

Details of experience in respect of M/s. during the previous Years is as given below:

Sl. No.	Name of the Firm	Period of Contract	No. of Months	Value of Contract	Supporting documents details

NOTE: Documents in support of the Experience submitted to be enclosed with Technical Bid

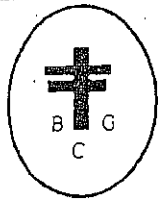
Place

SIGNATURE OF TENDERER

Date

		PRICE BID
Tender No. D-21010 / 04 / 2021 – 22 (Stores) dated 09.03.2022		
SUPPLY OF HIGH SPEED DIESEL AT BCGVL, GUINDY, CHENNAI		
Sl. No.	Description	Amount Rs.
1	High Speed Diesel (Rate per Litre)	Market Rate (on the date of supply)
2	Percentage of Discount offered on prevailing market rate (in %)	
3	Transport charges, if any	
	GST @	
NOTE		
1	The selection of the bidder will be on the basis of the H1 of the Discount allowed on Market Price & L1 of Transport charges. No comparison will be made on individual item/activity basis.	
2	Rates finalised will be effective for a period of 03 years. Rates shall be quoted indicating the breakup in Indian Rupees only	
3	Tenderers are required to indicate Basic Rate, Custom duty, Excise duty, Sales Tax and any other leviable taxes / Charges separately in the relevant columns of the proforma. Any taxes/duties/charges reflected outside the Proforma will not be accepted Tenderer must attach copies of Govt. Notification in support of all applicable Taxes/duties/ charges etc. The firm has to mention prevailing custom duty/other taxes in the proforma along with price bid and must attach copy of Govt.notification in this regard. If custom Duty/ any other taxes is quoted/ reflected as Nil or 'Zero' under relevant column of price bid, no custom Duty Exemption Certificate(CDEC)/ any other tax exemption will be granted. Subsequently upon placement of supply Order, no further request will be entertained in this regard. Final payment would be made only on production of other tax clearance.	
Place : Signature of Tenderer		
Date : Name		
Seal		

BCG VACCINE LABORATORY, GUINDY, CHENNAI-32



Format name

Vendor qualification Questionnaire

Format number

Revision Number

Effective date

QAD/SOP/GEN/003-01

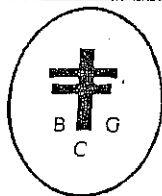
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Annexure -01Vendor /manufacturer qualification query form

Product NAME			
S. No	QUESTION	ANSWER	REMARKS
1.0 Administrative Information			
1.1	Vendor Name		
1.2	Address:- Head Office		
1.3	Address:- Manufacturing Unit		
1.4	Contact Person :- Technical Matters		
1.5	Contact Person :- Commercial dept		

BCG VACCINE LABORATORY, GUINDY, CHENNAI-32



Format name

Vendor qualification Questionnaire

Format number

Revision Number

Effective date

QAD/SOP/GEN/003-01

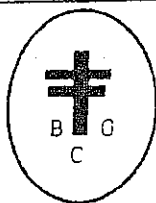
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01/12/2015

PRODUCT NAME:

S. No	QUESTION	ANSWER	REMARKS
1.6	Contact Person -: Quality Assurance		
1.7	The firm intends to enter into the rate contract or intends to supply the following to the institute : chemicals/reagents/media/disinfectants/cleaning agents /others (please specify)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
1.8	Annex the list of your products		
1.9	Total Manufacturing Site Area		
1.10	Total Constructed Area		
1.11	Is your company ISO certified? If yes please specify the year and certification body & type of certification	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
1.12	Have your manufacturing facility been inspected by NRA/WHO agencies etc? if yes please provide the copy of NRA certificate?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
1.13	Is the requested products as per Indian pharmacopeia and its version	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	

BCG VACCINE LABORATORY, GUINDY, CHENNAI-32



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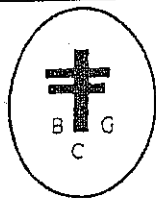
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01/12/2015

PRODUCT NAME:

S. No	QUESTION	ANSWER	REMARKS
1.14	Have your facility been inspected by any regulatory body within last 2 years if yes please give the name of agency, date & status of audit?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
1.15	Do you inform us about the changes in your manufacturing facility and manufacturing process including change in the vendor of your input material?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
1.16	Details of Storage facilities	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
1.17	i) Will the firm (inclusive of its supply chain) be willing to be inspected by the institute's vendor audit team ii) If yes period of prior notice required for inspecting your firm	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	

BCG VACCINE LABORATORY, GUINDY, CHENNAI-32



Form name

Vendor qualification Questionnaire

Form number

Revision Number

Effective date

QAD/SOP/GEN/003-01

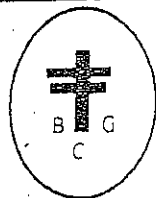
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01/12/2015

2.0 Technical Information

2.1	Do you have the written instruction and policies to implement Quality System?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
2.2	Whether Quality Unit is independent from the manufacturing department?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
2.3	Does the quality system include change control, deviation control, document control, self-inspection & vendor qualification policy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
2.4	Does your company have annual training plan for the personnel?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
2.5	Do you have written validation program and validation is executed as per the program?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
2.6	Do you have the written calibration program for measuring & testing instruments?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
2.7	Do you have the written preventive maintenance program for equipments?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
2.8	Do you have the IN-HOUSE testing facility under the control of QA/QC for testing and release the inputs and the finish products?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
2.9	Does your warehousing and production facility have appropriate measures for the segregation of the material and prevention of mix-up and cross contamination?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	

BCG VACCINE LABORATORY, GUINDY, CHENNAI-32



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01/12/2015

2.10

For Material manufactures:- Compliance to standards

☐ Yes ☐ No ☐ NA

3.0 Technical Package: Provide following information as technical package.

3.1

Brief of the manufacturing site

☐ Yes ☐ No ☐ NA

3.2

Release and /or regulatory specifications

☐ Yes ☐ No ☐ NA

3.3

Impurity profile (if applicable)

☐ Yes ☐ No ☐ NA

3.4

Process flow chart

☐ Yes ☐ No ☐ NA

3.5

Process validation reports (If available)?

☐ Yes ☐ No ☐ NA

3.6

Material release specification and standard test procedure

☐ Yes ☐ No ☐ NA

3.7

Drawing & Material of construction (MOC) certificate for packing material

☐ Yes ☐ No ☐ NA

3.8

Stability data

☐ Yes ☐ No ☐ NA

3.9

Equipment list with qualification documents.

☐ Yes ☐ No ☐ NA

3.10

Packing details

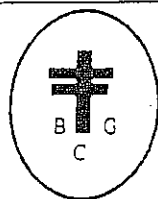
☐ Yes ☐ No ☐ NA

3.1

Mode of despatch

☐ Yes ☐ No ☐ NA

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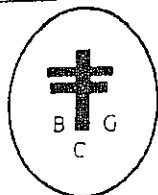
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3.2	If material is to be stored at or below temperature , how does the company ensure the material is held at the required temperature during transport		
3.3	Certificate of Analysis	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	

Note:

1. Indian manufacturers/distributor/suppliers are required to ensure that their reply reaches us within 20 days of issue of this letter, while Indian agents/distributors(of foreign principals) are required to get details from their manufacturers and forward the same to us within 30days of receipt of this letter.
2. Please list out major consumer of your products in parental drug, vaccine and sera manufacturers.
3. Documents once submitted can only be modified with the permission of the committee.
4. All pages submitted should be signed in full and overwriting/corrections should be initialed.
5. IT PAN number and sales tax number.
6. All correspondence should be addressed to The Director, BCG Vaccine Laboratory, Guindy, Chennai – 32.

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CERTIFICATE

I/We M/s _____ with office at

_____ do hereby undertake that the information provided are true to my knowledge and any changes in the above form QAD/SOP/GEN/003-01 will be intimated to concerned within 7 days of occurrence, failing which BCGVL Guindy Will be in its powers to take any action as deemed fit.

Dated _____

Authorized Signatory

For _____

Name _____

Designation _____