

**SPECIAL ECONOMIC ZONE**

**PUNE CLUSTER.**

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**AGENDA**

**Meeting of the Unit Approval Committee of Special  
Economic Zone for Biotechnology of M/s. SEZ  
Biotech Services Pvt. Ltd., PUNE – SEZ.**

VENUE : Mahratta Chamber Of Commerce Industries & Agriculture, 505,  
A-Wing, MCCIA Trade Tower, ICC Complex, 403, Senapati  
Bapat Road, Pune, Maharashtra 411016.

DATE : Thursday, 19<sup>th</sup> April 2018.

TIME :

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Meeting of the Unit Approval Committee of Special Economic Zone for Biotechnology of M/s. SEZ Biotech Services Pvt. Ltd., Pune held under the chairmanship of Development Commissioner, SEEPZ-SEZ on 19<sup>th</sup> April, 2018.

**INDEX**

<b>Agenda Item No.</b>	<b>Subject</b>
<b>Agenda item No. 01: -</b>	Confirmation of Minutes of the meeting held on 05.12.2017.
<b>Agenda item No. 02: -</b>	Application for Broad banding facility for adding two more products (vaccines) in their existing LOA with additional area - M/s. Serum Institute of India Pvt. Ltd. (PBP-1)- <b>M/s. SEZ Biotech Services Pvt. Ltd., Pune - SEZ.</b>

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**Minutes of the 11<sup>th</sup> Meeting of the Approval Committee held under the Chairmanship of Development Commissioner for Sector Specific Special Economic Zone for Biotechnology at Manjiri Budruk, Pune of M/s. SEZ Bio-Tech Services Pvt. Ltd. held on 05.12.2017.**

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1. Name of the SEZ : M/s. SEZ Bio-Tech Services Pvt. Ltd.  
2. Sector : Biotechnology  
3. Meeting no. : 11  
4. Date : 05.12.2017

**Members Present: -**

1. Shri. Pravin Chandra : Member  
Jt. Development Commissioner  
SEEPZ-SEZ  
2. Smt. S. R. Motwani : Nominee of the Addl. Directorate General  
Dy. Director General of Foreign Trade  
of Foreign Trade  
3. Shri. Prashant Patil : Nominee of GST, Pune 1.  
Dy. Commissioner  
4. Shri. Usha Gaikwad : Nominee of Income Tax, Pune.  
Dy. Commissioner IT, Pune.  
5. Shri. D. S. Mann : Nominee of Customs, Pune  
Asstt. Commissioner  
6. Shri. Dhaval Shirke : Nominee of Customs, Pune  
Sr. Authorized Officer  
Pune SEZ  
7. Shri. P. C. Nambiar : M/s. SEZ Bio-Tech Services Pvt. Ltd.  
Director

**8. Special Invitee :**

Shri. V. P. Shukla  
Jt. Development Commissioner  
SEEPZ-SEZ

**Agenda Item No.01: Confirmation of the minutes of the 10<sup>th</sup> meeting held on 21.04.2017.**

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The Minutes of the 10<sup>th</sup> Meeting held on 21.04.2017 were confirmed.

**Agenda Item No. 02: - Approval for Broad banding facility for adding two more Vaccines in their existing LOA with an additional area.**

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The unit has made request for Broad banding of two items in their existing LOA alongwith requirement of Capital Goods with increase in area and revision of projections.

The unit's representative explain the proposal and stated that the proposed items to be included in the LOP will be exported during 2019.

The Committee decided that the issue of depreciation/amortization of capital goods installed in the unit may be examined with reference to the SEZ Act/Rules and resubmit.

Meeting ended with a vote of thanks to the Chair.



**Chairperson - cum -  
Development Commissioner**

**OFFICE OF THE DEVELOPMENT COMMISSIONER,  
SEEPZ SPECIAL ECONOMIC ZONE,  
ANDHERI (EAST), MUMBAI**

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**AGENDA NOTE FOR CONSIDERATION OF UNIT APPROVAL COMMITTEE**

**a) Proposal :-**

Application of M/s. Serum Institute of India Pvt. Ltd. (PBP-1) for Broad banding facility for adding two more products (vaccines) in their existing LOA with additional area - M/s. SEZ Biotech Services Pvt. Ltd. (SEZ).

**b) Specific Issue on which decision of UAC is required :-**

- Application of the unit for Broad banding facility for adding two more products (vaccines) in their existing LOA No. SEEPZ/NEWSEZ/SIIPL-SBSPL/03/15-16/01276 dated 10.03.2016 with additional area was placed before UAC dated 05.12.2017.
- Decision of UAC was to examine the issue of depreciation/amortization of capital goods as per the SEZ Act and Rules.
- Decision on above matter along with approval for broad banding.

**c) Relevant provision of SEZ, Act, 2006 & Rules:**

In terms of proviso to Rule 19 (2) of SEZ Rules, 2006, which states as under:

***“Provided that the Approval Committee may also approve proposals for broad – banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity, if it meets the requirements of rule 18j”.***

**d) Other Information :**

M/s. Serum Institute of India Pvt. Ltd. (PBP-1) has been granted Letter of Approval No. SEEPZ/NEWSEZ/SIIPL-SBSPL/03/15-16/01276 dated 10.03.2016 for Viral Vaccines in single and Multi doses, Meningococcal polysaccharide Conjugate Vaccine, Dengue Vaccine and Dengue Monoclonal Antibody vaccine. The unit has not yet commenced their production. The LOA of the Unit is valid till **09.03.2019**. ....2/-

: 2 :

The unit vide letter dated **27.09.2017** and **03.04.2018** has requested for adding two more products (vaccines) in their existing LOA with additional area.

It may be stated that the application of the Unit was considered in the UAC held on 05.12.2017 and accordingly, it was decided to examine the issue of depreciation/amortization of capital goods installed in the unit with reference to the SEZ Act/Rules.

The details are as mentioned below:

**Additional Vaccines proposed:**

Sr.No.	Products	Unit	Production Capacity	ITC Code	HS Code
1	Biosimilar Monoclonal Antibodies (In Single or Multi Dose or In Bulk Form)	Doses/ Litres/ Grms.	13 Million Doses	30021290	
2	Human Papilloma Virus (HPV) Vaccine (In Single or Multi Dose or In Bulk Form)	Doses/ Litres/ Grms.	13 Million Doses	30022019	

**A) Requirement of Capital Goods and Inputs:**

Particulars	Import		Indigenous		Total	
	Existing	Addition	Existing	Addition	Import	Indigenous
Capital Goods (List Enclosed)	19,000	17,000	8,000	11,400	36,000	19,400
Raw Materials, Packing Materials, Consumables Spares, etc. (List Enclosed)	6,710	5,210	5,735	5,035	11,920	10,770

: 3 :

**B) Investment:**

A	Plant and Machinery	Existing	Additional	Total
	(i) Indigenous	8,000.00	11,400.00	19,400.00
	(ii) Import CIF Value	19,000.00	17,000.00	36,000.00
	(iii) (i) + (ii)	27,000.00	28,400.00	55,400.00
<b>B</b>	<b>Details of source(s) of Finance</b>	Self Finance through internal accruals.		

**C) Location/Area:**

Building No. and Floor	Existing Area (Sq. Mtr)	Additional Area (Sq. Mtr.)	Total Area (Sq. Mtr.)
M - SEZ - 1	18195.25	3802.46	21997.71
M - SEZ - 2	0	18882.61	18882.61
M - SEZ - 3	0	21997.71	21997.71
M - SEZ - 3A	0	13630.21	13630.21
<b>Total Area</b>	<b>18195.25</b>	<b>58312.99</b>	<b>76508.24</b>

**D) Employment:**

	Existing Projection	Additional Projection	Total Projection
<b>Men</b>	200	170	370
<b>Women</b>	25	30	55

**E) Revised projections for Five Years:**

Particulars	1 <sup>st</sup> Year 2017-18		2 <sup>nd</sup> Year 2018-19		3 <sup>rd</sup> Year 2019-20	
	Existing	Additional	Existing	Additional	Existing	Additional
FOB value of Exports in five years.	-	-	-	-	7,500	2,500
Foreign Exchange out go in five years.	10,450	10,950	5,285	4,785	6,075	2,875
<b>NET Foreign Exchange Earning in five years.</b>	<b>(10,450)</b>	<b>(10,950)</b>	<b>(5,285)</b>	<b>(4,785)</b>	<b>1,425</b>	<b>(375)</b>

Particulars	4th Year 2020-21		5th Year 2021-22		Total (5 Yrs.)	Total (5 Years) Revised USD'000 (@Rs. 65/USD)
	Existing	Additional	Existing	Additional	Revised (Existing + Additional)	
FOB value of Exports in five years	10,000	12,500	30,000	20,000	82,500	126,923
Foreign Exchange out go in five years	4,225	4,825	9,025	6,625	65,120	100,185
<b>NET Foreign Exchange Earning in five years</b>	<b>5,775</b>	<b>7,675</b>	<b>20,975</b>	<b>13,375</b>	<b>17,380</b>	<b>26,738</b>

**Brief Background of the product:**

Monoclonal Antibodies (mAb) are mono specific antibodies that are made by identical immune cells that are all clones of a unique parent cell, in contrast to polyclonal antibodies which are made from several different immune cells. The Quadrivalent HPV vaccine is indicated in girls and women of 9-26 years of age for the prevention caused by the HPV.

**ADC's Recommendation:**

As per the decision of UAC dated 05.12.2017 matter is examined.

As such there is no provision /specific clarification in regard to date for amortization of capital goods.

As per practices, amortization is being done from the year of import.

Recommended to UAC for decision.

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1967-2017

# SERUM INSTITUTE OF INDIA PVT. LTD

Cyrus Poonawalla Group

(SEZ UNIT : PBP - I)

Poonawalla Biotechnology Park SEZ (Developed by SEZ Biotech Services Pvt. Ltd.)

Manjari BK, Tal. Haveli, Pune - 412 307, Maharashtra, INDIA ■ Tel.: +91-20-26602281/26993975/76 ■ Fax: +91-20-26993974/3921  
E-mail: [exim@seruminstitute.com](mailto:exim@seruminstitute.com) ■ [www.seruminstitute.com](http://www.seruminstitute.com) ■ CIN: U80903PN1984PTC032945

PBP/SIIL/PBP-I/18-19

April 3<sup>rd</sup>, 2018

The Development Commissioner  
Office of the Development Commissioner  
SEEPZ-SEZ  
Andheri (E)  
MUMBAI - 400 096

Dear Sir,

Sub : Application for Broad Banding facility as per Rule 19 of SEZ Rules, 2006 for adding new products.

Ref : Letter of approval No: SEEPZ/NEWSEZ/SIPL-SBSPL/03/15- 16/01276 dated:10.03.2016 and amendment dated 29.12.2017.

Your kind attention is drawn to our letter No: SIPL/PBP-I/BB-I/17-18 dated 27.09.17 and Minutes of the approval committee held on 05.12.2017.

Subsequent to the above, the validity of Letter of Approval has been extended upto 09.03.2019. As we expect to commence our Production before 31<sup>st</sup> March 2019 it has become imperative that we identify new products for expeditious operation of our unit. Based on this revised business plan we have got the additional area of 58,312.99 Sq Mtr, allocated by the Developer and a registered lease deed covering the entire area of 76,508.24 Sq Mtr area has already been submitted to your office vide our letter dated 15.11.2017.

Hence we would request you to please add the following products as tabulated below as additional items of manufacture

Sr No	Products	Unit	Production Capacity	ITC HS Code
1	BIOSIMILAR MONOCLONAL ANTIBODIES(IN SINGLE OR MULTI DOSE OR IN BULK FORM)	DOSES/LTRS /GRMS	13 MILLION DOSES	3002 12 90

*Poonawalla*  
*AD J.D. Chavan*  
*P.I. put up for UAC*  
*6/4*

*06/04/18*

*22/04/18*

*22/04/18*



# SERUM INSTITUTE OF INDIA PVT. LTD.

Cyrus Poonawalla Group

(SEZ UNIT : PBP - I)

Poonawalla Biotechnology Park SEZ (Developed by SEZ Biotech Services Pvt. Ltd.)

Address: BK. Tal. Haveli, Pune - 412 307, Maharashtra, INDIA ■ Tel.: +91-20-26602281/26993975/76 ■ Fax: +91-20-26993974/3921  
E-mail: exim@seruminstitute.com ■ www.seruminstitute.com ■ CIN: U80903PN1984PTC032945

492

2	HUMAN PAPILLOMA VIRUS (HPV) VACCINE (IN SINGLE OR MULTI DOSE OR IN BULK FORM)	DOSES/LTRS /GRMS	75 MILLION DOSES	3002 20 19
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The revised Projection of Investment, requirement of Capital goods and Inputs , revised Net Foreign Exchange Earnings , Revised Foreign exchange Balance Sheet etc have already been submitted to you vide our letter dated 27.09.17.

In view of the above, we shall be grateful if you will kindly add the following two items as tabulated above in our LOA, as early as possible and oblige

Thanking you,

Yours truly,

For **SERUM INSTITUTE OF INDIA PRIVATE LIMITED (SEZ Unit :PBP-I)**

  
**P.C. NAMBIAR**  
**DIRECTOR – GROUP EXIM**

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# SERUM INSTITUTE OF INDIA PVT. LTD.

(FORMERLY KNOWN AS SERUM INSTITUTE OF INDIA LTD.)

Cyrus Poonawalla Group

REGD. OFFICE AND LABORATORIES : 212/2, HADAPSAR, PUNE - 411028, INDIA. ■ www.seruminstitute.com  
Tel.: +91-20-2660 2281 / 2699 3975 / 76 ■ Fax: +91-20-2699 3974 / 3921 ■ E-mail : exim@seruminstitute.com  
CIN - U80903PN1984PTC032945

October 23, 2017.

The Development Commissioner  
Office of the Development Commissioner,  
SEEPZ Special Economic Zone  
Andheri (E)  
MUMBAI 400 096

Re: **Application for Broad Banding facility as per Rule 19 of SEZ Rules, 2006. for adding new products.**

This has reference to your letter dated 11/10/2017 on the above mentioned subject asking us to furnish more details (copy enclosed).

In this connection, we would like state as under :-

1. The reason for not showing FOB value of exports during the years 2017-18 and 2018-19 in the revised projections is due to the reason that our export is likely to start by end of December, 2019. Hence, we have shown the FOB value of exports from the year 2019-20. This is mainly because, import and indigenous procurement of capital goods, their installation and validation by local FDA authorities; import and indigenous procurement of inputs, manufacturing of products for export and their approval by Central Government Laboratory, etc., would take lot of time.
2. Timeline of manufacturing of proposed products would be July, 2019.
3. Design and production facilities and manufacturing process of the new products to be added to the LOA are different from the existing products. Therefore, we have given the requirement of capital goods, raw materials, consumables, etc. as well as manufacturing process of the new products along with our application.

Hope, the above information would be enough to process our application. We request you to process our application as early as possible.

Thanking you,

Yours faithfully,

For SERUM INSTITUTE OF INDIA PVT. LTD. (SEZ UNIT: PBP-i)

P.C. NAMBIAR  
DIRECTOR (GROUP EXIM)  
/ravi

## Cyrus Poonawalla Group

OFFICE AND LABORATORIES : 212/2, HADAPSAR, PUNE - 411028, INDIA. ■ www.seruminstitute.com  
 91-20-2660 2281 2699 3975 / 76 ■ Fax: +91-20-2699 3974 / 3921 ■ E-mail : exim@seruminstitute.com  
 809003PN1984PTC032945

SIIP/PPB - I/BB-1/17-18

27.09.2017

The Development Commissioner  
 Office of the Development Commissioner  
 SEEPZ-SEZ  
 Andheri East  
 MUMBAI - 400 096.

Dear Sir,

Ref Letter of Approval No. SEEPZ/NEWSEZ/SIIP-PPB/03/15-16/01276  
dated 10.03.2016 and Amendment dated 10.03.2017.

Sub Application for Broad Banding facility as per Rule 19 of SEZ Rules, 2006  
for adding two more Vaccines with an additional area.

You were kind enough to issue us above Letter of Approval for setting up our Unit in Poonawalla Biotechnology Park SEZ, developed by SEZ Bio Tech Services Pvt Ltd., at Manjari Budruk, Pune 412307.

We are pleased to inform you that installation of Capital Goods required for manufacturing the approved vaccines are in progress.

We have been exploring the possibility of manufacturing new vaccines in our Unit in addition to the existing approved vaccines, to meet the requirement of vaccines in International market. We have identified the following vaccines which is having great potential in the international market. The details of the said product, its production capacity, etc. are as under:-

Sr No	Products	Unit	Production Capacity	ITC HS Code
1	BIOSIMILAR MONOCLONAL ANTIBODIES (IN SINGLE OR MULTI DOSE OR IN BULK FORM)	DOSES/ LTRS/ GRMS..	13 MILLION DOSES.	3002 12 90
2	HUMAN PAPILLOMA VIRUS (HPV) VACCINE (IN SINGLE OR MULTI DOSE OR IN BULK FORM)	DOSES / LTRS/ GRMS	75 MILLION DOSES	3002 20 19

Government Recognised Four Star Export House



## **Brief background of the Product:**

Monoclonal Antibodies (mAb) are mono specific antibodies that are made by identical immune cells that are all clones of a unique parent cell, in contrast to polyclonal antibodies which are made from several different immune cells. We have identified ten bio-similar MABs for treatment of various auto immune diseases and cancer for manufacture in this project. Detailed manufacturing process and write up enclosed.

The Quadrivalent HPV vaccine is indicated in girls and women 9-26 years of age for the prevention caused by the HPV and the following diseases associated with these HPV type: cervical cancer, vulvar and vaginal cancer etc. Detailed write up and Manufacturing process is Enclosed

## **Technical support:**

This Vaccine has been developed in-house by our scientists.

## **Manufacturing Facilities:**

Serum Institute of India Private Limited (SIPL) is today recognized in the world as a top class supplier of quality vaccines. SIPL has state of the art manufacturing facility complying with the current Good Manufacturing Practice (cGMP) and are producing various Vaccines and Drugs; and are supplying them at competitive prices. We are glad to say that our Vaccines are being used in the National Immunization Programme of several countries. The in-house expertise and experience give us the skill and advantage to expand and produce new products.

## **Employment**

	Existing	Additional	Total
Men	200	170	370
Women	25	30	55



## Location / Area:

To take care of the additional area requirement for manufacturing the new vaccines, we want to add additional area in to our Unit as per details given below:-

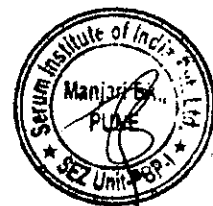
Building No and Floor	Existing Area (Sq. Mtr)	Additional Area (Sq. Mtr)	Total Area (SQ. Mtrs.)
M - SEZ - 1	18195.25	3802.46	21997.71
M - SEZ - 2	0	18882.61	18882.61
M - SEZ - 3	0	21997.71	21997.71
M - SEZ - 3A	0	13630.21	13630.21
<b>TOTAL AREA</b>	<b>18195.25</b>	<b>58312.99</b>	<b>76508.24</b>

## Marketing Strategy:

Serum Institute of India is ranked as India's No. 1 biotechnology company, manufacturing highly specialized life saving biological like vaccines using cutting edge genetic and cell based technologies, antisera and other medical specialties.

Timely supplies of quality Vaccines under a dedicated cold chain condition has enabled the Company to gain the confidence of International Organizations such as World Health Organization (WHO), UNICEF, Pan American Health Organization (PAHO) etc. in reaching out to counties in the remotest place of world. Serum Institute of India is today recognized as a top class supplier of quality vaccines in the world.

We are in the business for more than 35 years and currently we export to more than 140 countries in the world, through UNICEF, PAHO and other Government and semi-Government agencies. Marketing of our products becomes easy as our products are already established and accepted in the international market due to it's quality and competitive prices. Further, we have enough technically qualified professionals for marketing our products. We also have marketing agencies of international repute in many countries for marketing our products. We propose to use our existing net-work and also have marketing tie-ups with more Agencies of International repute for entering into the new markets for the upcoming new products



### FDA Licences :

We have necessary approval from Food & Drug Administration (FDA), Maharashtra State.

### INVESTMENT

(Rs. In Lakhs)

A	Plant and Machinery	Existing	Additional	Total
	(i) Indigenous	8,000.00	11,400.00	19,400.00
	(ii) Import CIF Value	19,000.00	17,000.00	36,000.00
	(iii) (i) + (ii)	27,000.00	28,400.00	55,400.00
B	Details of source(s) of finance	Self Finance through internal accruals.		

### Requirement of Capital Goods and Inputs :

(Values are Rupees in Lakhs)

	Import		Indigenous		Total	
	Existing	Additional	Existing	Additional	Import	Indigenous
Capital Goods ( List Enclosed)	19,000	17,000	8,000	11,400	36,000	19,400
Raw Materials, Packing Materials, Consumables Spares, etc. (List Enclosed)	6,710	5,210	5,735	5,035	11,920	10,770



In view of the above, we seek your approval for manufacturing and exporting the above mentioned products, in addition to the products already approved by you. We are submitting herewith the following documents for your record :-

1. List of Capital Goods.
2. List of major raw materials, consumables, chemicals, Packing Materials, spares, etc.
3. Revised Projections.
4. Manufacturing Flow-charts.
5. Manufacturing Write-up.
6. Ground Plans for the additional area.
7. Provisional Space allotment letter from the Developer

We shall be grateful if you will kindly incorporate the new products in our LOA, as early as possible and oblige.

Thanking you,

Yours faithfully,

For SERUM INSTITUTE OF INDIA PVT. LTD. (SEZ UNIT PBP - I)



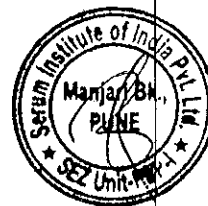
P. C. NAMBIAR  
DIRECTOR - GROUP EXIM

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LIST OF CAPITAL GOODS REQUIRED FOR THE NEW PRODUCTS  
IMPORTED AND / OR INDIGENOUS

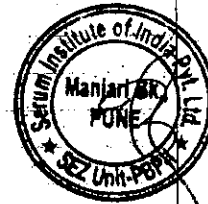
Sr. No	ITEM DESCRIPTION
1	AHU WITH SPARES AND ACCESSORIES
2	AIR SHOWERS
3	AUTOMATIC WASHERS
4	BAG HOLDER VESSELS
5	BIO SAFETY CABINETS
6	BUFFER PREPARATION SYSTEMS
7	CEDEX BIO
8	CEDEX HIRES
9	CENTRIFUGE
10	CHILLERS
11	CLEAN ROOM PARTITION SPARES AND ACCESSORIES
12	CHROMATOGRAPHY COLUMNS
13	CHROMATOGRAPHY SYSTEMS
14	CIP AND SIP MACHINES
15	CO2 INCUBATORS
16	CO2 SHAKER INCUBATORS
17	COLUMN PACKING STATIONS
18	CONDUCTIVITY METERS
19	CONTINUOUS CENTRIFUGES
20	DEPTH FILTRATION SYSTEMS
21	DOUBLE DOOR AUTOCLAVES
22	DRY HEAT STABILISERS
23	DUAL pH & CONDUCTIVITY METERS
24	DYNAMILLS
25	ELECTRICAL EQUIPMENTS, SPARES AND ACCESSORIES
26	FERMENTER SYSTEMS
27	FILLING AND STOPPERING MACHINES
28	FILTER INTEGRITY TESTERS
29	FILTRATION SKIDS
30	FILTRATION SYSTEMS
31	FREEZE AND THAW SYSTEMS
32	FUME HOODS
33	GLOW INTEGRITY TESTERS
34	HOISTS
35	HVAC SPARES AND ACCESSORIES



Sr. No

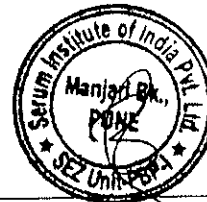
ITEM DESCRIPTION

- 36 INCUBATOR SHAKERS
- 37 INSTRUMENTATION APPRATUS, SPARES AND ACCESSORIES
- 38 INTEGRITY TESTERS
- 39 LAMINAR AIR FLOW EQUIPMENTS
- 30 LIQUID NITROGEN SYSTMMS
- 41 LIQUID NITROGEN VAPOUR STORAGE SYSTMMS
- 42 LYOPHILIZERS
- 43 MAGNETIC STIRRERS
- 44 MALVERN SIZERS
- 45 MEDIA FILTRATION SYSTEMS
- 46 MICROCENTRIFUGES
- 47 MICRON HOLLOW FIBRE SYSTEMS
- 48 MICROSCOPES
- 49 MICROSCOPE WITH CAMERAS
- 50 MIXING VESSELS
- 51 NON JACKETED SS VESSELS
- 52 OSMOMTERS
- 53 PARTICLE COUNTERS
- 54 PERISTALTIC PUMPS
- 55 PH BUFFER MIXING SYSTEMS
- 56 pH METERS
- 57 PLUNGER INSERTION AND LABELLING MACHNES
- 58 POUCH SEALING MACHINE
- 59 PRODUCTION BIOREACTOR SYSTEMS
- 60 SEED BIOREACTORS
- 61 SINGLE USE MIXER SYSTEMS
- 62 UTILITIES
- 63 VESSELS
- 64 SS VESSELS
- 65 SS VESSELS FOR INDU ADDITION
- 66 TFF SYSTEMS
- 67 TR CHILLERS
- 68 TURBIDO METERS
- 69 VIRUS FILTRATION SYSTEMS
- 70 VISUAL INSPECTION MACHINES
- 71 WEIGHING BALANCES
- 72 WORKING CAPACITY SS JACKETED VESSELS



LIST OF RAW MATERIALS, CONSUMABLES, PACKING MATERIALS ETC  
REQUIRED FOR THE NEW PRODUCTS. IMPORTED AND / OR INDIGENOUS

Sr. No	ITEM DESCRIPTION
1	ALUMINIUM CAPS / SEALS
2	AMMONIUM SOLUTION
3	ANIONS AND CATION EXCHANGE CHROMATOGRAPHY RESINS
4	BOPP TAPS
5	CARTONS
6	CELL CULTURE MEDIA
7	CITRIC ACID
8	COLD DOGS / BRINE BOTTLES
9	CORRUGATED BOXES
10	EPS BOXES
11	GLASS AMPOULES
12	GLASS VIALS
13	GLYCERIN
14	METHANOL
15	PLASTIC BAGS
16	PRE FILLED SYRINGES (PFS)
17	PROTEIN A RESINS
18	PVC TRAYS
19	RUBBER STOPPERS
20	SODIUM BICARBONATE
21	SODIUM CHLORIDE
22	SODIUM HYDROXIDE PALLETS
23	STICKERS / LABELS
24	STRAPPING ROLLS
25	TRIS / TRIZMA BASE
26	TRIS HYDROCHLORIDE
27	UREA
28	VACCINE VIAL MONITOR MARKS (VVM)



EMENT SHOWING THE REVISED PROJECTIONS FOR FIVE YEARS

RS. IN LAKHS

RTICULARS	1ST YEAR 2017 - 18		2ND YEAR 2018 - 19		3RD YEAR 2019 - 20		4TH YEAR 2020 - 21		5TH YEAR 2021 - 22		TOTAL (5 YRS.) REVISED (EXISTING + ADDITIONAL)	TOTAL (5 YRS.) REVISED USD '000 (@Rs.65/USD)
	EXISTING	ADDITIONAL	EXISTING	ADDITIONAL	EXISTING	ADDITIONAL	EXISTING	ADDITIONAL	EXISTING	ADDITIONAL		
OB VALUE OF EXPORTS IN FIVE YEARS					7,500	2,500	10,000	12,500	30,000	20,000	82,500	126,923
OREIGN EXCHANGE OUTGO IN FIVE YEARS	10,450	10,950	5,285	4,785	6,075	2,875	4,225	4,825	9,025	6,625	65,120	100,185
ET FOREIGN EXCHANGE ARNING IN FIVE YEARS (1) - (2)	(10,450)	(10,950)	(5,285)	(4,785)	1,425	(375)	5,775	7,675	20,975	13,375	17,380	26,738



SERUM INSTITUTE OF INDIA PVT LTD PRP - I

Rs. in Lakhs

TOTAL

Foreign Exchange Balance Sheet

(@Rs.65/ USD)

	2018	2019	2020	2021	2022	TOTAL						
	EXISTING	ADDITIONAL	EXISTING	ADDITIONAL	EXISTING	ADDITIONAL						
Foreign Exchange Earning on FOB Value	0	0	0	0	7500	2500	10000	12500	30000	20000	82500	126923
Foreign Exchange Outflow												
Import of Machinery	10,000	10,500	3,500	3,000	3,500	1,500	1,000	1,000	1,000	1,000	36,000	55,385
Import of Raw Materials, Packing Materials, Consumables	-	-	1,000	1,000	750	250	1,000	1,250	3,000	2,000	10,250	15,769
Import of Spares and Components	-	-	10	10	150	50	200	250	600	400	1,670	2,569
Repatriation of Dividends and profit to Foreign Collaborators	-	-	-	-	-	-	-	-	-	-	-	-
Royalty	-	-	-	-	-	-	-	-	-	-	-	-
Lump sum Know-how Fee	-	-	-	-	-	-	-	-	-	-	-	-
Design & Drawing Fee	-	-	-	-	-	-	-	-	-	-	-	-
Payment to foreign Technicians	250	250	250	250	250	250	300	300	300	300	2,700	4,154
Payment on Training Indian Technicians Abroad	50	50	75	75	75	75	75	75	75	75	700	1,077
Commission of Export etc.	-	-	-	-	900	300	1,200	1,500	3,600	2,400	9,900	15,231
Foreign Travel	-	-	300	300	300	300	300	300	300	300	2,400	3,675
Amount of interest to be paid on external commercial borrowing/deferred payment credit	-	-	-	-	-	-	-	-	-	-	-	-
Any other payments - Registration Expenses	100	100	100	100	100	100	100	100	100	100	1,000	1,538
Books and Periodicals	50	50	50	50	50	50	50	50	50	50	500	769
TOTAL (i) to (xiii)	10,450	10,950	5,285	4,785	6,075	2,875	4,225	4,825	9,025	6,625	65,120	100,185
NET FOREIGN EXCHANGE EARNING IN 5 YEARS	(10,450)	(10,950)	(5,285)	(4,785)	1,425	(375)	5,775	7,675	20,975	13,375	17,380	26,738



# HPV Vaccine Manufacturing Process

MSL

WSL

Shake Flask I

Shake Flask II

Pre-Seed fermenter

Seed fermenter

Production fermenter

Cell Washing

Cell Lysis

Lysate Centrifugation

Ion Exchange Chromatography

Gel permeation Chromatography

Constant Volume Diafiltration

Cold Room

Monovalent Adsorbed HPV VLP's

Blending/filling

Filling

Labelling

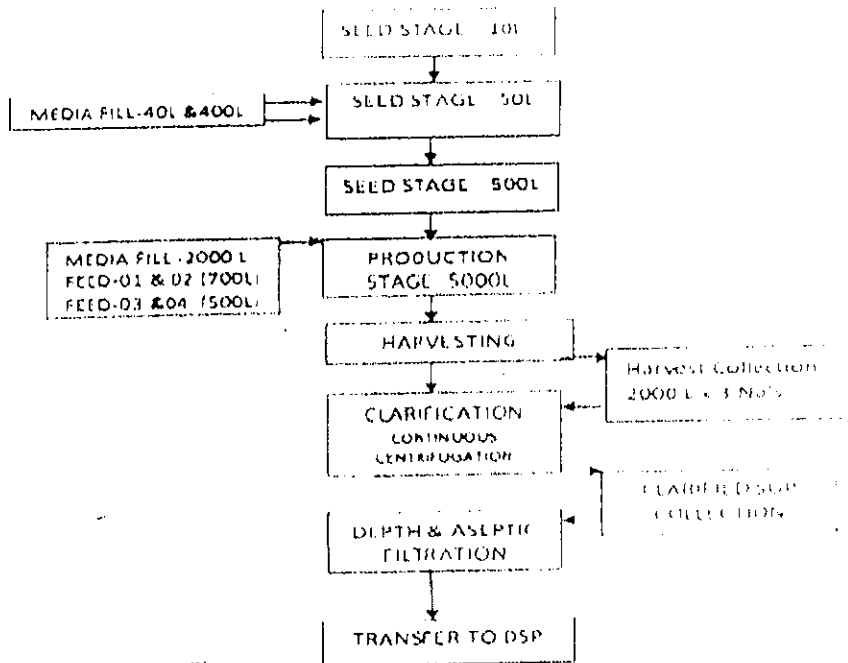
Packaging

Dispatch

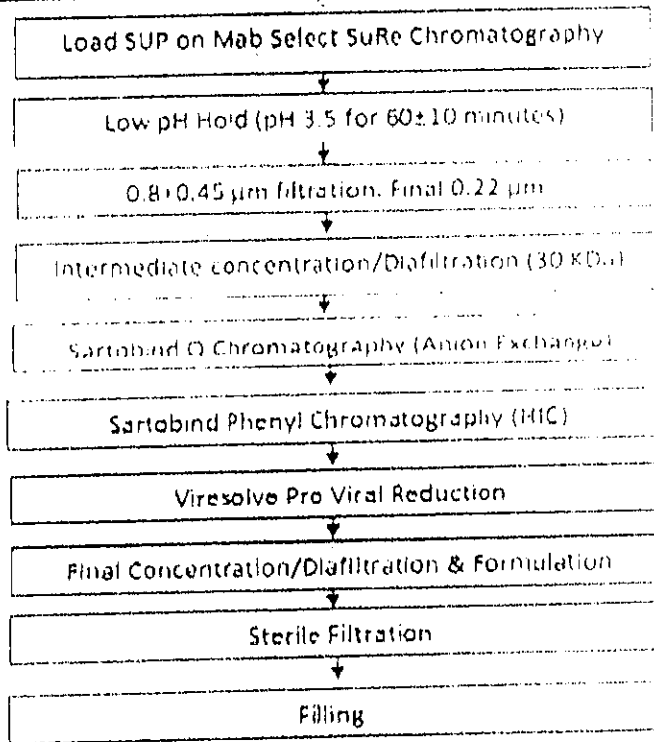


# Production flow charts:

## Upstream Process Flow



## Down Stream Process Flow



## BRIEF DETAILS ABOUT THE PRODUCTS

### 1. HUMAN PAPILLOMA VIRUS (HPV) vaccine

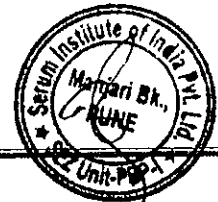
The Quadrivalent Human Papillomavirus (HPV) (Types, 6, 11, 16, 18) recombinant vaccine contains as active ingredients, highly purified virus-like particles (VLPs) of the recombinant major capsid (L1) protein of HPV types 6, 11, 16, and 18. The Quadrivalent HPV vaccine is indicated in girls and women 9-26 years of age for the prevention of infection caused by the HPV (Types 6, 11, 16, and 18) and the following diseases associated with these HPV types: cervical cancer, vulvar and vaginal cancer, genital warts (condyloma acuminata), cervical adenocarcinoma *in situ* (AIS), cervical intraepithelial neoplasia (CIN) grades 1, 2 and 3, vulvar intraepithelial neoplasia (VIN) grades 2 and 3, and vaginal intraepithelial neoplasia (VAIN) grades 2 and 3. The Quadrivalent human papillomavirus [types 6, 11, 16, 18] recombinant vaccine) is presented as a suspension for injection. It should be administered intramuscularly as three separate 0.5 mL-doses according to the schedule outlined in the dosing guidelines available in the Product Monograph."

### 2. BIOSIMILAR MONOCLONAL ANTIBODIES:

Antibodies are proteins produced by the **B lymphocytes** of the immune system in response to foreign proteins, called **antigens**. Antibodies function as markers, binding to the antigen so that the antigen molecules can be recognized and destroyed by phagocytes. The part of the antigen that the antibody binds to is called the **epitope**. The epitope is thus a short amino acid sequence that the antibody is able to recognize.

Structurally antibodies are proteins consisting of four polypeptide chains. These four (two heavy chains and 2 light chains) chains form a quaternary structure somewhat resembling a Y shape.

Monoclonal antibodies (mAb) are mono specific antibodies that are made by identical immune cells that are all clones of a unique parent cell, in contrast to polyclonal antibodies which are made from several different immune cells.



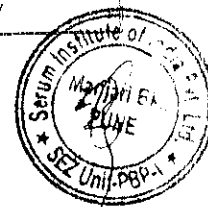


Monoclonal antibodies have monovalent affinity, in that they bind to the same epitope.

We have identified ten bio-similar MABs for treatment of various auto immune diseases and cancer for manufacture in this project.

The list of mABs proposed to be manufactured and their applications is as given below:

Sr. No	MAB	Use/ Indication
1	Adalimumab	Rheumatoid arthritis, Psoriasis, Crohn's & Ulcerative Colitis
2	Trastuzumab	HER2-positive metastatic breast cancer
3	Rituximab	Hematological cancers, rheumatoid arthritis, Autoimmune diseases, Anti-rejection treatment for organ transplants, non-Hodgkin's lymphoma
4	Denosumab	osteoporosis, giant cell tumors, multiple myeloma with bone metastases, and hypercalcemia of malignancy
5	Palivizumab	Premature Birth during cold season, Chronic lung disease of prematurity, Congenital heart disease
6	Omalizumab	Allergic asthma, Chronic spontaneous urticaria
7	Natalizumab	Multiple sclerosis, Crohn's disease
8	Ustekinumab	Multiple sclerosis, sarcoidosis and psoriatic arthritis
9	Tocilizumab	Rheumatoid arthritis, Systemic juvenile idiopathic arthritis, Castleman's disease, Neuromyelitis optica
10	Bevacizumab	Colorectal cancer, Lung cancer, Breast cancer, Renal cancers, Brain cancers, age-related macular degeneration (AMD) and diabetic retinopathy



The Manufacturing Process for Bio similar products consists of following steps

- 1) **UPSTREAM:** In this area the CHO Cells are expanded in flask and bioreactors. The process is carried out as per the procedure also includes addition of feeding's during production stage at 5000L scale, where the desired protein is expressed, the total time for completion of a single batch is around 30 days, on completion of upstream process the clarified harvest is transferred to downstream process area and collected in 5 kL collection tank.
- 2) **DOWNSTREAM:** In this area the Clarified sup is loaded onto chromatography systems and in 4 stage purification process the final purified protein is collected in sterile disposable bags which are later formulated. Stringent aseptic environment is maintained to avoid increase in bacterial load the total time required for completion of a single batch is 3 -4 days.
- 3) **FORMULATION AREA:** In this area the bulk is final formulated and aseptically filled in sterile Disposable bags under FFU, this area is highly aseptic area, as to avoid any contamination bulk and is designated to be Class B, the final Bulk bags are moved to cold room via pass box. Total time for the batch processing is less than 24 hrs.
- 4) **WASHING /MATERIAL PREP AREA:** This area is used for cleaning of used material in UPSTREAM, DOWN STREAM and FORMULATION AREA, all the used materials are cleaned and loaded into autoclave for sterilization and use in respective areas.





