

Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

Year 2025				
S. no	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Biological E Limited, Plot No.1, Biotech Park, Phase-II, Kolthur Village, Shameerpet, Medchal – Malkajgiri District, Telangana – 500078	COVID-19 Vaccine SARS-CoV-2-RBD203 N1_XBB.1.5	Active immunization against COVID-19 disease in individuals of 5 years of age and above who have received primary vaccinations series & to be administered in two dose schedule (0.5 mL each) 28 days apart (Day 0 & Day 28).	MF/BIO/21/000136, Date: 13-01-2025
2	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N.H.No. 8A, Opp. Ramdev Masala, Village – Changodar, Taluka: Sanand, Dist.: Ahmedabad, Gujarat -382213, India	Measles and Rubella Vaccine (Live) I.P. (Freeze Dried)- Multidose vial (5.0 ml-10 dose)	For active immunization in children of 9 months of age and older against Measles and Rubella infections simultaneously	MF/BIO/25/000001, dated 14-01-2025
3	M/s. Serum Institute of India Pvt. Ltd. S. No. 105-110, Manjari Bk. Manjari Bk. Pune Maharashtra (India) – 412307	Diphtheria and Tetanus Vaccine (Adsorbed)	For primary vaccination and revaccination of adults and adolescents, who are having contraindications of DTP	BIO/MA/24/000087, Date: 20-01-2025
4	M/s GCBC Vaccines Pvt Ltd, Survey. No 274, Athvelly Village, Medchal Mandal, Medchal-Malkajgiri District, Hyderabad Telangana, India 501401	Cholera Vaccine, Inactivated, Oral I.P	For active immunization against Vibrio Cholera	BIO/MA/24/000132, Date: 23-01-2025
5	M/s. Biological E. Limited, SEZ Unit, Sy. No. 549, 550, 552 to 556, Kolthur Village, Shameerpet, Medchal Malkajgiri, District: Telangana – 500078 (India).	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed) liquid pentavalent vaccine	Active immunization of Against Diphtheria, pertussis, tetanus, Hepatitis b, Hib type b infection	13-02-2025

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6	M/s. Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) – 411028	BCG for Immunotherapy (80 mg/vial)	For intravesical use in the treatment and prophylaxis of primary or recurrent carcinoma in situ (CIS) of the urinary bladder and for prophylaxis following trans urethral reaction (TUR) of primary recurrent stage Ta and/or T1 papillary tumors. (It is not for prevention of Tuberculosis).	24-02-2025
7	M/s. Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) – 411028	Rotavirus Vaccine (Live Attenuated, Oral) (Liquid)	For active immunization of healthy infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection when administered as a 3-dose series. The three dose regimen should be Completed by one year of age.	MF/810/19/000031 Date: 18-03-2025
8	M/s Indian Immunological Limited, Rakshapuram Gachibowli Post, Hyderabad Rangareddi Hyderabad (India) – 500032	Diphtheria & Tetanus vaccine for Adults & Adolescents I.P.	For active immunization against Diphtheria and Tetanus in Adolescents (10 years to below 18years) & Adults (age 18 years to 60 years).	MF/BIO/25/000037 Date: 21-03-2025

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S.no	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N.H.No. 8A, Opp. Ramdev Masala, Village – Changodar, Taluka: Sanand, Dist.: Ahmedabad, Gujarat (India) – 382213.	Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) - Multi dose Vial (5.0 ml - 10 dose).	It is indicated for prevention of Measles, Mumps and Rubella virus infections.	MF/BIO/24/000069, Date: 25-June-2024
2	M/s Serum Institute of India Pvt. Ltd., S. No. 105 110, Manjari BK, Tal Haveli, Pune 412307, Maharashtra (India)	Covid-19 Vaccine, Adjuvanted 2023-24 Formula [SARSCoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, Omicron XBB 1.5 variant] (COVOVAX)	Vaccine is indicated for active immunization to prevent COVID – 19 disease (a) in individuals of ≥ 12 to < 18 years of age as primary series of two doses (0.5mL each) 3 weeks apart (b) as single precautionary dose in individuals of ≥ 18 years of age, who have received primary series of vaccinations for restricted use in emergency situation.	BIO/MA/23/000137, dated; 06-June-2024
3	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune, Maharashtra - 411028	Measles and Rubella Vaccine (Live Attenuated) (Freeze-Dried), (10 Dose) (0.5ml/Vial)	For active immunization against Measles and Rubella in infants, children, adolescents of age up to 10 years.	MF/BIO/24/000055 dated 20-May-2024
4	M/s Zydus Lifesciences Limited, Plot , Survey No. 23, 25/P, 37, 40/P, 42 to 47,49 & 50, Sarkhej-Bavla N.H. No. 8A, Opp. Ramdev Masala, Village – Changodar, Taluka: Sanand, Dist.: Ahmedabad, Gujarat (India) - 382213,	Measles and Rubella Vaccine (Live) I.P. (Freeze Dried)- Multi Dose vial (2.5ml - 5 dose).	For active immunization in children of 9 months of age and older against Measles and Rubella infections simultaneously	MF/BIO/24/000052, Date: 16-May-2024

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5	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune, Maharashtra - 411028	Measles Vaccine, Live Attenuated (Freeze-Dried)	For active immunization of all susceptible children against measles at 9 months of age.	MF/BIO/24/000045 dated 25-April-2024
6	M/s Bharat Biotech International Ltd, Genome Valley, Shameerpet, Hyderabad, India -500078.	Cholera Vaccine (Inactivated, Oral), V. cholerae (O1 El Tor Hikojima Serotype recombinant strain) formaldehyde inactivated whole Cell, Phosphate Buffered Saline.	For active immunization against Diarrhoeal infection caused by Vibrio cholerae to the children, adolescents and adults aged 1 year and above with two doses on Day 0 and Day 14.	MF/BIO/24/000043 dated 16-April-2024
7	M/s Bharat Biotech International Ltd, Genome Valley, Shameerpet, Hyderabad, India -500078.	Rotavirus Vaccine (Live Attenuated, Oral) I.P (ROTAVAC 5D)" vaccine without antibiotics.	Active Immunization of infants from the age of 6-8 weeks for prevention of gastroenteritis due to rotavirus infection.	MF/BIO/24/000028 dated 07-March-2024

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S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1.	M/s Cadila Pharmaceuticals Limited, 1389, Dholka, Ahmadabad, Gujarat- 382225, India.	Quadrivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine, I.P	For active immunization in adults and children from 6 months of age for the prophylaxis against influenza disease caused by influenza virus subtype A and B contained in the vaccine.	MF/BIO/23/000003 dated 18-Jan-2023
2.	M/s Gennova Biopharmaceuticals Limited	Lyophilized mRNA Vaccine for Injection (COVID-19) [GEMCOVAC®-OM]	The vaccine is indicated as a single booster dose in individuals aged ≥18 years administered at least 4 months after completion of primary vaccination with either COVISHIELD™ or COVAXIN® for restricted use in emergency situation.	MF/BIO/23/000055, dated 19-June-2023

Additional Indications				
1.	M/s. Zydus Lifesciences Limited, Plot Survey No.23, 25/P, 37, 40/P, 42 to 47, Opposite Ramdev Masala, Sarkhej-Bavla N.H. No. 8A, Changodar, Ahmedabad (Dist.) India -382 213.	Novel Corona Virus 2019-nCoV Vaccine (Recombinant) (3 mg, Single dose)	for administration of heterologous booster (third) dose of Novel Corona Virus 2019- nCoV Vaccine (Recombinant) (3mg, Single dose) to individuals aged ≥18 years after 6 months of primary vaccination (two doses) of either COVAXIN or COVISHIELD vaccine for restricted use in emergency situation	20-April-2023
2.	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune,	SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine	for administration of heterologous booster (third) dose to individuals aged ≥18 years after 6 months of primary vaccination (two doses) of	16-Jan-2023

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	Maharashtra - 411028		either COVAXIN or COVISHIELD vaccines for restricted use in emergency situation	
3.	M/s. Zydus Lifesciences Ltd, Plot Survey No. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad Gujarat (India) – 382213	Inactivated Influenza Vaccine (Split Virion) IP (Tetravalent) -	For active immunization of pediatrics & Children from 6 months to 35 months age with two dose schedule 0.5 ml each to 17 years of age as an additional indication (a dose of 0.5 ml for 3 years to 17 years age group and a dose of 0.25ml for 6 months to group) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses	24-May-2023 (BIO/MA/22/000146)

Year 2022				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1.	M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India - 500078.	Whole-Virion Inactivated Coronavirus (SARS-CoV-2)vaccine	For sale or for distribution in Adult population	27-JAN-2022
2.	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune, Maharashtra - 411028	ChAdOx1 nCoV-19 Corona VirusVaccine (Recombinant)	For sale or for distribution in Adult population	27-JAN-2022

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3.	M/s Biological E. Limited, 18/1 & 3, Azamabad, Hyderabad, Telangana - 500020.	SARS-CoV-2 (Covid-19) Vaccine containing Receptor Binding Domain of SARS- CoV-2	For active immunization against COVID- 19 disease in adults aged 18 years and above when given in two doses at day 0 & day 28 for restricted use in emergency situation	MF/BIO/22/000011 Dated 11-FEB-2022
4.	M/s Hetero Biopharma Limited, H. No. 8-3-166/1 & 2, 105 To 108, 1 st Floor, G Block, East Wing, Challa Estates, Erragadda, Hyderabad - 500018	Recombinant adenoviral vector vaccine containing particles of serotype 26 containing the protein S gene of the SARS-CoV- 2 virus	For the prevention of the COVID-19) in adults aged over 18 year, when administered in single dose of (0.5ml) for restricted use in emergency situation	MF/BIO/22/000024 dated 16-MAR-2022
5.	M/s Zydus Lifesciences Limited., Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Opp. Ramdev Masala, Sarkhej- Bavla, N.H. No. 8A, Village- Changodar, Taluka - Sanand, Dist. Ahmedabad - 382213,	Novel Corona virus-2019- nCoV Vaccine (Recombinant)	For active immunization to prevent COVID-19 caused by SARS- CoV- 2 in individuals 12 years of age and older when given in two separate doses of 3mg (0.3ml) each to be given at an interval of 28 days each (day 0, day 28).	MF/BIO/22/000034 Dated 25-Apr-2022
6.	M/s Panacea Biotec Ltd., Ambala-Chandigarh Highway, Post office Lalru, District Sahibzada Ajit Singh Nagar Punjab- 140 501, India	Adsorbed Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and Haemophilus influenzae Type b Conjugate Vaccine I.P.	For active immunization for prevention against Diphtheria, Tetanus, Pertussis (Whooping Cough), infections caused by Haemophilus influenzae Type b & Poliomyelitis. Posology: One paediatric dose is of 0.5 ml to be administered Intramuscularly with an interval of	MF/BIO/22/000043 dated: 20-May-2022

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			four weeks between doses, starting at 6 weeks of age (6, 10 and 14 weeks of birth)	
7.	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram Gachibowli Post Rangareddi Hyderabad (India) - 500032	Measles and Rubella Vaccine (Live) I.P.	For active immunization in children of 9 months of age and older against Measles and Rubella. (0.5 ml single dose).	MF/BIO/22/000058 dated 27-JUNE-2022.
8.	M/s Gennova Biopharmaceuticals Limited	Lyophilized mRNA Vaccine for Injection (COVID-19) [HGCO-19]	For active immunization against COVID- 19 disease in adults aged 18 years and above when given in two doses at day 0 & day 28.	MF/BIO/22/000064 dated 28-JUN-2022
9.	M/s Seasons Biologicals Private Limited,	Tetanus Vaccine (Absorbed) I.P	For active immunization against tetanus infection when administered as single dose of 0.5 ml in the age group of 10 to 45 years.	MF/BIO/22/000068 dated 04-JULY-2022
10.	M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) – 411028	Quadrivalent Human Papilloma Virus (Serotypes 6,11, 16 & 18) Vaccine (Recombinant) (qHPV)	For active immunization in the age group of 9-14 years (male and female), two- doses schedule (0 and 6 months) and for age group of 15-26 years (male and female), three-dose schedule (0, 2 and 6 months) for prevention of the disease caused by Human Papilloma Virus types 6, 11, 16 and 18.	MF/BIO/22/000072 Dated 12-JULY-2022

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11.	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram Gachibowli Post Rangareddi Hyderabad (India) - 500032	Diphtheria & Tetanus vaccine for Adults & Adolescents I.P.	For active immunization against Diphtheria and Tetanus in Adolescents (10 years to below 18 years) & Adults (age 18 years to 60 years).	MF/BIO/22/000078 dated 25-Aug-2022
12.	M/s BharatBiotech International Ltd., Genome Valley Shamirpet, Hyderabad, Telangana, India – 500 078	ChAd36-SARS-CoV-S COVID-19 (Chimpanzee Adenovirus Vectored) recombinant COVID- 19 Vaccine (Nasal)	For active immunization against COVID- 19 in the age group of 18 years and above when given in two doses [0.5ml each administered intranasally as 4 drops (0.25 mL) in each nostril] at day 0 & day 28 interval.	MF/BIO/22/000083 dated 05-Sep-2022
13.	M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) – 411028	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis-B (rDNA), Poliomyelitis (Inactivated) and Haemophilus influenzae type b Conjugate Vaccine (Adsorbed) I.P.	For active immunization of infants, at or above the age of 6 weeks against Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliomyelitis and invasive disease caused by <i>Haemophilus influenzae</i> type b for 3 dose regimen (6, 10 & 14 weeks) for primary vaccination and Booster dose at the age of 12-24 months.	MF/BIO/22/000086 Dated 14-SEPT-2022
14.	M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) – 411028	Diphtheria, Tetanus and Pertussis (Acellular, component) Vaccine [adsorbed, reduced antigen(s) content]	For active booster immunization against Tetanus, Diphtheria, and Pertussis in individuals aged 4 years to 65 years.	MF/BIO/22/000088 dated 21-SEP-2022

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15	M/s Serum Institute of India Pvt Ltd, 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) – 411028	[Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)]	For active immunization of individuals aged 18-85 years against invasive meningococcal disease caused by Neisseria Meningitidis serogroups A, C, Y,W, and X.	MF/BIO/22/000089 Dated 26-SEPT-2022
16.	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited) Rakshapuram, Gachibowli Hyderabad, Telangana-500032	Inactivated Hepatitis A Vaccine, IP (Adsorbed) IP	For prevention of Hepatitis A infection for 0.5mL dose of children (above 1 years) & adolescents and 1 mL in adults (aged 10 years to 49 years).	MF/BIO/22/000095 Dated: 17-OCT-2022
17.	M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana INDIA 500078.	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. (14 Valent)	For active Immunization against invasive disease caused by Streptococcus Pneumonia serotype 1,3,4,5,6B,7F,9V,14 18C,19A,19F,22F,23F and 33F in infants from 6 weeks of age group for 3 dose schedule (6,10 & 14 weeks).	MF/BIO/22/000112 Dated: 10-DEC-2022

Approval of New indications of Approved Vaccines

S. No.	Name of Firm	Name of Vaccine	Indication	Date of approval
1.	M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana INDIA 500078.	Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19)	For Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19) for use in age group of ≥12 to <18 years with the dose schedule of 0 & 28 days for restricted use in emergency situation.	21-FEB-2022

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2.	M/s Serum Institute of India Pvt. Ltd. 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India)-411028.	SARS-CoV-2 rS Protein (COVID- 19) recombinant spike protein Nanoparticle Vaccine	For SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine for use in age group of ≥12 to <18 years with the dose schedule of 0 & 21 days for restricted use in emergency situation.	09-MAR-2022
3.	M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India -500 078.	Whole Virion inactivated coronavirus vaccine	Whole Virion inactivated corona virus vaccine for use in age group of >6 to <12 years with the dose schedule of 0 & 28 days for restricted use in emergency situation.	25-APR-2022
4.	M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana INDIA 500078.	Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19)	for Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19) for use in age group of ≥5 to <12 years with the dose schedule of 0 & 28 days for restricted use in emergency situation.	25-APR-2022
5.	M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana INDIA 500078.	SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19)	For administration as heterologous booster (third) dose to individuals aged ≥18years to 80 years after 6 months of administration of primary vaccination (two doses) of COVAXIN or COVISHIELD vaccine for restricted use in emergency situation.	03-JUNE-2022

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6.	M/s Serum Institute of India Pvt. Ltd., 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India)-411028	SARS-CoV-2 rS Protein (COVID- 19) recombinant spike protein Nanoparticle Vaccine	SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine for use in the age group of ≥7 to <12 years for restricted use in emergency situation.	28-JUNE-2022
7.	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Opp. Ramdev Masala, Sarkhej- Bavla, N.H. No. 8A, Village - Changodar, Taluk-Sanand, Dist. Ahmedabad - 382 213	Typhoid Vi Conjugate Vaccine.P.	For active immunization against <i>Salmonella typhi</i> infection in 6 months to 65 years age group.	08-SEPT-2022
8.	M/s Serum Institute of India Pvt. Ltd., 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India)-411028	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (IO-Valent)	For additional indication to permission no. MF/BIO/20/000059 dated 14-Jul-2020 as to be administered as 2+1 schedule (6 weeks, 14 weeks & 9 months of age)	01-NOV-2022 BIO/MA/22/000063
9	M/s BharatBiotech International Ltd., Genome Valley Shamirpet, Hyderabad, Telangana, India – 500 078	ChAd36-SARS-CoV-S (Chimpanzee Adenovirus vectored) recombinant COVID-19 vaccine	For new (additional) indication to permission no. MF/BIO/22/000083 dated 06.09.2022 administer booster dose (third dose) after 6 months to individuals of age >18 years who have already administered primary (two doses) of COVAXIN or COVISHIELD vaccines.	25-NOV-2022 BIO/MA/22/000095

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Year: 2021				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1.	M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road, Hadapsar Pune, Maharashtra, India.	ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)	For Restricted use in emergency situation: For active immunization of individuals of ≥ 18 years old for the prevention of corona virus disease (COVID-19) when administered in two doses schedule. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies.	MF/BIO/21/000001 dated 03-Jan-2021
2.	M/s BharatBiotech International Limited, Sy. No. 230, 231 & 235, Genome Valley, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana-500078, India.	Whole Virion Inactivated Corona Virus Vaccine, [BBV152]	For Restricted use in emergency situation in clinical trial mode: For active immunization against Corona Virus Disease (COVID-19) for age ≥ 18 years when administered in two doses interval of day 0 & day 28.	MF/BIO/21/000002 dated 03-Jan-2021
3.	M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road, Hadapsar Pune, Maharashtra, India.	Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) I.P.	For the primary immunization of infants, at or above the age of 6 weeks, and of children through six years of age against diphtheria, tetanus and whooping cough.	MF/BIO/21/000003 dated 04-JAN-2021

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4.	M/s Serum Institute of India Pvt., Ltd., S.No. 105-110, Manjari, Budruk, Pune, Maharashtra 412307, India.	ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)	For Restricted use in emergency situation: For active immunization of individuals of ≥ 18 years old for the prevention of corona virus disease (COVID-19) when administered in two doses schedule. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies.	MF/BIO/21/000019 Dated 11-Feb-2021
5.	M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana -500078	Inactivated Hepatitis A Vaccine (Adsorbed), IP	For active immunization against Hepatitis A virus (HAV) in 1 to 15 years of age group	MF/BIO/21/000033 dated 13-Apr-2021
6.	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) – 411 028.	BCG for immunotherapy I.P.	For treatment of flat Urothelial cell carcinoma in situ of urinary bladder and as adjunctive therapy following transurethral resection of primary or relapsing superficial non-invasive papillary tumors that are limited to the bladder mucosa (stage Ta or T1). Intravesical BCG Immunotherapy has been shown to reduce tumor recurrence and prevent progression	21 June 2021 BIO/MA/21/000044

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7.	M/s Ra (biologicals) Panacea Biotec Ltd., A-27, B-1 Extension Mohan Cooperative Industrial Estate, Mathura Road New Delhi – 110044, India.	Gam-COVID-Vac combined vector vaccine (Component I & Component II) Sputnik V vaccine	For Restricted use in emergency situation: For the prevention of the novel Coronavirus infection (COVID-19) in adults aged over 18, when given in two separate doses three weeks apart. Day 0: Component I (0.5 ml) & Day 21: Component II (0.5ml)	MF/BIO/21/000057 Dated 02-Jul-2021
8.	M/s Zydus Lifesciences Limited, Zydus Corporate Park Scheme No. 63, Survey No. 536, Near Nirma University, Vaishnov Devi Circle Khoraj (Gandhinagar) S. G. Highway, Ahmedabad – 382481, Gujarat	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P.	For active immunization of children 10 years of age or older, adolescents and adults, against tetanus and diphtheria.	MF/BIO/21/000059 dated 15-Jul-2021
9.	M/s BharatBiotech International Limited at M/s Chiron Behring Vaccines Private Limited, Plot No. 3502, G.I.D.C., Estate P. B No. 136, Dist. Bharuch, Ankleshwar, Gujarat (India)-393 002.	Whole Virion Inactivated Corona Virus Vaccine, [BBV152]	For Restricted use in emergency situation: For active immunization against Corona Virus Disease (COVID-19) for age ≥18 years when administered in two doses interval of day 0 & day 28.	MF/BIO/21/000069 dated 09-Aug-2021
10.	M/s. Biological E. Limited, SEZ- Unit Sy.No:549, 550, 552 to 556, Kolthur Village, Shameerpet, Medchal- Malkajgiri District, Telangana, India	COVID-19 vaccine (Ad26.COV2-S [recombinant]) (Janssen Vaccine)	For active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older when given in single dose (0.5 mL).	MF/BIO/21/000080 Dated 18-Aug-2021

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	-500 078.			
11.	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Opp. Ramdev Masala, Sarkhej- Bavla, N.H. No. 8A, Village - Changodar, Taluka – Sanand Dist. Ahmedabad - 382 213	Novel Corona virus-2019-nCoV Vaccine (Recombinant)	For Restricted use in emergency situation: For active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older when given in three separate doses of 2mg (0.2ml) each to be given at an interval of 28 days each (day 0, day 28 and day 56).	MF/BIO/21/000081 Dated 20-Aug-2021
12.	M/s BharatBiotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India -500078.	Typhoid Vi conjugate vaccine IP [Typhoid (Vi Capsular Polysaccharide) – Tetanus Toxoid conjugate vaccine]	For active immunization against <i>Salmonella Typhi</i> infection in ≥6 months to ≤65 year age group	23-Aug-2021 (Additional indication)
13.	M/s BharatBiotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India -500078.	Diphtheria, Tetanus, Pertussis (Whole Cell) and <i>Haemophilus influenzae</i> Type b Conjugate Vaccine (Adsorbed) IP.	For the primary immunization of infants aged 6 weeks and above as three dose schedule at 6, 10 & 14 weeks against disease like diphtheria, tetanus and whooping cough and those caused by <i>Haemophilus Influenzae</i> Type b.	MF/BIO/21/000107 dated 20-SEP-2021

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14.	M/s CENTRALRESEARCH INSTITUTE KASAULI DIST- SOLAN KASAULI India Pincode : 173204	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P.	For active immunization as booster dose at the age of 10 years and 16 years against tetanus and diphtheria	MF/BIO/21/000112 dated 08-Oct-2021
15.	M/s. Hetero Biopharma Limited H.No. 8-3-166/1 & 2, 105 To 108, 1st Floor, G Block, East Wing, Challa Estates, Erragadda, Hyderabad India Pincode : 500018	Gam-COVID-Vac combined vector vaccine (Component I & Component II) Sputnik V vaccine	For the prevention of the novel Coronavirus infection (COVID-19) in adults aged over 18, when given in two separate doses three weeks apart. Day 0: Component I (0.5 ml) & Day 21: Component II (0.5ml)	MF/BIO/21/000110 Dated 05-Oct-2021
16.	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram Gachibowli Post Rangareddi Hyderabad (India) - 500032	Tetanus Vaccine (Adsorbed) I.P.	For active immunization at more than equals to 6 weeks against Tetanus. Also For Prevention of tetanus in all age groups following injury or animal bite and to persons who are at increased risk of attaining injuries through their occupation or recreational activities.	MF/BIO/21/000117 dated 09-NOV-2021
17.	M/s Serum Institute of India Pvt., Ltd., S. No. 105-110, Manjari, Budruk, Pune, Maharashtra 412307	BCG for immunotherapy I.P., 40mg/ml	For treatment of flat Urothelial cell carcinoma in situ of urinary bladder and as adjunctive therapy following transurethral resection of primary or relapsing superficial non-invasive papillary tumors that are limited to the bladder mucosa (stage Ta or T1). Intravesical BCG Immunotherapy has been shown to reduce tumor recurrence and prevent progression.	MF/BIO/21/000128 dated 16.12.2021

Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

18.	M/s BharatBiotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India -500 078.	Whole Virion inactivated coronavirus vaccine	Additional indication of whole virion inactivated corona virus vaccine for use in age group of >12 to 18 years with the dose schedule of 0 and 28 days for restricted use in emergency situation.	24.12.2021
19.	M/s Serum Institute of India Pvt.Ltd. S.No. 105-110, Manjari BK, Tal –Haveli, Pune- 412307, Maharashtra (India)	SARS-CoV-2 rS Protein (COVID- 19) recombinant spike protein Nanoparticle Vaccine	For active immunization to prevent COVID-19 caused by SARS CoV-2 in individuals 18 years of age and older when administered in two dose schedule of day 0 & day 21.	MF/BIO/21/000138 Dated 28-Dec-2021
20.	M/s Serum Institute of India Pvt. Ltd. 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India)- 411028	SARS-CoV-2 rS Protein (COVID- 19) recombinant spike protein Nanoparticle Vaccine	For active immunization to prevent COVID-19 caused by SARS CoV-2 in individuals 18 years of age and older when administered in two dose schedule of day 0 & day 21.	MF/BIO/21/000137 Dated 28-Dec-2021
21.	M/s Biological E. Limited Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal- Malkajgiri District, Telangana INDIA 500078	SARS-CoV-2 (Covid-19) Vaccine containing Receptor Binding Domain of SARS-CoV-2	For active immunization against COVID-19 disease in adults aged 18 years and above when given in two doses at day 0 & day 28.	MF/BIO/21/000136 Dated 28-Dec-2021
22.	M/s Serum Institute of India Pvt. Ltd. 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India)- 411028	Influenza Vaccine (Human, Live Attenuated) I.P., Quadrivalent	For active Immunization against influenza disease caused by two influenza A subtype viruses and two influenza Type B viruses in the age group of 2 years and above.	MF/BIO/21/000139 Dated 30-Dec-2021

Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

Year 2020				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet Mandal, Medchal- Malkajgiri District,Telangana- 500078,India	Typhoid Vi Conjugate Vaccine,IP	For active immunization against infection caused by Salmonella typhi in infants, children, adolescents and adults aged ≥ 6 months to ≤ 45 years.	MF/BIO/20/000001 dated 28.01.2020
2	M/s Serum Institute of India Pvt., Ltd., S. No. 105-110, Manjari, Budruk, Pune, Maharashtra 412307,India	Bacillus Calmette-Guerin Vaccine I.P. (Freeze-Dried)	For prevention of tuberculosis. (Dose of 0.05 ml for children under one month of age and 0.1 ml for children over one month of age and adults)	MF/BIO/20/000037 Dated 29.04.2020
3	M/s. Cadila Pharmaceuticals Limited 1389-Trasad Road Dholka Ahmedabad - 382225 Gujarat (India)	Recombinant Rabies G Protein Vaccine	Active immunization against rabies for Post-exposure treatment (after exposure) in 18 to 65 years of age: Treatment after contact with animals which are rabid or suspected to be rabid, or after contact with an inoculated rabies carcass	MF/BIO/20/000040 dated 08.05.2020

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Details of Manufacturing Permissions of Human Vaccines

4	M/s Zydus Lifesciences Limited, plot survey no. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand, Ahmedabad-382213, Gujarat, India	Hepatitis B Vaccine (r-DNA) I.P.	For active immunization against Hepatitis B vaccine infection in adults up to 50 years of age.	MF/BIO/20/000052 dated 09.06.2020
5	M/s Zydus Lifesciences Limited, plot survey no. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand, Ahmedabad-382213, Gujarat, India	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (r-DNA) and Haemophilus Influenzae Type b Conjugate Vaccine (Adsorbed) I.P.	For active immunization of infants, at or above the age of 6 weeks against Diphtheria, Tetanus, Whooping cough, Hepatitis B and Haemophilus influenza type b infections for 3 dose regimen.	MF/BIO/20/000053 dated 19.06. 2020
6	M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road, Hadapsar Pune, Maharashtra, India.	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. (10- Valent)	For active immunization against invasive disease & pneumonia caused by <i>Streptococcus pneumonia</i> serotypes 1,5, 9V, 14, 19A, 19F, 23F, 7F, 6A & 6B in infants from 6 weeks of age group for 3 dose regimen (dosing schedule : 6, 10 & 14 weeks)	MF/BIO/20/000059 dated 14.07.2020

Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

Year 2019				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Venky Parenterals, Unit of Sriguru Capital Services Limited Advipolam Yanam Puducherry (India) - 533464	Tetanus Vaccine (Adsorbed), I.P.	For active immunization against all childrens from age of 6 weeks onwards and those who are exposed to occupational /risks such as road workers, Athletes, agricultural workers, industrial workers, defense personnel,homeguards and police personnel.	MF/BIO/19/000001 dated 28-Jan-2019
2	M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune Maharashtra (India)- 411028	Poliomyelitis Vaccine (Inactivated) I.P. (Manufactured using Poliomyelitis bulks imported from M/s Bilthoven Biologicals B.V. (BBIO), The Netherlands)	For active immunization of infants (as young as 6 weeks of age), children and adults for the prevention of poliomyelitis caused by poliovirus Types 1, 2, and 3.	MF/BIO/19/000002 dated 31-Jan-2019
3	M/s Bio Vaccines (India) Private Limited 46-A, Sector A Sanwer Road, Industrial Area, Madhya Pradesh 452015	Tetanus Vaccine (Adsorbed) I. P.	For active immunization against tetanus between 10 to 60 years age group.	MF/BIO/19/000015 dated 18.03.2019
4	M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune Maharashtra (India)- 411028	Rotavirus Vaccine(Live Attenuated, Oral) IP (Liquid)	For active immunization of healthy infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection when administered asa 3-dose series. The three dose regimen should be Completed by one year of age.	MF/BIO/19/000031 dated 10.06.2019

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Details of Manufacturing Permissions of Human Vaccines

5	M/s BCG Vaccine Laboratory, 110, 33 Feet Wide Road, Mount Road, Guindy, Chennai Guindy, Tamil Nadu (India) – 600 032	Bacillus Calmette-Guerin vaccine (Freeze Dried) IP	For immunization of infants from birth untill age of 1 year against childhood tuberculosis.	MF/BIO/19/000036 dated 26-Jul-2019
6	M/s Cadila Pharmaceuticals Limited, 1389-Trasad Road, Dholka (India) – 387 81, India	Mycobacterium w (Heat Killed)	Indicated as an adjuvant in sepsis (due to gram negative infections) treatment when given as 0.1ml for three consecutive days in age group of 18 to 65 years.	MF/BIO/19/000057 dated 28.11.2019

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Details of Manufacturing Permissions of Human Vaccines

Year 2018				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s BharatBiotech International Limited, Genome Valley, Shameerpet, Hyderabad-500078, A.P., India	Rotavirus Vaccine (Live Attenuated, Oral) I.P. [ROTVAC5D]	Active immunization of infants from the age of 6-8 weeks for preventions of gastroenteritis due to rotavirus infection.	MF/BIO/18/000022, dated: 31.08.2018
2	M/s. Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad Gujarat (India) – 382213	Measles and Rubella Vaccine (Live), I.P. (Freeze Dried)	For active immunization in children of 9 months of age and older against Measles and Rubella infections simultaneously	MF/BIO/18/000036 dated: 26.12.2018

Approval of New indications of Approved Vaccines

S. No.	Name of Firm	Name of Vaccine	Indication	Date of approval
1	M/s. Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad Gujarat (India) – 382213	Inactivated Influenza Vaccine (Split Virion) IP (Tetravalent) -	For active immunization of pediatrics & Children from 6 months to 17 years of age as an additional indication (a dose of 0.5 ml for 3 years to 17 years age group and a dose of 0.25ml for 6 months to 35 months age group) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses	10.12.2018 (BIO/MA/18/000030)

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Details of Manufacturing Permissions of Human Vaccines

Year 2017				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram Gachibowli Post Rangareddi Hyderabad (India) - 500032	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and <i>Haemophilus influenzae</i> Type b Conjugate Vaccine (Adsorbed)	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and <i>Haemophilus influenzae</i> Type b Conjugate Vaccine (Adsorbed) is indicated for the active immunization of infants, at or above the age of 6 weeks against Diphtheria, Tetanus, whooping cough, Hepatitis-B and <i>Haemophilus influenza</i> type b infections	MF-131/2017, dated: 09.06.2017
2	M/s Bio-MedGhaziabad (P) Ltd.,	Varicella Vaccine Freeze dried (Live) I.P.	Varicella Vaccine, Live, I.P. is indicated for active immunization against Varicella virus (Chicken Pox) for use in children of 1 to 12 years of age.	MF-183/2017, dated: 31.07.2017
3	M/s BiologicalTelangana E. Limited,	Measles and Rubella Vaccine (Live), I.P. (Attenuated, Freeze Dried)	For active immunization against Measles and Rubella in 9 to 12 months healthy infants at risk.	MF- 190/2017, dated: 16.08.2017
4	M/s. Zydus Lifesciences Limited, Ahmedabad Gujarat	Typhoid Vi Conjugate VaccineI.P.	For active immunization against <i>Salmonella typhi</i> infection in adults, children and infants.	MF-274/2017, Dated:15.12.2017

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Details of Manufacturing Permissions of Human Vaccines

Year-2016				
S. No.	Name of Firm	Name of Vaccine	Indication	PermissionDate No. &
1	M/s Serum Institute of India Pvt. Ltd., Pune	Rabies Vaccine Human I.P. (Freeze Dried)	Rabies Vaccine Human I.P. is indicated for the prevention of rabies in children and adults. It can be used before and after exposure, as a primary immunization or as a booster dose.	MF-77/2016, dated: 20.05.2016
2	M/s Panacea Biotec Ltd., New Delhi	Easy Four-TT (DTwP-Hib) Vaccine	For active immunization against Diphtheria, Tetanus, Pertussis (Whooping cough) and infection caused by Haemophilus Type-b.	MF-99/2016, dated: 13.06.2016
3	M/s. Zydus Lifesciences Limited, Ahmedabad, Gujarat	Measles, Rubella Mumps Vaccine (Live) I.P.(Freeze Dried	For prevention of Measles , Rubella & Mumps Virus Infection	MF-104/2016, Dated 30.06.2016
4	M/s. Zydus Lifesciences Limited, Ahmedabad, Gujarat	Tetanus Vaccine (Adsorbed)I.P.	For prevention of Clostridium Tetani.	MF-117/2016, Dated:13.07.2016
5	M/s. Zydus Lifesciences Limited, Ahmedabad, Gujarat	Measles Vaccine (Live) I.P.(Freeze Dried)	Measles vaccines (Live) I.P. (Freeze Dried) is immunization of all susceptible children against measles. It is recommended to be given to children at 9 months of age or, as	MF-123/2016, Dated :14.07.2016

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Details of Manufacturing Permissions of Human Vaccines

			soon as thereafter, to protect against measles in early life.	
6	M/s Bharat Biotech International Ltd., Hyderabad	Inactivated JE vaccine	For active immunization of disease caused by Japanese Encephalitis Virus (JEV)	MF-149/2016, dated: 29.08.2016
7	M/s. Zydus Lifesciences Ltd., Ahmedabad, Gujarat	Inactivated Influenza Vaccine (Split Virion) I. P. (Tetravalent)	The vaccine indicated in adults (≥18 years of age) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.	MF-176/2016, dated: 01.11.2016

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Details of Manufacturing Permissions of Human Vaccines

8	M/s Panacea Biotec Ltd., NewDelhi	DTwP-HepB-Hib-IPV Vaccine	For active immunization for prevention against Diphtheria, Tetanus, Pertussis (Whooping Cough), Hepatitis B infection, Infections caused by Haemophilus influenzae type b and poliomyelitis	MF-186/2016, dated:16.11.2016
9	M/s. Zydus Lifesciences Limited Ahmedabad Gujarat	Diphtheria, Tetanus, Pertussis(whole cell) Vaccine (Adsorbed) I.P.	For prevention of Clostridium tetani and Corynebacterium diphtheriae and Bordetella Pertussis	MF-192/2016, dated :28.11.2016
10	M/s. Zydus Lifesciences Limited Ahmedabad Gujarat	Inactivated Influenza Vaccine (Split Virion) I. P. (Trivalent)	The vaccine indicated in adults (≥18 years of age) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.	MF- 204/2016,dated: 07.12.2016
11	M/s Serum Institute of India Pvt. Ltd., Pune	Rotavirus Vaccine (Attenuated, Oral) I.P. (Freeze Dried)	It is indicated for active immunization of healthy infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection when administered as a 3 dose series.	MF- 222/2016,dated: 23.12.2016
12	M/s. Zydus Lifesciences Limited Ahmedabad Gujarat	Varicella Vaccine (Live) I.P. (Freeze Dried)	For active immunization for the prevention of varicella in age group between 1-12 years	MF-18/2017, dated: 18.01.2017

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Details of Manufacturing Permissions of Human Vaccines

Year-2015				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Cadila Pharmaceuticals, Survey No. 1389, Trasad Road, Dholka, Ahmedabad-387810	Monovalent H1N1- VLP 09 Vaccine	For active immunization for the prevention of disease caused by H1N1 2009 influenza virus in the age group of 18 years and above.	MF-70/2015, dated: 12.03.2015
2	M/s Sanofi Healthcare India Pvt Ltd Hyderabad	Inactivated Polio vaccine	For active immunization against Poliomyelitis caused by Poliovirus types 1, 2 and 3 in infants, children and adults both for primary immunization and for boosters.	MF-147/2015, dated:19.06.2015
3	M/s Bharat Biotech Limited., Hyderabad	Rabies Vaccine, Thiomersal Free	Active Immunizing Agent against Rabies caused by Rabies Virus Infection	MF-.200/2015, dated:11.09.2015
4	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram Gachibowli Post Rangareddi Hyderabad (India) - 500032	Rabies Vaccine, Human I.P. (1ml)	Pre-exposure & Post-exposure prophylaxis against Rabies Infection.	MF- 244/2015, dated:08.12.2015
5	M/s Human Biologicals Institute (A division of Indian	Rabies Vaccine, Human I.P. (0.5ml)	Pre-exposure & Post-exposure prophylaxis against Rabies Infection.	MF-245/2015, dated:08.12.2015

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Details of Manufacturing Permissions of Human Vaccines

	Immunologicals Limited),Rakshapuram Gachibowli Post Rangareddi Hyderabad (India) - 500032			
6	M/s Cadila Pharmaceuticals Ltd.	Trivalent Influenza Vaccine	Active immunization of adults, 18 years of age and above against disease caused by Influenza virus subtypes A& Types B contained in the vaccine.	MF-252/2015, dated:16.12.2015

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Details of Manufacturing Permissions of Human Vaccines

Year-2014				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s HLL Biotech Limited, Plot No. 1, S. P. Biotech Park, Phase-II, Kolthur Village, Shameerpet Mandal, R. R. District, Andhra Pradesh-500078.	Hepatitis B vaccine (r-DNA)	Indicated for the prevention of HepatitisB infection	MF-243/2014, dated:14.11.2014
2	M/s HLL Biotech Limited, Plot No. 1, S. P. Biotech Park, Phase-II, Kolthur Village, Shameerpet Mandal, R. R. District, Andhra Pradesh-500078.	DTP- Hib –Hep	Active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis –B and Haemophilus Type b infection	MF-245/2014, dated:17.11.2014
3	M/s Biomed Pvt Limited, C-96, Site – 1, Bulandshahr Road Industrial Area, Ghaziabad – 201 009 (U.P.) INDIA	Rabies vaccine human (cellculture IP)	Pre exposure immunization- The vaccine is recommended for the prevention of Rabies in subjects at a continuous risk of exposure.	MF253/2014 ,dated:20.11.2014
4	M/s Biomed Pvt Limited, C-96, Site–1, Bulandshahr Road Industrial Area, Ghaziabad – 201 009 (U.P.) INDIA	Oral Poliomyelitis vaccine, Live IP.	For active Immunization against Poliomyelitis virus.	MF-269/2014, dated:10.12.2014

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5	M/s Biomed Pvt Limited, C-96, Site – 1, Bulandshahr Road Industrial Area, Ghaziabad – 201 009(U.P.) INDIA	Typhoid Polysaccharide vaccine (IP)	For prevention of Typhoid fever	MF-123/2014, dated:02.06.2014
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Details of Manufacturing Permissions of Human Vaccines

Year-2013				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Bharat Immunologicals & Biologicals Corporation Limited, Village Chola, Bulandshahr-203203 (U.P.)	Bivalent Oral Polio Vaccine- Sabin strain (Type I and Type III) (Bulk source from M/s P.T. Bio Farma, Indonesia)	For the immunization of against Poliovirus type I and type III.	MF-78/2013, dated: 23.04.2013
2	M/s Bharat Immunologicals & Biologicals Corporation Limited, Village Chola, Bulandshahr-203203 (U.P.)	Trivalent Oral Polio Vaccine- Sabin (Type 1, Type 2 and Type 3) (Bulk source from M/s P.T. Bio Farma, Indonesia)	For the immunization of against Polio virus type I, type II and type III.	MF-79/2013, dated: 22.05.2013.
3	M/s Bharat Biotech Internal limited, Genome Valley, Shameerpet Mandal, Hyderabad, Andhra Pradesh India-500078	Poliomyelitis Vaccine, Live (Oral), I.P., Trivalent-Sabin (Type1, Type 2 and Type 3)	Active immunization against Poliomyelitis caused by type 1, type 2 and type 3 infection.	MF-154/2013, dated:24.07.2013.

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4	M/s Bio-Med (P) Ltd., C- 96, B.S. Road, Indl. Area, Ghaziabad-201009, U.P., India.	Poliomyelitis Vaccine, Live (Oral), I.P., Trivalent	Poliomyelitis vaccine, Live (Oral) I.P. (trivalent) is indicated for active immunization of Poliomyelitis virus. Infants should receive at least three doses of OPV at minimum interval of 4 weeks. WHO recommends the following schedule in endemic countries at birth, 6, 10, 14 weeks.	MF-188/2013, dated: 16.08. 2013.
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Details of Manufacturing Permissions of Human Vaccines

Year-2013				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
5	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411-028	Influenza Vaccine, Live attenuated (Human) Seasonal Trivalent freeze dried 2013 Southern Hemisphere influenza season	For active Immunization against influenza disease caused by influenza subtype A and type B viruses in the age group of 2 years and above	MF 193/2013, date: 03.09.2013
6	M/s Bharat Biotech Internal limited, Genome Valley, Shameerpet Mandal, Hyderabad, Andhra Pradesh India-500078	Oral Rotavirus Vaccine (ORV)116E	Active Immunization of infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection.	MF- 192/2013, dated 03.09.2013
7	M/s Biological E Ltd, Plot No. 1, SP Biotech Park, Phase II, Kolthur(V), Shameerpet (M), Ranga reddy (Dist.) Andhra Pradesh	Hepatitis B vaccine (rDNA) I.P.	Indicated for the prevention of HepatitisB infections	MF- 197/2013 dated 05.09. 2013
8	M/s GlaxoSmithKline Asia Pvt Ltd., A-10/1, M.I.D.C. Ambad-Pathardi Phara, Ambad, Nashik-422010	Hepatitis B vaccine (rDNA) IP(Engerix B)	Active immunization against HBV infection caused by all known subtypes in subjects of all ages considered at risk of exposure to HBV	MF-70/2013 dated: 09.09.2013

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Year-2013				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
9	M/s Dano Vaccines & Biologicals Private Ltd. 575, Sivareddyguda, Ghatkesar, R.R. Distt., Andhra Pradesh, 501301.	Tetanus Toxoid (Adsorbed) I.P	For active immunization against Tetanus.	MF-146/2013, dated:08.07.2013
10	M/s Biologicals E. Ltd.,18/1 & 3, Azamabad, Hyderabad-500 020 A. P.India.	Diphtheria and Tetanus Vaccine (Adsorbed) IP	Indication for prevention of Disease caused by Diphtheria and Tetanus in Adults and adolescents.	MF- 142/2013, dated:12.07.2013
11	M/s Biologicals E. Ltd., 18/1 & 3, Azamabad, Hyderabad-500 020 A. P. India.	Tetanus Vaccine (Adsorbed) IP	Indicated for prevention of Tetanus Infections.	MF- 196/2013, dated:04.09.2013
12	M/s Biologicals E. Ltd.,18/1 & 3, Azamabad, Hyderabad-500 020 A. P. India.	Diphtheria, Tetanus and whole cell Pertussis Vaccine (Adsorbed) IP	Indicated as Prophylaxis for Diphtheria,Tetanus and Pertussis	MF-201/2013, dated:13.09.2013

Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

Year-2012				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Bharat Biotech International limited, Genome Valley, Shameerpet Mandal, Hyderabad, Andhra Pradesh India- 500078	Inactivated Japanese Encephalitis Vaccine	For the Immunization of disease caused by Japanese Encephalitis virus (JEV). Dosage schedule Adult/Children (1 to 50 years)-Two doses of 0.5ml on day 0 and day 28±2.	MF- 181/2012, dated;07.06.2012
2	M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad-500078	Typhoid (Vi Capsular Polysaccharide) - Tetanus Toxoid Conjugate vaccine	For active immunization against Salmonella Typhi infection in ≥6 months to 45 year age group.	MF-244/2012 Dated: 20.12.2012

Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

Year-2011				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Panacea Biotec Ltd.,B-1 Extn. /A-27, McIE, Mathura Road, New Delhi-110 044, India.	Bivalent Oral Poliomyelitis Vaccine Type 1 and Type 3, Live (Oral) (bOPV) [Bulk Source: Sanofi Pasteur, France]	For Prophylactic for prevention caused by Type 1 and Type 3 strains of poliovirus	MF-195/11, dated: 29.04. 2011
2	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411 028, India.	Influenza Vaccine (Whole Virion, Inactivated) (Pandemic H1N1 Vaccine), (Embryonated hen eggs derived and inactivated by betapropiolactone	Inactivated H1N1 split virion vaccine is an inactivated influenza virus vaccine indicated for active immunization of children above 3 years of age and adults against influenza disease caused by Pandemic (H1N1) 2009 virus.	MF- 242/2011, dated: 02.06.2011
3	M/s. Zydus Lifesciences Limited, Sarkhej-Bavla, N.H. 8A, Moraiya, Tal. Sanand, Ahmedabad-380 015.	Rabies Vaccine, Human IP (Purified Chick embryo cell culture rabies vaccine) PCECVPM	For active Immunization against rabies;- For Intramuscular administration, use 1 full dose(1ml) for pre & Post exposure prophylaxis For Intradermal administration, use 0.1 ml per ID site for Post exposure prophylaxis	MF- 320/2011, dated:16.08.2011
4	M/s Biological E Ltd, Plot No. 1, SP Biotech Park, Phase II, Kolthur(V), Shameerpet(M), Ranga Reddy (Dist.) Andhra Pradesh	Japanese Encephalitis Inactivated Vaccine	For the immunization of disease caused by Japanese Encephalitis virus (JEV) for adult (18-49 years) and Children (1-3 years) Dosage Schedule: Adult-Single dose of 0.5 ml and Children –Two dose of 0.25 ml at 4 week apart.	MF- 456/2011, dated:29.09.2011

Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

5	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411 -028	Meningococcal A Conjugate vaccine, Lyophilized (Clear glass vial with white Aluminium flip-off seals)	For active immunization against invasive meningococcal disease caused by Meningococcus group A only, in the children of age 2 years, adolescent and adults up to 29 years of age.	MF 458/2011, dated:18.10.2011
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Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

Year-2010				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s. Bharat Biotech International Ltd., Genome Valley, Shameerpet (Mandal), Reddy (Dist), Hyderabad-500078 (AP)	Bivalent Polio Type 1 & Type 3 vaccine , Live Oral	For active Immunization against Type 1 & Type 3 Poliomyelitis infection in Children from 0 to 5 years of age.	MF-224/10, dated: 12.03.2010
2	M/s. Zydus Lifesciences Limited., Sarkhej-Bavla, N.H. No. 8A, Moraiya, Tal, Sanand, Dist. Ahmedabad– 382 210	Inactivated Influenza vaccine (Whole virion) IP Pandemic Influenza (H1N1) 2009, Monovalent vaccine).	For active immunization against influenza disease caused by pandemic (H1N1) 2009 virus in the age group of 18 years and above.	MF-466/10, dated:11.05.2010
3	M/s Serum Institute of India Ltd.,212/2, Hadapsar,Pune-411 028,	Influenza Vaccine (Live Attenuated freeze dried) for Intranasal.	For active immunization against influenza disease caused by pandemic (H1N1) 2009 virus in the age group of 03 years and above.	MF-558/10, dated: 18.06.2010
4	M/s Panacea Biotech Ltd., B-1 Ext/A-27, Mohan Co-op Indl. Estate , Mathura Road, New-Delhi- 110 044	DTwP-vaccine (adsorbed)	For the primary immunization of infants at or above the age of 6 weeks & of children through 6 years of age against Diphtheria, Tetanus & Whooping cough	MF 822/10, dated: 21.09.2010
5	M/s Biological E. Ltd., 18/1 and 3, Azamabad, Hyderabad-	Liquid pentavalent vaccine	Active immunization of Against Diphtheria, pertussis, tetanus, Hepatitis b, Hib type b infection	MF 843/10, dated: 29.09.2010

Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

	500 020			
6	M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad- 500 078 (A.P.)	Pandemic Influenza Vaccine A(H1N1) Virusvaccine(Inactivated)	For active immunization of persons of age 18 years to 65 years against influenza disease caused by pandemic influenza A (H1N1) 2009 virus	MF-847/10, dated: 30.09.2010
7	M/s Panacea Biotech Ltd., B-1 Extn. A-27, Mohan Co- op. indl. Estate, Mathura Road, new Delhi- 110 044.	Inactivated H1N1 split virion Influenza vaccine (adjuvanted)	For active immunization of children above 3 years of age and adults against disease caused by Pandemic (H1N1) 2009 virus.	MF-898/10, dated:08.11.2010

Annexure-I(b)
Details of Manufacturing Permissions of Human Vaccines

Year-2009				
S. No.	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s Biomed (P) Ltd., C-96, Site No1, Bulandsahar Road, Industrial Area, Ghaziabad ,U.P.	Meningococcal polysaccharide vaccine (Group A &C)	For active immunization against Neisseria meningitidis Group A &C	MF-7/09, dated:12.01. 2009
2	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411 028,India.	Diphtheria, Tetanus, Pertussis, Hepatitis-B and Haemophilus Influenzae Type b Conjugate Vaccine Adsorbed, liquid.	For active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis- B and Haemophilus Influenzae Type b in infants.	MF-167/09, dated: 12.02.2009
3	M/s Panacea Biotec Ltd.,B-1 Extn.A/27., MCIE, Mathura Road, New Delhi	Oral Poliomyletis Vaccine (Type 1, 2, &3)	Active Immunization against infection caused by type 1, 2 & 3 Polioviruses.	MF-175/09, dated: 24.02.2009
4	M/s Panacea Biotec Ltd., ,B-1 Extn.A- 27,MCIE,Mathura Road, New-Delhi -110 044	Diphtheria ,Tetanus and whole cell pertussis (DTwP) vaccine	For the primary immunization of Infants ,at or above the age of 6 weeks ,and of children through six years of age against Diphtheria ,Tetanus and whooping cough	MF-282/09, dated: 19.03.2009
5	M/s Human Biologicals Ltd., (A Division of Indian Immunological Ltd.), Rakhshapuram, Gachibowli, Hyderabad (AP)	Rabies Vaccine (Vero Cell cultured , Freeze Dried)	For active immunization against Rabies, both as prophylaxis and post bite cases.	MF-295/09, dated: 23.03.2009

Details of Human Vaccines approved by CDSCO (for manufacture)
(Year 1998 to 2008)

S. No	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1998				
1	M/s Bharat Biotech International 726, Road-3, Banjara Hills, Hyderabad-500034	Hepatitis B Vaccine (recombinant DNA)	For active immunization against infection caused by Hepatitis-B Viruses.	12-30/86-DC, Date:- 14-10-1998
2003				
1	M/s Aventis Pasteur India Pvt. Ltd. Chaitanya 1, Chaman Farm Village, Bundh Road, Chattarpur, New Delhi-30	Inactivated adsorbed Hepatitis A Vaccine 80 antigen unit	For prevention of Infection caused of Hep. A virus in children in the age group of 12 months – 15 years.	MF-675/2003, Dated: 07-06-2003
2	M/s Cadila Healthcare Ltd. , Zyklus Towers, Satellite cross Roads, Ahmedabad-15	Purified Vi-Capsular Polysaccharide typhoid vaccine	For active immunization against typhoid fever in adults and children over 2 years of age.	MF-821/2003, Date: 09-09-2003
3	M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad – 500078	Vi capsular Polysaccharide Typhoid Vaccine	For immunization against typhoid fever.	12-3/2002-DC, Date: 23-01-2003
2004				
1	M/s Bio-Med Pvt. Ltd., Bulandsahar Road Indi. Area, Ghaziabad-201001	Haemophilus Influenza type-b conjugated Vaccine.	For prevention of invasive disease caused by Haemophilus Influenza type-b in children.	MF-1350/2004, Date: 14-06-2004

2	M/s Bio-Med Pvt. Ltd., KB-27, Kavi Nagar, Ghaziabad-201002 (UP) India	Meningococcal Polysaccharide Vaccine (Group A, C, W135 & Y)	For prevention of cerebrospinal meningitis caused by Neisseria meningitides group A, C, Y, W135 & Y. Vaccination is recommended for travelers moving in the endemic regions.	MF-1752/2004, Date: 23-09-2004
2005				
1	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411028	Combined DP (Whole Cell) T + r-Hepatitis B Vaccine.	For active immunization against Diphtheria, Tetanus, Pertussis and Hepatitis B in infants and children.	MF-2090/2005, Date: 28-02-2005
2006				
S. No	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
1	M/s. Biological E. Ltd., 1811 & 3, Azamabad, Hyderabad-500020, A.P	Combined DTPw (whole cell) + r-Hepatitis-B Vaccine.	For active immunisation against Diphtheria, Tetanus, Pertussis & Hep.-B in children.	MF-6567/06, Date – 24-04-2006
2	M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad – 500078	Anti-Rabies Vaccine (Verocell)	For active immunization against Rabies	MF-7076/2006, Date: 14-12-2006
3	M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad – 500078	Diphtheria, Tetanus & Pertussis Vaccine (adsorbed)	For the active immunization against Diphtheria, Tetanus & Pertussis	MF-6857/2006, Date: 28-08-2006

2007				
1	M/s Panacea Biotech Ltd., B-1 Extn. / A-27 Mohan Co-operative Industrial Estate, Mathura Road New Delhi-110044	Diphtheria+Pertussis+Tetanus Vaccine with Hepatitis B and Haemophilus influenza type B Vaccine.	For active immunization against Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenza type B infection.	MF-7912/2007, Date: 12-09-2007
2	M/s Panacea Biotech Ltd., B-1 Extn. / A-27 Mohan Co-operative Industrial Estate, Mathura Road New Delhi-110044	Haemophilus type b (Hib) conjugate vaccine.	For active immunization against Haemophilus influenza type b infection in children of the age group of 6 weeks to 5 years.	MF-7517/2007, Date: 06-06-2007
3	M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad – 500078	Haemophilus Influenza type b (Hib) conjugate vaccine	For active immunization against Haemophilus influenza type b infection in children of the age group of 6 weeks to 5 years.	MF-7581/2007, Date; 03-07-2007
4	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411028	Diphtheria, Tetanus, Pertussis (Whole Cell) + Haemophilus Influenza-b vaccine.	For the active immunization of infants, at or above the age of 6 weeks against Diphtheria, Tetanus, Whooping cough and Haemophilus influenza type-b infections.	MF-7929/2007, Date: 04-10-2007
5	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411028	DTPw Hepatitis B + Hib Vaccine	For active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis B and Haemophilus influenza type b	MF-7390/2007, Date: 03-05-2007
6	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411028	Haemophilus Influenza type b (Hib) conjugate vaccine	For active immunization against Haemophilus influenza type b infection in children of the age group of 6 weeks to 5 years.	MF-7100/2007, Date: 12-01-2007

S. No	Name of Firm	Name of Vaccine	Indication	Permission No. & Date
7	M/s Biological E Ltd., 18/1 & 3, Azamabad, Hyderabad-500020	Haemophilus Influenza type b (Hib) conjugate vaccine (Lyophilised)	For active immunization against Haemophilus influenza type b infection in children of the age group of 6 weeks to 5 years.	MF-7496/2007, Date: 08-06-2007
8	M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad – 500078	Monovalent Poliomyelitis Vaccine Type 1 Live (Oral).	For active immunization against Polio in children.	MF-7633/2007, Date: 20-07-2007
2008				
1	M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad – 500078	Diphtheria, Tetanus, Pertussis (W), r-Hepatitis B & Haemophilus Influenza Type-B Vaccine	For active immunization against Diphtheria, Tetanus, Pertussis (W), r-Hepatitis B & Haemophilus Influenza Type-B infection	MF-227/2008, Date: 31-01-2008
2	M/s Aventis Pasteur India Pvt. Ltd. Chaitanya 1, Chaman Farm Village, Bundh Road, Chattarpur, New Delhi-30	Diphtheria, Tetanus, Acellular Pertussis and Inactivated Poliomyelitis (DtaCP-IPV) combined vaccine. (From M/s sanofi Pasteur,France)	For the immunization of Diphtheria, Tetanus, Pertussis and poliomyelitis in infants from 2 months of age.	MF-370/2008, Date: 31-03-2008
3	M/s Green Signal Bio Pharma Pvt. Ltd., Old No. 86, New No. 114, Dr. Radhakrishna Salai, Mylapore, Chennai, Tamilnadu- 600004, India	BCG Vaccine (Live, Freeze Dried, attenuated)	For active immunization against tuberculosis	MF-1395/2008, Date: 22-12-2008
4	M/s Bio-Med Pvt. Ltd., C-96 Site 1, B.S. Road, Industrial, Area,Ghaziabad-201009 (UP)	Typhoid Vaccine (Vi Polysaccharide Conjugate)	For active immunization against Typhoid	MF-528/2008, Date: 09-05-2008

5	M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad – 500078	Monovalent Oral Poliomyelitis Type-3 vaccine	For the active immunization against Poliomyelitis.	MF-262/2008, Date: 29-02-2008
6	M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad – 500078	Diphtheria+ Tetanus +Pertussis + Hepatitis B + Haemophilus influenza Type B-Vaccine	For active immunizations against diphtheria, Tetanus, Pertussis, Hepatitis B & Haemophilus influenza Type B	MF-515/2008, Date: 12-05-2008