

## Manufacturing Permission of Human Vaccines

<b>Year 2021</b>				
<b>S. No.</b>	<b>Name of Firm</b>	<b>Name of Molecule Approved</b>	<b>Indication</b>	<b>Date</b>
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 $\geq 18$ 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.	Permission No. MF/BIO/21/000001 dated 03.01.2021
2	M/s Bharat Biotech 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 $\geq 12$ years when administered in two doses interval of day 0 & day 28.	Permission No. MF/BIO/21/000002 dated 03.01.2021

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<b>Year 2020</b>				
<b>S. No.</b>	<b>Name of Firm</b>	<b>Name of Molecule Approved</b>	<b>Indication</b>	<b>Date</b>
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 $\geq 6$ months to $\leq 45$ years.	MF/BIO/20/000001 dated 28.01.2020
2	M/s Zuventus Healthcare Ltd., Office No. 5119, 5 <sup>th</sup> Floor, "D" Wing, Oberoi Garden states, Chandivili, Andheri (E), Mumbai-400072,India	Rabies Vaccine, Human, IP(Vero Cell), (Freeze Dried)	For Pre-exposure prophylaxis and post exposure prophylaxis of Rabies. As per following schedule Pre-exposure prophylaxis : Day 0, Day 7 & Day 28 Post exposure prophylaxis : Day 0, Day 3, Day 7, Day 14 & Day 28	IMP/BIO/20/000002 dated: 14.02.2020
3	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
4	M/s Cadila	Hepatitis B Vaccine (r-	For active immunization against	MF/BIO/20/000052 dated

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	Healthcare 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	DNA) I.P.	Hepatitis B vaccine infection in adults up to 50 years of age.	09.06.2020
5	M/s Cadila Healthcare 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 influenzae 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</i> <i>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

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<b>Year 2019</b>				
<b>S. No.</b>	<b>Name of Firm</b>	<b>Name of Molecule Approved</b>	<b>Indication</b>	<b>Date</b>
1	M/s Bio Vaccines (India) Private Limited 46-A, Sector A Sanwer Road, Industrial Area, Madhya Pradesh (India) – 452015	Tetanus Vaccine (Adsorbed) I. P.	For active immunization against tetanus between 10 to 60 years age group.	Permission No. MF/BIO/19/000015 dated 18.03.2019
2	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 as a 3-dose series. The three dose regimen should be Completed by one year of age.	Permission No. MF/BIO/19/000031 dated 10.06.2019
3	M/s Cadila	Mycobacterium w (Heat	Indicated as an adjuvant in sepsis	MF/BIO/19/000057 dated

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Pharmaceuticals Limited, 1389- Trasad Road, Dholka (India) – 387 81, India	Killed)	(due to gram negative infections) treatment when given as 0.1ml for three consecutive days in age group of 18 to 65 years.	28.11.2019
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### Year 2018

S. No.	Name of Firm	Name of Molecule Approved	Indication	Date
1	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet, Hyderabad-500078, A.P., India	Rotavirus Vaccine (Live Attenuated, Oral) I.P. [ROTVAC 5D]	Active immunization of infants from the age of 6-8 weeks for preventions of gastroenteritis due to rotavirus infection.	Permission No. MF/BIO/18/000022, dated: 31.08.2018
2	M/s. Cadila Healthcare 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	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.	Permission No. MF/BIO/18/000036 dated: 26.12.2018

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Gujarat (India) - 382213				
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<b>Year 2017</b>				
<b>S. No.</b>	<b>Name of Firm</b>	<b>Name of Formulation</b>	<b>Indication</b>	<b>Permission No.</b>
1	M/s Human Biologicals Institute, (A Division of Indian Immunologicals Limited)., Hyderabad	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 influenzae</i> type b infections	Permission No. MF-131/2017, dated: 09.06.2017
2	M/s Bio-Med (P) Ltd., Ghaziabad	Varicella Vaccine (Live) I.P. Freeze dried	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.	Permission No. MF-183/2017, dated: 31.07.2017
3	M/s Biological E. Limited, Telangana	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.	Permission No. MF-190/2017, dated: 16.08.2017
4	M/s Cadila Healthcare Limited, Ahmedabad	Typhoid Vi Conjugate Vaccine I.P.	For active immunization against <i>Salmonella typhi</i> infection in adults, children and infants.	Permission No. MF-274/2017, dated :15.12.2017
<b>Year-2016</b>				

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S. No.	Name of Firm	Name of Formulation	Indication	Permission 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.	Permission No. 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.	Permission No. MF-99/2016, dated: 13.06.2016
3	M/s Cadila Healthcare Ltd., Ahmedabad	Measles, Rubella Mumps Vaccine (Live) I.P.(Freeze Dried)	For prevention of Measles, Rubella & Mumps Virus Infection	Permission No. MF-104/2016, dated: 30.06.2016
4	M/s Cadila Healthcare Ltd., Ahmedabad	Tetanus Vaccine (Adsorbed) I.P.	For prevention of Clostridium Tetani.	Permission No. MF-117/2016, dated: 13.07.2016
5	M/s Cadila Healthcare Ltd., Ahmedabad	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 soon as thereafter, to protect against measles in early life.	Permission No. MF-123/2016, dated :14.07.2016
6	M/s Bharat Biotech International Ltd., Hyderabad	Inactivated JE vaccine	For active immunization of disease caused by Japanese Encephalitis Virus (JEV)	Permission No. MF-149/2016, dated: 29.08.2016

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7	M/s Cadila Healthcare Ltd., Ahmedabad	Inactivated Influenza Vaccine (Split Virion) I. P. (Tetravalent)	The vaccine indicated in adults ( $\geq 18$ 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.	Permission No. MF-176/2016, dated: 01.11.2016
8	M/s Panacea Biotec Ltd., New Delhi	Easy Six(DTwP-HepB-Hib-IPV) Vaccine	For active immunization for prevention against Diphtheria, Tetanus, Pertusis (Whooping Cough), Hepatitis B infection, Infections caused by Haemophilus influenzae type b and poliomyelitis	Permission No. MF-186/2016, dated:16.11.2016
9	M/s Cadila Healthcare Ltd., Ahmedabad	Diphtheria, Tetanus, Pertusis (whole cell)Vaccine (Adsorbed) I.P.	For prevention of Clostridium tetani and Corynebacterium diphtheriae and Bordetella Pertussis	Permission No. MF-192/2016, dated: 28.11.2016
10	M/s Cadila Healthcare Ltd., Ahmedabad	Inactivated Influenza Vaccine (Split Virion) I. P. (Trivalent)	The vaccine indicated in adults ( $\geq 18$ 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.	Permission No. 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.	Permission No. MF-222/2016, dated: 23.12.2016
12	M/s Cadila Healthcare Ltd., Ahmedabad	Varicella Vaccine (Live) I.P. (Freeze Dried)	For active immunization for the prevention of varicella in age group between 1-12 years	Permission No. MF-18/2017, dated: 18.01.2017



## Manufacturing Permission of Human Vaccines

<b>Year-2015</b>				
<b>S. No.</b>	<b>Name of Firm</b>	<b>Name of Formulation</b>	<b>Indication</b>	<b>Permission No.</b>
1	M/s Cadila Pharmaceuticals, Survey No. 1389, Trasad Road, Dholka, Ahmedabad-387810	Monovalent H1N1-09 VLP Vaccine	For active immunization for the prevention of disease caused by H1N1 2009 influenza virus in the age group of 18 years and above.	Permission No. MF-70/2015, dated: 12.03.2015
2	M/s Shantha Biotech 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.	Permission No. 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	Permission No. MF-200/2015, dated: 11.09.2015
4	M/s Human Biological Ltd.	Rabies Vaccine, Human I.P. (1ml)	Pre-exposure & Post-exposure prophylaxis against Rabies Infection.	Permission No. MF-244/2015, dated: 08.12.2015
5	M/s Human Biological Ltd., Hyderabad	Rabies Vaccine, Human I.P. (0.5ml)	Pre-exposure & Post-exposure prophylaxis against Rabies Infection.	Permission no. MF-245/2015, dated: 08.12.2015
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.	Permission No. MF-252/2015, dated: 16.12.2015

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<b>Year-2014</b>				
<b>S. No</b>	<b>Name of Firm</b>	<b>Name of Formulation</b>	<b>Indication</b>	<b>Permission No.</b>
1	M/s Shantha Biotechnics Ltd., Hyderabad, A.P.	Fully liquid Pentavalent vaccine (DTwP-HepB-Hib vaccine)	Active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis-B, and Haemophilus influenza type b infections in 6-8, 10-12 and 14-16 weeks of age	Permission no. MF/55/2014 dated: 07/03/2014
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.	Hepatitis B vaccine (r-DNA)	Indicated for the prevention of Hepatitis B infection	Permission no. MF - 243/2014, dated: 14.11.2014
3	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	Permission no. MF- 245/2014, dated: 17.11.2014

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4	M/s Biomed Pvt Limited, C-96, Site – 1, Bulandshahr Road Industrial Area, Ghaziabad – 201 009 (U.P.) INDIA	Rabies vaccine human (cell culture IP )	Pre exposure immunization- The vaccine is recommended for the prevention of Rabies in subjects at a continuous risk of exposure.	Permission no. MF/253/2014, dated:20.11.2014
5	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.	Permission no. MF- 269/2014, dated: 10.12.2014
6	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	Permission no. MF- 123/2014, dated:02.06.2014

### Year-2013

S. No	Name of Firm	Name of Formulation	Indication	Permission No.
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## Manufacturing Permission of Human Vaccines

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 Polio virus type I and type III.	Permission no. 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.	Permission no. 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.	Permission no. MF-154/2013, dated: 24 .07.2013.
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.	Permission no. MF-188/2013, dated: 16.08. 2013.

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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	Permission no. MF-193/2013, dated 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.	Permission no. 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 Hepatitis B infections	Permission no. 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	Permission no. MF-70/2013 dated: 09.09.2013

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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.	Permission no. 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.	Permission no. 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.	Permission no. 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	Permission no. MF-201/2013, dated: 13.09.2013

### Year-2012

S. No.	Name of Firm	Name of Molecule Approved	Indication	Date
1	M/s Ranbaxy Lab Ltd., Sy. No. 16, Ekarajapura, Siddlaghatta Road, Hoskote, Bangalore-562114	Haemophilus Influenzae Type b (Hib) conjugate lyophilized vaccine	For active immunization against Haemophilus Influenzae Type b infection in children of the age group of 6 weeks to 5 years.	Permission no. MF-72/2012, dated: 14.03.2012

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2	M/s Ranbaxy Lab Ltd., Sy. No. 16, Ekarajapura, Siddlaghatta Road, Hoskote, Bangalore-562114	Vi capsular polysaccharide Salmonella typhi (Typhoid) vaccine	For active immunization against Typhoid fever for adults and children older than two years of age.	Permission no. MF-73/2012, dated: 14.03.2012
3	M/s Bharat Biotech Internal 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.	Permission no. MF-181/2012, dated; 07.06.2012
4	M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad-500078 A.P.	Typhoid (Vi Capsular Polysaccharide) - Tetanus Toxoid Conjugate vaccine	Typhoid (Vi Capsular Polysaccharide) - Tetanus Toxoid Conjugate vaccine	Form 46 (122B) Permission issued on vide permission no MF-244/2012 Dated: 20.12.2012

### Year-2011

S. No.	Name of Firm	Name of Molecule Approved	Indication	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	Permission no. 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	Inactivated H1N1 split virion vaccine is an inactivated influenza virus vaccine indicated for active immunization of children above 3 years of age and adults	Permission no. MF-242/2011, dated: 02.06.2011

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		eggs derived and inactivated by betapropiolactone	against influenza disease caused by Pandemic (H1N1) 2009 virus.	
3	M/s Cadila Healthcare Ltd., 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;- ( 1) For Intramuscular administration, use 1 full dose(1ml) for pre & Post exposure prophylaxis (2) For Intradermal administration, use 0.1 ml per ID site for Post exposure prophylaxis	Permission no. 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.	Permission no. MF-456/2011, dated: 29.09.2011
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.	Permission no. MF-458/2011, dated:18.10.2011

### Year-2010

S. No.	Name of Firm	Name of Molecule Approved	Indication	Date
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1	M/s. Bharat Biotech International Ltd., Genome Valley, Shameerpet (Mandal), Reddy (Dist), hyderabad-500 078 (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.	Permission no. MF-224/10, dated: 12.03.2010
2	M/s Cadila Healthcare Ltd., Sarkhej-Bavla, N.H. No. 8A, Moraiya, Tal, Sanand, Dist. Ahmedabad – 382 210, india.	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.	Permission no. MF-466/10, dated:11.05.2010
3	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411 028, India.	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.	Permission no. MF-558/10, dated: 18.06.2010
4	M/s Panacea Biotech Ltd., B-1 Ext/A-27, Mohan Co-opertae 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	Permission no. MF 822/10, dated: 21.09.2010
5	M/s Biol.E.Ltd., 18/1 and 3, Azamabad, Hyderabad- 500 020	Liquid pentavalent vaccine	Active immunization of Against Diphtheria, pertussis, tetanus, Hepatitis b, Hib type b infection	Permission no. MF 843/10, dated: 29.09.2010
6	M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad- 500 078 (A.P.)	Pandemic Influenza Vaccine A( H1N1) Virus vaccine (Inactivated)	For active immunization of persons of age 18 years to 65 years against influenza disease caused by pandemic influenza A (H1N1) 2009 virus	Permission no. 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-	Inactivated H1N1 split virion Influenza vaccine (adjuvanted )	Inactivated H1N1 split virion vaccine is an inactivated influenza virus vaccine indicated for active immunization of children above 3	Permission no. MF-898/10, dated:08.11.2010

## Manufacturing Permission of Human Vaccines

	110 044.		years of age and adults against disease caused by Pandemic (H1N1) 2009 virus.
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### Year-2009

S. No.	Name of Firm	Name of Molecule Approved	Indication	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	Permission No.MF-7/09, dated: 12.01. 2009
2	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411 028, India.	Diphtheria, Tetanus, Pertusis, Hepatitis-B and Haemophilus Influenzae Type b Conjugate Vaccine Adsorbed, liquid.	For active immunization against Diphtheria, Tetanus, Pertusis, Hepatitis-B and Haemophilus Influenzae Type b in infants.	Permission no. MF-167/09, dated: 12.02.2009
3	M/s Panacea Biotec Ltd., B-1 Extn.A/27., MCIE, Mathura Road, New Delhi	Oral Poliomyelitis Vaccine (Type 1, 2, &3)	Active Immunization agent against infection caused by type 1, 2 & 3 Polioviruses.	Permission no. MF-175/09, dated: 24.02.2009
4	M/s Shantha Biotech,Survey No: 272,Athvelli Village, Medchal Mandal,Ranga Reddy District -501 401 ,Hyderabad (A.P)	Killed Bivalent (O1 &O139) oral cholera vaccine	For active immunization against Vibrio Cholera	Permission No. MF-176/09, dated: 24.02.2009
5	M/s Panacea Biotec Ltd., ,B-1 Extn.A-27,MCIE,MAthira 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	Permission No. MF-282/09, dated: 19.03.2009

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			whooping cough	
6	M/s Human Biologicals Ltd., (A Division of Indian Immunological Ltd.), Rkhshapuram, Gachibowli, Hyderabad (AP)	Rabies Vaccine (Vero Cell cultured , Freezed Dried)	For active immunization against Rabies, both as prophylaxis and post bite cases.	Permission no. MF-295/09, dated: 23.03.2009
7	M/s Biovel Life Science,Sy No 16,Ekarajapura ,Hasigala Post,8 <sup>th</sup> Km,Siddlagatta Road, Hosakote,Bangalore-562 114	Haemophilus Influenza type b (Hib) conjugate vaccine	For active immunization against Haemophilus Infuenzae Type b infection in children of the age group of 6 weeks to 5 years.	Permission No. MF-299/09, dated :24.03.2009
8	M/s Biovel Life Science (P) Ltd., Sy. NO 16, Ekarajapura,Hasigala Post, 8 <sup>th</sup> Km, Siddlagatta Road, Hosakote,Bangalore-562 114	Vi Capsular Polysaccharide Typhoid vaccine	For active immunization against typhoid fever for adults and children older than two years of age.	Permission No.MF-298/09, dated 24.05.2009
9	M/s Biol.E.Ltd.,18/1 and 83, Azamabad, Hyderabad-500 020	Reconstituted pentavalent vaccine(diphtheria, tetanus, Pertussis (whole cell),Hepatitis b (r DNA) and hib conjugate vaccine (adsorbed)	For active immunization against Diptheria, Pertussis ,Tetanus,Hepatitis B, Haemophilus Influenza type b infections	Permission No. MF-800, dated :23.09. 2009
10	M/s Panacea Biotec Ltd, B-1 Extn./A-27, Mohan Co-op. Indusrial estate,	Bivalent Poilo Ty 1& Type 3 vaccine , Live Oral	For active Immunization against Type 1 & Type 3 Poliomyelitis infection in Children from 0 to 5	Permission no. MF-951/09, dated: 19.11. 2009

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	Mathura Road New Delhi-110 044		years of age.	
11	M/s Hafkine Bio-Pharma Co. Ltd., Acharya Donde Marg, Parel, Mumbai-400 012, India.	Bivalent Polio Ty 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.	Permission no. MF-1072/09, dated:01.01.2010