As on 15.03.20	23

				STATUS OF APPLICATIONS FOR RET	AIL PRICI	Ε		As on 15.03.2023
Sl. No.	Acknowledgement Number	IPDMS Reference Number	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Date of receipt of application	STATUS
1	RPON2022030077		Enoxaparin Sodium Injection IP 3ml Multidose Vial 300mg/3ml	Each ml contains: Enoxaparin Sodium IP 100mg (10,000 anti-Xa IU) Benzyl Alcohol IP 15mg (As preservativ)	Injection	M/s Virchow Biotech Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	03.03.2022	Clarification sought from SNCM
2	RPON2022060299		Methylprednisolone Sodium Succinate for injection USP 125mg	Each Vial contains: Methylprednisolone Sodium Succinate eq. to Methylprednisolone USP 125mg	Injection	M/s Sri Ram Healthcare Pvt. Ltd. / M/s Eris Lifesciences Limited	06-06-2022	Clarification sought from Company
3	RPON2022060305		Enoxaparin Sodium Injection IP 10mg/0.1ml	Each 0.1ml pre-filled syringe contains: Enoxaparin Sodium IP 10mg	Injection	M/s Themis Medicare Limited	13-06-2022	Clarification sought from SNCM
4	RPON2022090451		Adsorbed Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and Haemophilus influenzae Type b Conjugate Vaccine IP	Each dose of 0.5ml contains: Diphtheria Toxoid \geq 301U Tetanus Toxoid \geq 601U Inactiveated w-B.pertussis \geq 4 IU Purified capsular polysaccharide of Haemophilus influenzae type b conjugated to 18-33 μg of Tetanus Toxoid (carrier protein) 10 μg Inactivated Salk Poliovirus Type 1* 40DU** Inactivated Salk Poliovirus Type 2* 8 DU** Inactivated Salk Poliovirus Type 3* 32 DU** Aluminium content (Al+++) (As Aluminium Phosphate gel NMT 1.25mg 2-phenoxyethanol 3.3mg Physiological saline q.s.	Vaccine	M/s Panacea Biotec Limited	23-09-2022	To be placed before Expert Committee
5	RPON2022110522		Ibuprofen Injection	Each ml contains: Ibuprofen IP 100mg	Injection	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	03-11-2022	To be placed before Expert Committee
6	RPON2022120587	122120002	L-Carnitine, Methylcobalamin & Folic Acid Tablets	Each film coated tablet contains: L-Carnitine L-Tartate eq. to L-Carnitine 500mg Methylcobalamin IP 1500mcg Folic Acid IP 1.5mg	Tablet	M/s Win-Medicare Pvt. Ltd.	02-12-2022	Under Examination
7	RPON2022120607		IP, Esomeprazole	Each Strip contains: A. Clarithromycin Tablets IP 2 Tablets Each film coated tablet contains: Clarithromycin IP 500mg B. Esomeprazole Tablets IP 2 Tablets Each Enteric coated tablet contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg C. Amoxicillin Tablets USP 2 Tablets Each Film coated tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 750mg	Tablets	M/s Malik Lifesciences Pvt. Ltd. / M/ Zuventus Healthcare Limited	13-12-2022	Placed before 110th Authority Meeting
8	RPON2022120608	122120009	Rosuvastatin & Clopidogrel Capsules	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (as granules) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	Capsule	M/s USV Ltd.	13-12-2022	Under Examination

			Rosuvastatin & Clopidogrel Capsules	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (as		M/s USV Ltd.		Under Examination
9	RPON2022120609	122120010	olopidogi el capsules	granules) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	Capsule		13-12-2022	
10	RPON2022120625		Citrate, Potassium	Each sachet of 4.38g contains: Zinc Sulfate Monohydrate IP 0.011g Sodium Citrate IP 0.58g Potassium Chloride IP 0.30g Sodium Chloride IP 0.52g Dextrose Anhydrous IP 2.70g	Sachet	M/s FDC Limited	17-12-2022	Placed before 110th Authority Meeting
11	RPON2022120637		Dapagliflozin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (as Extended Release)	Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Prime Labs Pvt. Ltd.Ltd.	23-12-2022	Placed before 110th Authority Meeting
12	RPON2022120638		Dapagliflozin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (as Extended Release)	Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Prime Labs Pvt. Ltd.Ltd.	23-12-2022	Placed before 110th Authority Meeting
13	RPON2023010006		Itraconazole Capsules 130mg (Supra- Bioavailable Formulation)	Each Hard Gelatin Capsule contains: Itraconazole BP 130mg	Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	11-01-2023	Placed before 110th Authority Meeting
14	RPON2023010011		Telmisartan & Chlorthalidone Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Chlorthalidone IP 6.25mg	Tablet	M/s Innova Captab Limied / M/s Indoco Remedies Limited	16-01-2023	Placed before 110th Authority Meeting
15	RPON2023010013		Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 500mg	Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	16-01-2023	Placed before 110th Authority Meeting
16	RPON2023010014		Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 1000mg	Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	16-01-2023	Placed before 110th Authority Meeting
17	RPON2023010015		Dapagliflozin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Metformin Hydrochloride IP (Extended Release) 500mg	Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Ltd.	17-01-2023	Placed before 110th Authority Meeting
18	RPON2023010016		Dapagliflozin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP (Extended Release) 1000mg	Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Ltd.	17-01-2023	Placed before 110th Authority Meeting
19	RPON2023010017		Dapagliflozin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP (Extended Release) 500mg	Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Ltd.	17-01-2023	Placed before 110th Authority Meeting
20	RPON2023010018		Camylofin Dihydrochloride and Paracetamol Tablets	Each film coated tablet contains: Camylofin Dihydrochloride 50mg Paracetamol IP 325mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	18-01-2023	Placed before 110th Authority Meeting

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21	RPON2023010019		Bisoprolol Fumarate & Amlodipine Besylate tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	Tablet	M/s Tha Madras Pharmaceuticals / M/s Cipla Ltd.	20-01-2023	Placed before 110th Authority Meeting
22	RPON2023010020		Amlodipine Besylate tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	Tablet	M/s Tha Madras Pharmaceuticals / M/s Cipla Ltd.	20-01-2023	Placed before 110th Authority Meeting
23	RPON2023010022	123010006	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 500mg	Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	23-01-2023	Placed before 110th Authority Meeting
24	RPON2023010023	123010007	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 1000mg	Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	23-01-2023	Placed before 110th Authority Meeting
25	RPON2023010024		Bilastine and Montelukast Ondispersible Tablets	Each uncoated Orodispersible tablet contains: Montelukast Sodium IP Eq. to Montelukast 10mg Bilastine 20mg	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Sun Pharmaceuticals Industries Limited	23-01-2023	Placed before 110th Authority Meeting
26	RPON2023010025	122120021	Omeprazole & Domperidone Capsules IP	Each hard gelatin capsule contains: Omeprazole IP 20mg (as gastro-resistant pallets) Domperidone IP 10mg (as pallets)	Capsule	M/s Torrent Pharmaceuticals Limited	24-01-2023	Placed before 110th Authority Meeting
27	RPON2023010027		Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Alkem Laboratories Ltd.	27-01-2023	Placed before 110th Authority Meeting
28	RPON2023010028		Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Alkem Laboratories Ltd.	27-01-2023	Placed before 110th Authority Meeting
29	RPON2023010029		Levocetirizine, Montelukast & (SR) Ambroxol Hydrochloride Tablets	Each uncoated bilayered tablet contains: Levocetirizine Dihydrochloride IP 5mg Montelukast Sodium IP eq. to Anhydrous Montelikast 10mg Ambroxol Hydrochloride IP 75mg (As Sustained Release)	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	30-01-2023	Placed before 110th Authority Meeting
30	RPON2023010030		Glimepiride tablets IP	Each uncoated tablet contains: Glimepiride IP 4mg	Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	30-01-2023	Placed before 110th Authority Meeting
31	RPON2023010033		Glimepiride tablets IP	Each uncoated tablet contains: Glimepiride IP 3mg	Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	30-01-2023	Placed before 110th Authority Meeting
32	RPON2023010035		Chlorpheniramine Maleate and Phenylephrine Hydrochloride Syrup	Each 5ml contains: Chlorpheniramine Maleate IP 2mg Phenylephrine Hydrochloride IP 5mg	Syrup	M/s Stedman Pharmaceuticals Pct. Ltd.	30-01-2023	Placed before 110th Authority Meeting

33	RPON2023010038		Erythropoietin Injection BP 600 IU/ml	Each pre-filled Syringe contains: Erythropoietin Concentrtaed Solution Ph. Eur. 6000IU Albumin Human USP 2.5mg Sodium Chloride BP/Ph Eur 5.8mg Sodium Citrate BP/Ph. Eur 5.8mg Citric Acid monohydrate IP 5.8mg Water for Injections BP/Ph Eur q.s. to 1ml	Injection	M/s Gennova Blopharmaceuticals Ltd. / M/s Wockhardt Limited	31-01-2023	Placed before 110th Authority Meeting
34	RPON2023010039		Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	31-01-2023	Placed before 110th Authority Meeting
35	RPON2023010040		Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	31-01-2023	Placed before 110th Authority Meeting
36	RPON2023010044		Gliclazide (MR) and Metformin Hydrochloride (ER) Tablets	Each uncoated bilayered tablet contains: Gliclazide IP 30mg (in MR form) Metformin Hydrochloride IP 500mg (as Extended Release)	Tablet	M/s Swiss Garniers Genexiaa Sciences Pvt. Ltd. / M/s Servier India Pvt. Ltd.	24-01-2023	Placed before 110th Authority Meeting
37	RPON2023010026		Aspirin & Clopidogrel Capsule	Each hard gelatin capsule contains: Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two, light brown coloured film coated tablets, each containing clopidogrel 37.5mg) Titamium Dioxide IP Aspirin IP 75mg (as enteric coated pellets)	Capsule	M/s Windlas Biotech Limted / M/s Modi- Mundipharma Pvt. Ltd.	01-02-2023	Under Examination
38	RPON2023010041		Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Lupin Limited	01-02-2023	Placed before 110th Authority Meeting
39	RPON2023010042		Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Lupin Limited	01-02-2023	Placed before 110th Authority Meeting
40	RPON2023010043		Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Zydus Healthcare Limited	01-02-2023	Placed before 110th Authority Meeting
41	RPON2023020045	123010004	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	Tablet	M/s Sanofi India Limited	01-02-2023	To be placed before Expert Committee
42	RPON2023020046		Bisoprolol Fumarate & Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	Tablet	M/s J. K. Printpack /M/s Zydus Healthcare Limited	02-02-2023	Placed before 110th Authority Meeting
43	RPON2023020047	123010005	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	Tablet	M/s Sanofi India Limited	01-02-2023	To be placed before Expert Committee

44	RPON2023020048		Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Zydus Healthcare Limited	06-02-2023	Placed before 110th Authority Meeting
45	RPON2023020049		Glycopyrronium Ph. Eur, Formoterol Fumarate IP and Budesonide Inhalation powder	Each Cpasule contains: Glycopyrronium Bromide Ph. Eur eq. to Glycopyrronium 25mcg, Formoterol Fumarate (As Formoterol Fumarate Dihydrate IP) 12mcg Budesonide IP 400mg	Tablet	M/s Lupin Limited	06-02-2023	Placed before 110th Authority Meeting
46	RPON2023020052	122120017	Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	Tablet	M/s Torrent Pharmaceuticals Limited	07-02-2023	To be placed before Expert Committee
47	RPON2023020053	122120018	Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	Tablet	M/s Torrent Pharmaceuticals Limited	07-02-2023	To be placed before Expert Committee
48	RPON2023020054		Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Eris Lifesciences Limited	09-02-2023	Placed before 110th Authority Meeting
49	RPON2023020055		Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Eris Lifesciences Limited	09-02-2023	Placed before 110th Authority Meeting
50	RPON2023020056		Cilnidipine & Telmisartan Tablets	Each film coated tablet contains: Cilnidipine IP 20mg Telmisartan IP 40mg	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	10-02-2023	Placed before 110th Authority Meeting
51	RPON2023020057		Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Cipla Limited	10-02-2023	Placed before 110th Authority Meeting
52	RPON2023020058		Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Cipla Limited	10-02-2023	Placed before 110th Authority Meeting
53	RPON2023020060		Paracetamol, Phenylephrine Hydrochloride, Caffeine & Diphenhydramine Hydrochloride Tablets	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5mg Diphenhydramine Hydrochloride IP 25mg Caffeine (Anhydrous) IP 30mg	Tablet	M/s Bioconic Remedies / M/s Dales Laboratories Pvt. Ltd.	13-02-2023	Under Examination
54	RPON2023020061		Ceftazidime and Avibactam powder for concentrate for solution for infusion	Each vial contains: Ceftazidime (as ceftazidime Pentahydrate) IP 2gram Avibactam Sodium eq. to Avibactam 0.5gm	Injection	M/s BDR Pharmaceuticals Internation Pvt. Ltd. / M/s Wockhardt Limited	13-02-2023	Placed before 110th Authority Meeting
55	RPON2023020062		Cilnidipine, Telmisartan & Chlorthalidone Tablets	Each film coated tablet contains: Cilnidipine IP 10mg Telmisartan IP 40mg Chlorthalidone IP 6.25mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	15-02-2023	Placed before 110th Authority Meeting

56	RPON2023020063	Amoxycillin and Potassium Clavulanate Oral Suspension (Combipack with Steril Water for Reconstitution of Dry Syrup)	Each combipack contains: A. Amoxycillin and Potassium Clavulanate Oral suspenssion IP Composition: Each 5ml of reconstituted suspension contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg B. 2 Ampoules of sterile water for reconstitution of dry syrup each ampoule contains: sterile water for injection IP 25ml	Oral Suspension	M/s Malik Lifesciences Pvt. Ltd. / M/s Dr. Reddy's Laboratories Limited	15-02-2023	Under Examination
57	RPON2023020064	Ofloxacin and Metronidazole suspension	Each 5ml contains: Ofloxacin IP 50mg Metronidazole Benzoate IP eq. to Metronidazole 100mg	Suspension	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	16-02-2023	Clarification sought from Company
58	RPON2023020065	Ofloxacin and Betamethasone Sodium Phosphat Eye / Ear Drops	Each 5ml contains: Ofloxacin IP 0.3% w/v Betamethasone Sodium Phosphate IP 0.1% w/v Benzalkonium Chloride Solution IP 0.02% v/v (As preservative)	Drops	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	16-02-2023	Clarification sought from Company
59	RPON2023020066	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	Each uncoated Bilayered Tablet Contain: Sitagliptin Phosphate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500mg (Sustained Release Form)	Tablet	M/s Alkem Healthcare (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd	17-02-2023	To be placed before Expert Committee
60	RPON2023020067	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	Each uncoated Bilayered Tablet Contain: Sitagliptin Phosphate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	Tablet	M/s Alkem Healthcare (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd	17-02-2023	To be placed before Expert Committee
61	RPON2023020068	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine maleate Tablets	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 10mg Chlorpheniramine maleate IP 2mg	Tablet	M/s East African (India) Overseas / M/s Alkem Laboratories Ltd.	17-02-2023	Under Examination
62	RPON2023020069	Zinc Sulfate Monohydrate ,Sodium Citrate, Potassium Chloride, Sodium Chloride, Dextrose Anhydrous Sachet	Each sachet contains: Zinc Sulfate Monohydrate IP 0.011g Sodium Citrate IP 0.58g Potassium Chloride IP 0.30g Sodium Chloride IP 0.52g Dextrose Anhydrous IP 2.70g	Sachet	M/s Acme Diet Care Pvt. Ltd.	17-02-2023	To be placed before Expert Committee
63	RPON2023020070	Azelnidipine and Temisartan Tablet	Each uncoated bilayered tablet contains: Azelnidipine IP 16mg Temisartan IP 40mg.	Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Glenmark Pharmaceuticals Limited	17-02-2023	Under Examination
64	RPON2023020071	Tranexamic Acid and Etamsylate Tablets	Each film coated tablet contains: Etamsylate BP 250mg Tranexamic Acid IP 500mg.	Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	17-02-2023	Clarification sought from Company

65	RPON2023020072	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Extended Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin IP (As Sustained release) 100mg Metformin Hydrochloride IP 500mg (as Sustained Release)	Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	20-02-2023	To be placed before Expert Committee
66	RPON2023020073	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Extended Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin IP (As Sustained release) 100mg Metformin Hydrochloride IP 1000mg (as Sustained Release)	Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	20-02-2023	To be placed before Expert Committee
67	RPON2023020074	Paroxetine (CR) and Clonazepam Capsule	Each hard Gelatin capsule contains: Paroxetine Hydrochloride Hemihydrate IP eq. to Paroxetine 12.5mg (As enteric coated controlled release tablet) Clonazepam IP 0.5mg (as uncoated clonazepam Tablets IP)	Tablet	M/s Windlas Biotech Limited / M/s Eris Lifesciences Limited	20-02-2023	Under Examination
68	RPON2023020075	Paroxetine (CR) and Clonazepam Capsule	Each hard Gelatin capsule contains: Paroxetine Hydrochloride Hemihydrate IP eq. to Paroxetine 25mg (As enteric coated controlled release tablet) Clonazepam IP 0.5mg (as uncoated clonazepam Tablets IP)	Tablet	M/s Windlas Biotech Limited / M/s Eris Lifesciences Limited	20-02-2023	Under Examination
69	RPON2023020076	Diclofenac Diethylamir Methyl Salicylate, Menthol & Virgin Linseed spray	t, Virgin Linseed Oil BP 3% w/w Diclofenac Diethylamine IP 1.16% w/w eq. to Diclofenac Sodium IP 1% w/w Methyl Salicylate IP 10%w/w Menthol IP 5%w/w	Spray	M/s Pontika Aerotech Limited / M/s Abbott Healthcare Pvt. Ltd.	20-02-2023	Under Examination
70	RPON2023020077	Itraconazole Capsules 65mg (Supra- Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole BP 65mg	Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	21-02-2023	Under Examination
71	RPON2023020078	Amoxycillin & Potassium Clavulanate Tablets IP	Each film coated tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 875mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	Tablet	M/s Theon Pharmaceuticals Limited / M/s FDC Limited	23-02-2023	Under Examination
72	RPON2023020079	Phenylephrine Hydrochloride and Chlorpheniramine Maleate Drops IP	Each ml contains: Phenylephrine Hydrochloride IP 5mg Chlorpheniramine Maleate IP 2mg	Oral Drop	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Apex Laboratories Pvt. Ltd.	23-02-2023	Under Examination
73	RPON2023020080	Chlorhexidine gluconate, Metronidazole and Lignocaine Hydrochloride Gel	Composition: Chlorhexidine gluconate solution IP eq. to Chlorhexadine 1 % w/w, Metronidazole Bezoate IP eq. to Metronidazole 1% w/w Lignocaine Hydrochloride IP 2% w/w	Gel	M/s Alaina Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	27-02-2023	Under Examination
74	RPON2023020081	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Extended Release) Tablets	Each uncoated bilayer tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	27-02-2023	To be placed before Expert Committee

75	RPON2023020082	Vildagliptin (As	Each uncoated bilayer tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	27-02-2023	To be placed before Expert Committee
76	RPON2023020083	Itraconazole Capsules 65mg (Supra- Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole BP 65mg	Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	27-02-2023	Under Examination
77	RPON2023020084	Itraconazole Capsules 130mg (Supra- Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole BP 130mg	Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	27-02-2023	Under Examination
78	RPON2023020085	Magnesium and Domperidone	Each hard gelatin capsule contains: Esomeprazole Magnesium IP eq. to Esomeprazole 40mg (as enterics coated pellets) Domperidone IP 30mg (as sustained release pellets)	Capsule	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	27-02-2023	Under Examination
79	RPON2023020086		Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	27-02-2023	To be placed before Expert Committee
80	RPON2023020087		Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	27-02-2023	To be placed before Expert Committee
81	RPON2023020088	Inositol + Folic Acid + Pyridoxine Hydrochloride + Chromium Picolinate and	Each film coated table contains: Alpha Lipoic Acid IP 200mg Mecobalamin IP 1500mcg Myo-Inositol IP 100mg Folic Acid IP 1.5mg Pyridoxine Hydrochloride IP 3mg Chromium Picolinate IP eq. to Elemental chromium 200mcg Benfortiamine 200mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Zydus Healthcare Limited	27-02-2023	Under Examination
82	RPON2023020089	Pantoprazole (EC) and Levosulpiride (SR) Capsules	Each hard gelatin capsule contains: Pantoprazole Sodium eq. to Pantoprazole IP 40mg (as enteric coated pellets) Levosulpiride 75mg (As sustained release pellets)	Capsule	M/s Theon Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	27-02-2023	Under Examination
83	RPON2023020090	Aceclofenac and Paracetamol Tablets	Each film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg	Tablet	M/s Aagya Biotech Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	27-02-2023	Under Examination
84	RPON2023020091	Mecobalamin, L- Methylfolate Calcium & Pyridoxal-5-Phosphate Tablets		Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	28-02-2023	Under Examination
85	RPON2023030092	Linezolid Infusion	Each 100ml contains: Linezolid IP 200mg Dextrose Anhydrous IP 5mg water for Injection	Injection	M/s AXA Parenterals Ltd. / M/s Themis Medicare Limited	01-03-2023	Under Examination

86	RPON2023030093		Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	Tablet	M/s Exemed Pharmaceuticals / M/s Mankind Pharma Ltd.	02-03-2023	To be placed before Expert Committee
87	RPON2023030094		Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	Tablet	M/s Exemed Pharmaceuticals / M/s Mankind Pharma Ltd.	03-03-2023	To be placed before Expert Committee
88	RPON2023030095		Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	03-03-2023	To be placed before Expert Committee
89	RPON2023030096		Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	03-03-2023	To be placed before Expert Committee
90	RPON2023030097		Paraccetamol and Caffeine Tablets IP	Each uncoated tablet contains: Paracetamol IP 500mg Caffeine IP 50mg	Tablet	M/s Troikaa Pharmaceuticals Limited	04-03-2023	Under Examination
91	RPON2023030098	123030003	Azelnidipine and Temisartan Tablet	Each uncoated bilayered tablet contains: Azelnidipine IP 16mg Temisartan IP 40mg.	Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	04-03-2023	Under Examination
92	RPON2023030099	123030001	Vitamin D3 Oral Solution	Each 5ml contains: Cholecalciferol IP (In nano Droplet form) 60000IU	Oral Solution	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	04-03-2023	Under Examination
93	RPON2023030100	123030002	Tacrolimus Capsule	Each hard gelatin capsule contains: Tacrolimus IP eq. to Anhydrous Tacrolimus 0.25mg	Capsule	M/s Rivpra Formulation s Pvt. Ltd. / M/s RPG Life Sciences Ltd.	04-03-2023	Under Examination
94	RPON2023030101		Ambroxol Hydrochloride, Salbutamol Sulphate, Guaiphenesin & Methol Liquid	Each 5ml contains: Ambroxol Hydrochloride IP 15mg Salbutamol Sulphate IP eq. to Salbutamol 1mg Guaiphenesin IP 50mg Methol IP 1mg	Syrup	M/s Naxpar Pharma Pvt. Ltd. / M/s Geno Pharmaceuticals Pvt. Ltd.	07-03-2023	Under Examination
95	RPON2023030102		Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	07-03-2023	To be placed before Expert Committee

96	RPON2023030103	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	07-03-2023	To be placed before Expert Committee
97	RPON2023030104	Enteric coated Esomeprazole and Domperidone SR Capsule	Each hard gelatin capsule contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg Domperidone IP (as Sustained release pellets) 30mg	M/s Inventia Healthcare Limited / M/s Dr. Reddy's Laboratories	15-03-2023	Under Examination