

FIXED DOSE COMBINATIONS APPROVED BY DCG (I) From January 2023 to December 2023			
S. No	FDC	Indication	Approval Date
1	Vildagliptin (as Sustained Release) + Metformin Hydrochloride IP (as Sustained Release) (100mg + 500mg & 100mg + 1000mg) film coated bilayered tablets	For the treatment of Type II diabetes mellitus inadequately controlled on Metformin monotherapy	06.01.2023
2	Cilnidipine IP 20mg + Telmisartan IP 40mg film coated tablets (In additional Strength)	It is indicated for the treatment of essential hypertension	06.01.2023
3	Combipack of 26 hormone-containing film coated tablets in the following: (i) 2 dark yellow each containing 3mg Estradiol Valerate EP (ii) 5 Medium red tablets each containing 2mg Estradiol Velerate EP and 2mg Dienogest IP (iii) 17 light yellow tablets each containing 2mg Estradiol Velerate EP and 3mg Dienogest IP (iv) 2 dark red tablets each containing 1mg Estradiol Valerate EP 2 hormone-free white film coated tablets-regarding.	For the treatment of heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception.	06.01.2023
4	Trifluridine IP + Tipiracil Hydrochloride (20mg + 8.190mg & 15mg + 6.140mg) film coated tablets	Indicated for the treatment of: 1. Adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy 2. Adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/ neu-targeted therapy.	30.01.2023
5	Dapagliflozin Propanedilol Monohydrate eq. to Dapagliflozin + Vildagliptin IP (as sustained release) + Metformin Hydrchloride IP (as sustained release) uncoated bilayered tablets (5mg + 100mg + 500mg & 5mg + 100mg + 1000mg)	For the treatment of patients with type 2 Diabetes mellitus	06.02.2023
6	Ezetimibe IP 10mg + Rosuvastatin Calcium IP eq. to Rosuvastatin 40mg film coated tablets (In additional Strength)	For the treatment of patients with primary hypercholesterolemia	06.02.2023
7	Vildagliptin 50mg + Dapagliflozin 5mg film coated tablets (In additional Strength)	Management of Type II diabetes mellitus (T2DM)	08.02.2023

8	Sitagliptin Phosphate IP eq. to Sitagliptin + Pioglitazone Hydrochloride IP eq. to Pioglitazone IP + Metformin Hydrochloride IP (as sustained release form) IP (100mg + 15mg + 500mg & 100mg + 15mg + 1000mg) uncoated bilayered tablets	It is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus	08.02.2023
9	Azelinidipine IP 16mg + Telmisartan IP 40mg uncoated bilayered tablets	For treatment of Stage-II Hypertension	08.02.2023
10	Combikit of Clarithromycin IP 500mg + Esomeprazole Magnesium IP eq. to Esomeprazole 40mg + Amoxicillin Trihydrate IP eq. to Amoxicillin 1000mg (In additional Strength)	For healing of duodenal ulcer associated with Helicobacter pylori and eradication of Helicobacter pylori in patients with active or healed peptic ulcer	15.02.2023
11	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP (5mg + 50mg + 500mg & 5mg + 50mg + 1000mg) film coated tablets	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	13.03.2023
12	Kabiven (3 Chamber Bag of Amino Acids and electrolytes + Fat emulsion 20% + Glucose 19%) emulsion for infusion	Parenteral Nutrition for patients and children above 2 years of age when oral or eternal nutrition is impossible, insufficient or contraindicated	17.03.2023
13	Kabiven Peripheral (3 Chamber Bag of Amino Acids and electrolytes + Fat emulsion 20% + Glucose 11%) emulsion for infusion	Parenteral Nutrition for patients and children above 2 years of age when oral or eternal nutrition is impossible, insufficient or contraindicated	17.03.2023
14	Indacaterol (as acetate) 150mcg + Glycopyrronium 50mcg + Mometasone Furoate IP 160mcg dry powder for inhalation in capsule (In additional Strength)	Indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of long acting beta 2 agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in a previous year.	24.04.2023
15	Tenofovir Alafenamide Fumarate IP 25mg + Emtricitabine IP 200mg + Bictegravir Sodium 50mg film coated tablets	For the treatment of human immunodeficiency virus type 1 (HIV-I) infection in adults who no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-2 RNA) less than 50 copies per ml) on a stable antiretroviral regimen for at least 3 month with no history of treatment failure and no known substitutions associated with resistance to Bictegravir, Emtricitabine and Tenofovir Alafenamide.	24.04.2023
16	Vildagliptin 50mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg uncoated tablet	For the treatment of Type 2 Diabetes Mellitus Inadequately Controlled on Metformin Monotherapy	16.05.2023
17	Alfuzosin Hydrochloride IP (as Extended Release) + Tadalafil IP .(10 mg +2.5mg & 10mg + 5mg) film coated tablets	For the treatment of patients with Lower urinary Tract Symptoms (LUTS) associated with benign Prostatic Hyperplasia (BPH)	07.06.2023

18	Alkyl Dimethyl Benzyl Ammonium Chloride 0.260%w/w / 26%w/w + Pyridine-2-Thiol 1-oxide, sodium salt 0.0250%w/w / 2.5%w/w Surface Disinfectant Solution	Cleaning and Disinfectant	07.06.2023
19	Linagliptin 5mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Film Coated Tablets	In patients with type 2 Diabetes Mellitus inadequately controlled on Metformin	03.07.2023
20	Metoprolol succinate IP 47.50 eq. to Metoprolol Tartrate (as extended release) 50mg + Telmisartan IP 40mg + Amlodipine Besilate IP eq. to Amlodipine 5mg film coated bilayered tablet	For the treatment of uncontrolled essential hypertension with stable coronary artery disease (CAD)	03.07.2023
21	Metoprolol succinate IP 47.50 eq. to Metoprolol Tartrate (as extended release) + Amlodipine Besilate IP eq. to Amlodipine + Chlorthalidone IP (50mg +5mg +6.25mg & 50mg + 5mg + 12.5mg) film coated bilayered tablets	For patients with uncontrolled essential hypertension	03.07.2023
22	Brimonidine Tartrate IP 2.0mg + Brinzolamide IP 10.0mg + Timolol Maleate IP eq. to Timolol 5mg + Benzalkonium Chloride Solution IP 0.2mg (as preservative) + Water for injection IP q.s. per ml ophthalmic suspension	For the treatment of patients with open angle glaucoma/ocular hypertension	13.07.2023
23	Dapagliflozin propanediol Monohydrate eq. to Dapagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP (As ER) (5mg + 50mg + 500mg & 5mg + 50mg + 1000mg) film coated tablet	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	13.07.2023
24	Linagliptin + Metformin Hydrochloride IP (as an extended release) (2.5mg + 1000mg, 5mg + 500mg & 5mg + 1000mg) film coated bilayered tablets (In additional Strength)	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with Linagliptin and Metformin is appropriate	28.07.2023
25	Metformin Hydrochloride IP (As SR form) + Vildagliptin (as SR form) (500mg + 50mg, 1000mg + 50mg, 500mg + 100mg & 1000mg + 100mg) film coated bilayered tablets	For the treatment of Type-II diabetes mellitus inadequately controlled on Metformin Monotherapy	04.08.2023
26	Combikit of: Each film coated tablet contains: Part A: Atazanavir Sulphate IP eq. to Atazanavir 300mg + Ritonavir IP 100mg Part B: Emtricitabine IP 200mg + Tenofovir Alafenamide Fumarate eq. to Tenofovir Alafenamide 10mg	For the treatment of adult patients with HIV infection	04.08.2023
27	Montelukast IP eq. to Montelukast 4mg + Fexofenadine Hydrochloride IP 60mg suspension (In additional Strength)	For the treatment of allergic rhinitis	04.08.2023

28	Metformin Hydrochloride IP (As sustained release) 500mg + Myo-Inositol IP 600mg film coated bilayered tablet	For Poly cystic Ovary Syndrome management	11.08.2023
29	Budesonide IP 200mcg + Glycopyrronium (as Glycopyrrolate IP) 12.5mcg + Formoterol Fumarate Dihydrate IP 6mcg inhaler	It is indicated as a maintenance treatment for patients with chronic obstructive pulmonary disease (COPD).	25.08.2023
30	Dapagliflozin propanediol monohydrate eq. to Dapagliflozin + Teneeligliptin Hydrobromide Hydrate eq. to Teneeligliptin IP + Metformin Hydrochloride (SR) IP + (10mg + 20mg + 500mg & 10mg + 20mg + 1000mg) film coated bilayered tablet	For the treatment of patients with type 2 diabetes mellitus inadequately controlled on metformin monotherapy.	12.09.2023
31	Indacaterol Maleate eq. to Indacaterol + Budesonide IP (75mcg+200mcg & 150mcg +400mcg) dry powder for inhalation in capsule (Additional Indication)	Indacaterol and Budesonide powder for inhalation is indicated for treatment of asthma where the use of corticosteroid and long acting beta agonist in combination is appropriate.	22.09.2023
32	Fluticasone Furoate 100mcg + Glycopyrronium Bromide Ph. Eur eq. to Glycopyrronium 50mcg + Vilanterol Trifenatate eq. to Vilanterol 25mcg Inhalation Powder in capsules	Maintenance treatment of patients with moderate to severe COPD.	26.09.2023
33	Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP + Glimepiride IP (50mg + 1000mg + 1mg & 50mg + 1000mg + 2mg) tablets	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	26.09.2023
34	Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride IP (as extended release) (10mg + 1mg + 1000mg & 10mg + 2mg + 1000mg) film coated tablets	Indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.	10.10.2023
35	Calcium Asparate 1120mg + Magnesium Hydroxide IP 180mg + Vitamin D3 IP 1000IU tablets	For Calcium and Vitamin D Deficiency	25.10.2023
36	Silodosin + Mirabegron (As extended release) (8mg + 25mg & 8mg + 50mg) film coated bilayered tablets	In adult patients diagnosed with Benign Prostatic Hyperplasia complicated by overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and frequency.	02.11.2023
37	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride (As extended release) (10mg + 1mg + 500mg & 10mg + 2mg + 500mg) film coated tablets (Additional strength)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	02.11.2023

38	Vilanterol Trifenatate eq. to Vilanterol 12.5mcg + Glycopyrrolate IP eq. to Glycopyrronium 25mcg + Fluticasone Furoate Ph. Eur 50mcg inhaler (metered dose inhalation)	It is indicated for treatment of patients with moderate to severe COPD.	02.11.2023
39	Glycopyrronium Bromide eq. to 50mcg of Glycopyrronium 63mcg + Vilanterol Trifenatate eq. to 25mcg Vilanterol 40mcg Inhalation Powder in capsule	Indicated as maintenance treatment for patients with Chronic Obstructive Pulmonary disease (COPD).	15.11.2023
40	Dapagliflozin 5mg + Vildagliptin 50mg + Metformin Hydrochloride IP 500mg film coated tablets (Additional strength)	Management of Type 2 Diabetes Mellitus (T2DM)	15.11.2023
41	Budesonide Ph. Eur. 160mcg + Glucopyrronium Ph. Eur 7.2mcg + Formoterol Fumarate Dihydrate Ph. Eur 5mcg inhalation preparations	Maintenance treatment of relieve symptoms and prevent exacerbations in adult patients with chronic obstructive pulmonary disease (COPD).	29.11.2023
42	Tramadol Hydrochloride IP 37.5mg + Acetaminophen IP 325mg effervescent tablets	For short term (five days or less) management of acute pain in adults	29.11.2023
43	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride (5mg + 1mg + 500mg, 5mg + 2mg + 500mg, 5mg + 1mg + 1000mg & 5mg + 2mg + 1000mg) film coated tablets (Additional strength)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	29.11.2023
44	Gliclazide IP (As sustained release) + Dapagliflozin (30mg + 10mg & 60mg + 10mg) film coated bilayered tablets	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on metformin monotherapy.	29.11.2023
45	Progesterone IP 100mg + Estradiol USP (as hemihydrates eq. to Anhydrous Estradiol) 1mg soft gelatin capsules	It is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.	29.11.2023
46	Alcohol IP 36.8%v/w + Ketoprofen IP 2.5%w/w gel	Symptomatic relief of acute painful musculoskeletal conditions caused by trauma, such as soft tissue injuries, including sports injuries, sprains, strains, contusions and musculo-tendonitis swelling, backache, and rheumatic pain. Pain of non-serious arthritis.	29.11.2023
47	Calcium Orotate 1120mg + Magnesium Hydroxide IP 180mg + Vitamin D3 IP 1000IU) film coated tablets	For calcium and vitamin D Deficiency	05.12.2023
48	Gliclazide IP (As sustained release) + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin (30mg + 100mg & 60mg + 100mg) film coated bilayered tablets	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on metformin monotherapy.	07.12.2023

49	Pioglitazone Hydrochloride IP 15mg + Vildagliptin (as sustained release form) 100mg film coated bilayered tablet	For the treatment of patients with type II diabetes mellitus.	07.12.2023
50	Bilastine 3.3mg + Dextromethorphan Hydrobromide 10mg + Phenylephrine Hydrochloride 5mg per 5ml syrup for oral administration	For relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.	07.12.2023
51	Vilanterol Trifenatate eq. to Vilanterol 12.5mcg + Glycopyrrolate IP eq. to Glycopyrronium 25mcg metered dose inhalation	Indicated as a maintenance treatment for patients with chronic obstructive pulmonary disease (COPD).	07.12.2023
52	Doxylamine Succinate USP 20mg + Pyridoxine Hydrochloride IP 20mg film coated extended release tablet	It is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.	07.12.2023
53	Levonorgestrel IP 0.15mg + Ethinylloestradiol IP 0.03mg uncoated tablets (Additional Indication)	Treatment of primary dysmenorrhea, treatment of abnormal uterine bleeding, treatment of endometriosis.	18.12.2023

Note 1: It may be stated that the above list of FDCs is prepared as per the records available with the office of DCG (I). In case any inconsistency is observed, same may be brought to the notice of DCG (I) for necessary action.

Note 2: As per DCGI letter dated 23.09.2011, 04.04.2012 & 13.09.2013 regarding limiting of Paracetamol in prescription combination products, lowering of Paracetamol content to 325mg is applicable to the combinations of paracetamol with other analgesic/anti-inflammatory drugs.