

# **FIXED DOSE COMBINATIONS APPROVED BY DCG(I)**

**From 01 January 2024 to 21 October 2024**

<b>S. No</b>	<b>FDC</b>	<b>Indication</b>	<b>Approval Date</b>
1	Ascorbic Acid IP 50mg + Cholecalciferol (Vitamin D3) IP 200IU + D-Panthenol IP 2.5mg + Nicotinamide IP 15mg + Pyridoxine Hydrochloride IP 1mg + Riboflavin Sodium Phosphate IP eq. to Riboflavin 1mg + Thiamine Hydrochloride IP 2mg + Vitamin A (as palmitate) IP 2500IU + Cyanocobalamin IP 1mcg + Citrus Bioflavonoid Compound 5mg/5ml syrup	For the treatment of vitamin deficiency state	11.01.2024
2	Hydrous Benzoyl Peroxide IP eq. to Anhydrous Benzoyl Peroxide 3.75% w/w + Clindamycin Phosphate IP 1.2% w/w eq. to Clindamycin 1% w/w topical gel <b>(Additional strength)</b>	For the topical treatment of acne vulgaris in patients 12 years age and older	11.01.2024
3	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg + Linagliptin 5mg tablet <b>(Additional strength)</b>	In the treatment of type 2 diabetes mellitus inadequately controlled on Metformin therapy	11.01.2024
4	Azelinidipine IP + Metoprolol Succinate IP eq. to Metoprolol Tartrate (SR) (8mg+25mg, 8mg+50mg, 16mg+25mg & 16mg+50mg) film coated bilayered tablets	For the treatment in stage 2 hypertension	11.01.2024
5	Levosulpiride (as uncoated sustained release tablet) 75mg + Rabeprazole Sodium IP (as enteric coated tablet) 40mg hard gelatin capsules <b>(Additional strength)</b>	For the treatment of Gastroesophageal Reflux Disease (GERD)	29.01.2024
6	Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg (as extended release) film coated bilayered tablets <b>(Additional strength)</b>	As an adjunct to diet and exercise to improve glycaemic control in adults patients with type II Diabetes Mellitus when treatment with Linagliptin and Metformin is appropriate.	29.01.2024
7	Methylcobalamin IP 1500mcg + Alpha Lipoic Acid USP 100mg + Vitamin D3 IP 8000IU + Calcium Carbonate IP eq. to elemental Calcium 225mg Vitamin K2-7 50mcg + Zinc Sulphate USP eq. to elemental Zinc USP 7.5mg + Magnesium Oxide IP eq. to elemental Magnesium IP 50mg hard gelatin capsules	For the treatment of Vitamins and Minerals deficiency in adult patients	28.02.2024
8	Glimepiride IP + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin (1mg + 100mg & 2mg + 100mg) film coated tablets	For the treatment of patients with type 2 diabetes mellitus, inadequately controlled on Metformin Monotherapy.	08.03.2024

9	Dapagliflozin propanediol Monohydrate eq. to Dapagliflozin + Linagliptin + Metformin Hydrochloride IP (as sustained release) (10mg + 5mg + 500mg & 10mg + 5mg + 1000mg) film coated bilayered tablets	Indicated in patients with type 2 diabetes mellitus inadequately controlled on Metformin alone.	08.03.2024
10	Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP + Glimepiride IP (50mg + 500mg + 1mg & 50mg + 500mg + 2mg) film coated tablet <b>(Additional strength)</b>	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	29.04.2024
11	Bioactive Concentrate from Small Marine Fish 0.1ml + Water for injection (WFI) 1ml solution for injection	Osteoarthritis of knee joints	29.04.2024
12	Fexofenadine Hydrochloride IP 180mg + Montelukast Sodium IP eq. to Montelukast 10mg film coated bilayered tablets	It is indicated for the treatment of adult patients with severe allergic rhinitis	03.05.2024
13	Indacaterol Maleate eq. to Indacaterol 75mcg + Budesonide IP 200mcg inhaler (Metered dose Inhaler) <b>(Additional Indication)</b>	It is indicated for treatment of patients with asthma where use of combination of inhaled regular corticosteroid and long acting beta agonist is appropriate	03.05.2024
14	Vilanterol Trifenatate eq. to Vilanterol 25mcg + Fluticasone Furoate 200mcg powder for inhalation in capsule	Treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2 agonist and inhaled corticosteroid) is appropriate: (i) Patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists. (ii) Patients already adequately controlled on both inhaled corticosteroid and long-acting beta2- agonist	03.05.2024
15	Bilastine 3.3mg + Dextromethorphan Hydrobromide IP 10mg + Phenylephrine Hydrochloride IP 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	14.05.2024
16	Sodium Alginate IP 500mg + Potassium Bicarbonate BP 100mg uncoated chewable tablets	Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn, indigestion (occurring due to the reflux of stomach contents), for instance, after gastric surgery, as a result of	14.05.2024

		hiatus hernia, during pregnancy, accompanying reflux oesophagitis, including symptoms of laryngopharyngeal reflux such as hoarseness and other voice disorders, sore throats and cough. It can also used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy	
17	Bupropion Hydrochloride IP (as extended release) 105mg + Dextromethorphan Hydrobromide IP 45mg film coated bilayered tablets	For the treatment of major depressive disorder (MDD) in adults	16.05.2024
18	Bilastine 40mg + Montelukast Sodium IP eq. to Montelukast IP 10mg film coated tablets	It is indicated for the management of severe allergic Rhinitis in adults for maximum duration of 4 weeks	06.06.2024
19	Silodosin JP 8mg + Tadalafil IP 5mg capsule	For the treatment of Lower Urinary Tract Symptoms (LUTS) associated with Benign Prostatic Hyperplasia (BPH) and Erectile Dysfunction (ED)	24.06.2024
20	Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (as sustained release) + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg film coated bilayered tablets	Indication in patients with heart failure post-acute myocardial infraction	10.07.2024
21	Levocarnitine IP 500mg + Methylcobalamin IP 1500mcg + Folic Acid IP 1.5mg + Vitamin E IP 200mg film coated tablet	For the treatment of nutritional deficiencies related with Vitamins and Carnitine deficiency state	15.07.2024
22	Metformin Hydrochloride IP (as sustained release) + Teneiglipitin Hydrobromide Hydrate IP eq. to Teneiglipitin + Dapagliflozin propanediol Monohydrate eq. to Dapagliflozin (1000mg + 20mg + 10mg & 500mg + 20mg + 5mg) tablets <b>(Additional strength)</b>	For the treatment of patients with Type 2 Diabetes Mellitus Inadequately controlled on Metformin monotherapy	19.07.2024
23	Glimepiride IP 0.5mg + Voglibose IP 0.2mg + Metformin Hydrochloride IP 500mg (as sustained release form) uncoated bilayered tablets <b>(Additional strength)</b>	It is indicated as 3rd line treatment of type 2 Diabetes Mellitus in adult patients when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control	22.07.2024

24	Didecyl Dimethyl Ammonium Chloride 80% solution eq. to Didecyl Dimethyl Ammonium Chloride 4.96% + Copper (II) Nitrate Trihydrate 0.04% + 4-Hydroxybenzaldehyde 0.12% + Sodium hydroxide 0.08% + Sodium dodecyl sulphate 0.15% + Perfume 0.10%, Water q.s. liquid solution	Surface disinfectant for persistent of all inanimate surfaces	30.07.2024
25	Atorvastatin Calcium IP eq. to Atorvastatin 80mg + Ezetimibe IP 10mg film coated tablets <b>(Additional strength)</b>	It is indicated for the treatment of patients with primary hypercholesterolemia	01.08.2024
26	Atorvastatin Calcium IP eq. to Atorvastatin 80mg + Ezetimibe IP 10mg film coated tablets <b>(Additional Indication)</b>	It is indicated to reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), either previously treated with a statin or not	05.08.2024
27	Bempedoic Acid + Rosuvastatin Calcium IP eq. to Rosuvastatin (180mg + 10mg, 180mg + 20mg & 180mg + 5mg) film coated tablets <b>(Additional strength)</b>	For the treatment of hypercholesterolemia	12.08.2024
28	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Bisoprolol Fumarate IP (10mg + 5mg & 10mg +10mg) film coated tablet	Indicated in patients with Heart Failure with Reduced Ejection Fraction (HFrEF)	16.08.2024
29	Bisoprolol Fumarate IP + Perindopril Arginine (5mg+ 10mg & 5mg + 5mg) film coated bilayered tablets	Indicated as substitution therapy for treatment of hypertension and/or stable coronary artery disease (in patients with a history of myocardial infraction and/or revascularization) and/or stable chronic heart failure with reduces systolic left ventricular function in adult patients adequately controlled with Bisoprolol and perindopril given concurrently at the same dose level	18.09.2024
30	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg film coated tablets	Indicated in patients with type 2 diabetes mellitus inadequately controlled on earlier metformin containing monotherapy	18.09.2024
31	Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin (25mg + 100mg & 10mg + 100mg) film coated tablet	It is indicated in patients with Type 2 Diabetes Mellitus inadequately controlled on Metformin Monotherapy	18.09.2024
32	Tamsulosin Hydrochloride (as extended	Substitution therapy in	01.10.2024

	release tablet) IP 0.4mg + Tadalafil IP (as film coated tablet) 2.5mg hard gelatin capsule	treatment of benign prostatic hyperplasia and erectile dysfunction in patients who are already taking Tamsulosin And Tadalafil concomitantly	
33	Polmacoxib 2mg + Paracetamol IP 325mg Uncoated tablet	For the short term use in acute somatic mild to moderate painful inflammatory conditions.	21.10.2024