

FIXED DOSE COMBINATIONS APPROVED BY DCG(I)

From 01 January 2024 to 21 October 2024

| S. No | FDC | Indication | Approval Date |
|--------------|---|---|----------------------|
| 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 (Additional strength) | 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 (Additional strength) | In the treatment of type 2 diabetes mellitus inadequately controlled on Metformin therapy | 11.01.2024 |
| 4 | Azelnidipine 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 (Additional strength) | 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 (Additional strength) | 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 (Additional strength) | 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) (Additional Indication) | 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 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 | 14.05.2024 |
| 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) + Tenzeligiptin Hydrobromide Hydrate IP eq. to Tenzeligiptin + Dapagliflozin propanediol Monohydrate eq. to Dapagliflozin (1000mg + 20mg + 10mg & 500mg + 20mg + 5mg) tablets (Additional strength) | 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 (Additional strength) | 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 (Additional strength) | 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 (Additional Indication) | 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 (Additional strength) | 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 release tablet) IP 0.4mg + Tadalafil IP (as film coated tablet) 2.5mg hard gelatin capsule | Substitution therapy in treatment of benign prostatic hyperplasia and erectile dysfunction in patients who are already taking Tamsulosin And Tadalafil concomitantly | 01.10.2024 |
| 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 |

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.