

FIXED DOSE COMBINATIONS APPROVED BY DCG (I) From 1st January 2022 to 25th August 2022

S. No	FDC	Indication	Approval Date
1.	Each film coated bilayered tablet contains: Benidipine Hydrochloride..... 4mg Telmisartan IP40mg (Additional Dosage Form)	For the treatment of hypertension	03.01.2022
2.	Each uncoated bilayered tablets contains: Glimepiride IP + Voglibose IP + Metformin HCl (SR) IP (1mg + 0.2mg + 1000mg & 2mg + 0.2mg + 1000mg) (Additional Strength)	As 3rd line treatment of type 2 diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control.	06.01.2022
3.	Each uncoated mouth dissolving tablets contains: Pyridoxine Hydrochloride IP 3mg + Folic acid IP 5mg + Vitamin D3 IP 1000IU + Methylcobalamin IP 1500mcg	For the management of diabetic neuropathy in patients with hyperhomocysteinemia.	01.02.2022
4.	Each hard gelatin capsule contains: Dutasteride IP.....0.5mg Silodosin.....4 mg (Additional Strength)	For the treatment of the signs and symptoms of BPH in men with an enlarged prostate.	03.02.2022
5.	Each film coated bilayered tablet contains: Efonidipine Hydrochloride Ethanolate.....40mg Telmisartan IP.....40mg	For the management of stage II hypertension.	07.02.2022
6.	Glycopyrrolate IP.....9mcg Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate.....4.8mcg Budesonide IP.....160mcg Meterd dose inhaler	For the treatment of patients with Chronic Obstructive Pulmonary Disease (COPD)	07.02.2022
7.	Each film coated tablets contains: Rosuvastatin Calcium IP eq. to Rosuvastatin + Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin (5mg + 20mg, 10mg + 20mg & 20mg + 20mg)	Dyslipidemia associated with Type II Diabetes Mellitus	25.02.2022

8.	Each film coated tablets contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin + Pioglitazone Hydrochloride eq. to Pioglitazone (20mg + 15mg & 20mg + 30mg)	For the treatment of type 2 diabetes mellitus	25.02.2022
9.	Per 5ml suspension contains: Bilastine.....10mg Montelukast Sodium IP Eq. to Montelukast....4mg	For the treatment of Allergic rhinitis in children aged 6 to 11 years (both inclusive) with a body weight of atleast 20kg.	11.03.2022
10.	Each Orodispersible tablets contains: Montelukast sodium eq. to Montelukast IP.....10mg Bilastine20mg (Additional Dosage form)	For the treatment of allergic rhinitis in adults.	11.03.2022
11.	Each film coated bilayered tablets contains: Mecobalamin IP.....1500mcg Nortriptyline Hydrochloride IP Eq. to Nortriptyline10mg Pregabalin PR (IP).....75mg	For the treatment of patients with diabetic peripheral neuropathic pain coexistent Vitamin B12 deficiency.	17.03.2022
12.	Lidocaine Hydrochloride IP 2% w/w + Diltiazem Hydrochloride IP 2% w/w gel	For the treatment of anal fissure.	24.03.2022
13.	Each film coated tablets contains: Sitagliptin Phosphate IP eq. to Sitagliptin + Metformin Hydrochloride IP (as sustained release form) (50mg +500mg, 50mg + 1000mg & 100mg + 1000mg) (Additional Strength)	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Sitagliptin and Metformin is appropriate	24.03.2022
14.	Each film coated tablets contains: Nortriptyline Hydrochloride IP eq. to Nortriptyline10mg Pregabalin IP.....50mg (Additional Strength)	For the treatment of neuropathic pain.	25.03.2022

15.	Each film coated tablets contains: Empagliflozin + Metformin Hydrochloride (as extended release) (5mg + 1000mg, 10mg + 1000mg, 12.5mg + 1000mg & 25mg + 1000mg)	It is indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on a regimen containing Empagliflozin or Metformin, or in patients already being treated with both Empagliflozin and Metformin.	29.03.2022
16.	Each film coated tablet contains: Metformin Hydrochloride IP (as immediate release form).....500mg Dapagliflozin.....5mg	It is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both Dapagliflozin and Metformin is appropriate.	04.04.2022
17.	Each film coated tablets contains: Linagliptin + Metformin Hydrochloride IP (as extended release) (2.5mg + 1000mg & 5mg + 1000mg) (Additional Strength)	Indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients with type-II diabetes mellitus when treatment with Linagliptin and Metformin is appropriate.	08.04.2022
18.	Each uncoated bilayered tablet contains: Vildagliptin (as sustained release) + Dapagliflozin (100mg + 5mg & 100mg + 10mg)	For the treatment of patients with type 2 Diabetes mellitus inadequately controlled on Metformin monotherapy.	08.04.2022
19.	Ripasudil Hydrochloride Hydrate eq. to Ripasudil.....0.4% w/v Timolol Maleate IP eq. to Timolol.....0.5% w/v Benzalkonium chloride IP....0.01%w/v Eye Drops	It is indicated for the treatment of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension.	18.04.2022
20.	Each Orodispersible tablet contains: Bilastine.....10mg Montelukast Sodium IP Eq. to Montelukast....4mg (Additional Dosage Form)	For the treatment of allergic rhinitis	09.05.2022

21.	Each uncoated sublingual tablet contains: Naloxone Hydrochloride IP eq. to Naloxone0.25mg Buprenorphine Hydrochloride IP eq. to Buprenorphine.....1mg (Additional Strength)	For the treatment of patients with opioid dependence	17.05.2022
22.	Each Film Coated Tablet contains: - Tenofovir Alafenamide Fumarate 28mg eq. to Tenofovir Alafenamide25mg Lamivudine USP.....300mg Dolutegravir Sodium eq. to Dolutegravir.....50mg	As a complete regimen for the treatment of HIV 1 infection in adults and pediatric patients weighing at least 25kg.	02.06.2022
23.	Calcium-3-Methyl-2-Oxo-Valerate Ketoanalogue to Isoleucine Calcium salt) IH 67.0mg + Calcium-4-Methyl-2-Oxo-Valerate Ketoanalogue to Leucine Calcium Salt) IH 101.0mg + Calcium-2-Oxo-3-Phenylpropionate (α-Ketoanalogue to Phenylalanine Calcium Salt) IH 68.0mg + Calcium-3-Methyl-2-Oxo-Butyrate (α-Ketoanalogue to Valine Calcium Salt) IH 86.0mg Calcium-DL-2-hydroxy-4 (methylthio) Butyrate (α-Ketoanalogue to methionine Calcium Salt) IH 59.0mg + L-Lysine acetate USP 105.0mg + L-Threonine USP 53.0mg + L-Tryptophan USP 23.0mg + Histidine Hydrochloride Monohydrate eq. to Histidine 38 mg + L-Tyrosine USP 30.0mg per 10ml Oral suspension (Additional Strength)	(Prevention and treatment of) damages due to faulty or deficient protein (metabolism in chronic kidney disease in connection with a limited dietary protein intake of 40g/day or less (adult). Usually this applies to patients whose glomerular filtration rate (GFR) is less than 25mL/min L- BP	22.06.2022
24.	Each hard gelatin capsules contains: Mirabegron (as extended release tablet) + Solifenacin Succinate (as immediate release tablet) (25mg + 5mg & 50mg + 5mg) (Additional Strength)	It is indicated for the treatment of overactive bladder (OAB)	22.06.2022
25.	Each uncoated bilayered tablet contains: Efonidipine Hydrochloride Ethanolate.....40mg Chlorthalidone IP.....12.5mg	In the management of hypertension	23.06.2022

26.	Each film coated tablet contains:- Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin + Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin (50mg+5mg & 100mg+10mg)	It is indicated for the treatment of type 2 diabetes mellitus inadequately controlled on metformin monotherapy	30.06.2022
27.	Each film coated tablet contains: Gabapentin IP.....200mg Nortriptyline Hydrochloride IP eq. to Nortriptyline.....10mg	For the treatment of Neuropathic pain	06.07.2022
28.	Each capsule contains: Fluticasone Furoate + Vilanterol Trifenatate eq. to Vilanterol (100mcg + 25mcg & 200mcg + 25mcg)	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 corticosteroids) is appropriate: • Patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta 2-agonists. • Patients already adequately controlled on both inhaled corticosteroid and long-acting beta 2-agonist.	06.07.2022
29.	Each film coated tablet contains: Gabapentin IP + Nortriptyline Hydrochloride IP eq. to Nortriptyline (100mg +10mg & 200mg +10mg) (Additional Dosage form)	For the treatment of Neuropathic pain	23.07.2022

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.