

Fixed Dose Combinations Approved By DCG (I) From January 2020 to June 2020

1.	Each uncoated bilayered tablet contains : Glimepiride IP + Voglibose IP + Metformin HCl IP (as ER) (1mg + 0.2mg + 500mg & 2mg + 0.2mg + 500mg)	As 3 rd 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.	14.01.2020
2.	Each Film coated tablet contains : Sildenafil + Dapoxetine (100mg + 60mg, 50mg + 60mg & 50mg + 30mg)	For the treatment of co-existing erectile dysfunction and premature ejaculation in men 18 to 64 years of age.	10.02.2020
3.	Each Uncoated Bilayered Tablet Contains: S(-) Amlodipine Besylate IP eq.to S(-) Amlodipine + Telmisartan IP (5mg + 40mg & 2.5mg + 40mg)	It is indicated for the treatment of essential hypertension.	14.02.2020
4.	Each film coated tablet contains: Efonidipine Hydrochloride Ethanolate.....20mg Telmisartan IP.....40mg	It is indicated for the management of stage 2 hypertension.	24.02.2020
5.	Each uncoated bilayered tablet contains: Gliclazide IP (as extended release form).....60mg Metformin Hydrochloride IP (as extended release form).....1000mg	For the treatment of noninsulin dependent diabetes (Type-II) in adult patients where single drug therapy, diet and exercise do not result in adequate glycaemic control.	03.03.2020
6.	Each film coated bilayered tablet Contains: Montelukast sodium eq. to Montelukast IP.....10mg Bilastine 20mg	For the treatment of allergic rhinitis in adults.	09.03.2020
7.	Each film coated bilayered tablet contains: Metoprolol Succinate IP eq. to Metoprolol Tartarate IP (as Extended Release) + Telmisartan IP + Chlorthalidone IP (25mg + 40mg + 12.5mg & 50mg + 40mg + 12.5mg)	For the treatment of essential hypertension with stable coronary artery disease.	17.03.2020

8.	Sodium Alginate IP 250mg + Sodium Bicarbonate IP 133.5mg + Calcium Carbonate IP 80mg per 5ml oral liquid.	Indicated for the treatment of heartburn and indigestion.	09.04.2020
9.	Each capsule contains: Glycopyrrolate USP eq. to Glycopyrronium..... 12.5mcg Formoterol Fumarate Dihydrate IP..... 12mcg Fluticasone Propionate IP.....250mcg Dry powder for inhalation	It is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	16.04.2020
10.	Sodium Hyaluronate.....0.15% w/v Polyethylene Glycol 400.....0.4%w/v Propylene Glycol0.3%w/v Lubricant eye drops	For the temporary relief of burning and irritation due to dryness of the eye and for use in lubricating and rewetting of all silicone hydrogel and soft hydrophilic contact lenses.	22.04.2020
11.	Each film coated bilayered tablet contains: Azilsartan Kamedoxomil eq to Azilsartan Medoxomil + Cilnidipine (40mg + 5mg & 40mg+ 10mg)	For the treatment of stage 2 hypertension.	24.04.2020
12.	Each film coated tablet contains: Capecitabine IP + Cyclophosphamide IP eq. to anhydrous Cyclophosphamide (400mg + 21.4mg eq. to 20mg & 700mg + 32.1mg eq. to 30mg)	For the treatment of patients with metastatic breast cancer after failure of prior anthracycline and /or taxane chemotherapy.	28.04.2020
13.	Tropicamide IP 0.2mg + Phenylephrine Hydrochloride IP 3.1mg + Lidocaine Hydrochloride IP 10mg per ml injection. Intracameral Injection	It is indicated for cataract surgery to obtain mydriasis and intraocular anesthesia during surgical procedure.	04.05.2020
14.	Each film coated tablet contains: Alogliptin Benzoate 17mg eq. to Alogliptin + Metformin Hydrochloride (12.5mg + 500mg & 12.5mg + 1000mg)	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	18.05.2020

15.	Each ml contains Timolol Maleate EP.....5mg Brinzolamide10mg Eye drops suspension.	Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.	14.5.2020
16.	Per 1000ml contains (after mixing) Glucose Monohydrate EP.....1.100gm Magnesium Chloride Hexahydrate EP.....0.1017gm Calcium Chloride Dihydrate EP.....0.2205gm Sodium Hydrogen Carbonate EP.....2.940gm Sodium Chloride EP.....6.136gm Solution for haemodialysis / haemofiltration (multiBic potassium free)	MultiBic Potassium-free is indicated for intravenous use as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration.	15.05.2020
17.	Per 12.5mg blister contains : Fluticasone Furoate100mcg Umeclidinium bromide 74.2mcg eq. to Umeclidinium.....62.5mcg Vilanterol trifenate 40mcg eq. to Vilanterol.....25mcg	Indicated for maintenance treatment to prevent and relieve symptoms associated with chronic obstructive pulmonary disease (COPD).	18.05.2020
18.	<p>MultiBic 2 mmol/l potassium</p> <p>Per 1000ml contains (After mixing) Potassium Chloride.....0.1491gm Sodium Chloride6.136gm Sodium Hydrogen Carbonate.....2.940gm Calcium Chloride Dihydrate.....0.2205gm Magnesium Chloride Hexahydrate.....0.1017gm Glucose Monohydrate1.100gm</p> <p>MultiBic 4 mmol/l potassium</p> <p>Per 1000ml contains (After mixing) Potassium Chloride0.2982gm Sodium Chloride6.136gm Sodium Hydrogen Carbonate.....2.940gm Calcium Chloride Dihydrate.....0.2205gm Magnesium Chloride Hexahydrate.....0.1017gm Glucose Monohydrate.....1.100gm</p> <p>Solution for Haemodialysis/Heamofiltration</p>	MultiBic 2 mmol/l and 4 mmol/l Potassium is indicated for intravenous use as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration.	15.05.2020

19.	<p>Disodium Phosphate Dihydrate EP.....1870g/L Potassium Chloride EP.....0.3140g/L Sodium Hydrogen Carbonate EP...2.1200g/L Sodium Chloride EP.....7.0100g/L Magnesium Chloride Hexahydrate EP..... 3.0500g/L</p> <p>Solution for Haemodialysis or Haemofiltration</p>	<p>Biphozyl is used as replacement solution and as a dialysate for treatment of acute kidney injury during continuous renal replacement therapy. Biphozyl is used in a post –acute phase after initiation of renal replacement therapy when therapy when pH, potassium and phosphate concentration have returned to normal. Biphozyl is also used when other buffer sources are available as well as during regional citrate anticoagulation. Moreover, Biphozyl is used in patients with hypercalcaemia. Biphozyl may also be used in cases of drug poisoning or intoxications when the substances are dialysable or filterable.</p>	21.05.2020
20.	<p>Sodium Citrate5.2900g/L Sodium Chloride.....5.0300g/L</p> <p>Solution for Haemofiltration</p>	<p>Regiocit is used as replacement fluid for continuous renal replacement therapy (CRRT) using regional citrate anticoagulation. Citrate is particularly relevant when systemic anticoagulation with heparin is contraindicated for example in patients with increased bleeding risk.</p>	21.05.2020

Note 1: It may be stated that the above list of FDC s 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.