

**Fixed Dose Combinations Approved By DCG (I) From 1<sup>st</sup> January 2020 to 31<sup>st</sup> December 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 <sup>rd</sup> 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 II 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.	<del>09.04.2020</del> 04.10.2018
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 Glycol .....0.3%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 II 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.	<p><del>Each ml contains Timolol Maleate EP.....5mg Brinzolamide .....10mg Eye drops suspension.</del></p>	<p><del>Decrease of intraocular pressure (IOP) in adult patients with open angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.</del></p>	<p>14.5.2020 (Inadvertently included, hence deleted)</p>
16.	<p>Per 1000ml contains (after mixing)</p> <p>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)</p>	<p>MultiBic Potassium-free is indicated for intravenous use as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration.</p>	15.05.2020
17.	<p>Per 12.5mg blister contains :</p> <p>Fluticasone Furoate .....100mcg Umeclidinium bromide 74.2mcg eq. to Umeclidinium.....62.5mcg Vilanterol trifenate 40mcg eq. to Vilanterol.....25mcg</p>	<p>Indicated for maintenance treatment to prevent and relieve symptoms associate with chronic obstructive pulmonary disease (COPD).</p>	18.05.2020
18.	<p><b>MultiBic 2 mmol/l potassium</b></p> <p>Per 1000ml contains (After mixing)</p> <p>Potassium Chloride.....0.1491gm Sodium Chloride .....6.136gm Sodium Hydrogen Carbonate.....2.940gm Calcium Chloride Dihydrate.....0.2205gm Magnesium Chloride Hexahydrate.....0.1017gm Glucose Monohydrate .....1.100gm</p> <p><b>MultiBic 4 mmol/l potassium</b></p> <p>Per 1000ml contains (After mixing)</p> <p>Potassium Chloride .....0.2982gm Sodium Chloride .....6.136gm 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>	<p>MultiBic 2 mmol/l and 4 mmol/l Potassium is indicated for intravenous use as substitution solution in haemofiltartion and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration.</p>	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 Citrate .....5.2900g/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
21.	<p>Each kit contains:</p> <p>A) 14 Ticagrelor tablets.....90mg  Each film coated tablet contains:  Ticagrelor IP.....90mg</p> <p>B) 7 Aspirin Gastro-resistant tablets  IP.....75mg  Each enteric coated tablet contains:  Aspirin IP.....75mg</p>	<p>For the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with acute coronary syndromes (ACS) including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG) where both Ticagrelor and Aspirin are required.</p>	29.05.2020
22.	<p>Amoxicillin Trihydrate.....759.04 mg eq. to  Amoxicillin free acid.....652.78 mg*</p> <p>Potassium Clavulanate.....61.48 mg eq. to  Clavulanic acid.....50.41mg *</p> <p>per 5ml powder for reconstitution into suspension</p> <p>(*652.78mg of amoxicillin free acid is eq. to 600mg amoxicillin with an overfilling of 8.8%. The quantity is adjusted based on purity. In a similar manner the quantity of potassium clavulanate is adjusted based on purity</p>	<p>It is indicated for short term treatment of paediatric patients with bacterial infections at the following sites when caused by amoxicillin-clavulanate-susceptible organisms:</p> <p>1. Upper Respiratory Tract Infections (including ENT) e.g.</p> <ul style="list-style-type: none"> <li>Acute otitis media (AOM), persistent AOM, or recurrent AOM, typically caused by Streptococcus pneumoniae Haemophilus influenzae and Moraxella catarrhalis.</li> </ul>	08.06.2020

	<p>although the potassium clavulanate/silicon dioxide blend ratio is always 1:1. 50.41mg of Clavulanic Acid represents 42.9mg of Clavulanic Acid with an overage of 8% and an overfilling of 8.8%.</p>	<ul style="list-style-type: none"> <li>• Tonsillo-pharyngitis and sinusitis, typically caused by Streptococcus pneumoniae.</li> <li>• Haemophilus Influenza Moraxella catarrhalis and Streptococcus pyogenes.</li> </ul> <p>2. Lower Respiratory Tract Infections e.g. lobar and bronchopneumonia typically caused by Streptococcus pneumoniae Haemophilus influenza and Moraxella catarrhalis</p> <p>3. <del>Skin and Soft Tissue Infections typically caused by Staphylococcus aureus and Streptococcus pyogenes.</del></p> <p>4. <del>Urinary tract infections e.g. cystitis, pyelonephritis</del></p> <ul style="list-style-type: none"> <li><del>• Penicillin minimum inhibitory concentration (MIC) less than or equal to 4 micrograms/ml</del></li> <li><del>• Some members of these species of bacteria produce beta lactamase, rendering them insensitive to amoxicillin alone.</del></li> </ul>	
23.	<p>Film coated bilayered tablets contains:</p> <p>Metformin Hydrochloride IP.....500mg</p> <p>Evogliptin Tartrate.....5mg</p> <p><b>(In additional Strength)</b></p>	<p>As an adjunct to diet and exercise to improve glycaemic control in adults patients with type 2 diabetes mellitus who are appropriate for co-administration of Evogliptin and Metformin. Patients with inadequate glycaemic control on Metformin monotherapy alternative for combination therapy of Evogliptin and Metformin.</p>	26.06.2020
24.	<p>Film coated bilayered tablet contains:</p> <p>Pregabalin IP (As prolonged Release).....75mg</p> <p>Etoricoxib IP.....60mg</p> <p><b>(In additional Strength)</b></p>	<p>For the treatment of chronic low back pain associated with neuropathic component.</p>	15.07.2020

25.	Glycopyrronium IP.....25mcg Formoterol Fumarate IP.....12mcg Budesonide IP.....400mcg Inhalation Powder	Indicated as a maintenance treatment for patients with chronic obstructive pulmonary disease (COPD).	17.07.2020
26.	Zinc chloride Ph. Eur. ....1050 µg Sodium fluoride Ph. Eur.....210.0 µg Potassium iodide Ph. Eur.....16.60 µg Sodium Molybdate dihydrate Ph. Eur. .....4.850 µg Sodium selenite anhydrous .....17.29 µg Copper chloride dihydrate USP ..... 102.3 µg Manganese chloride tetrahydrate USP .....19.79 µg Ferric chloride hexahydrate Ph. Eur. .....540.0 µg Chromic chloride hexahydrate USP .....5.330 µg Concentrate for Solution for Infusion	To meet basal to moderately increased requirements of trace elements in intravenous nutrition.	30.07.2020
27.	Each uncoated tablets contains: Aceclofenac IP.....200mg (as extended release) Rabeprazole.....20mg (as delayed release) <b>(In additional dosage form)</b>	It is indicated for the treatment of Painful inflammatory conditions associated with gastroduodenal ulcers.	10.08.2020
28.	Each uncoated tablets contains: Azelnidipine IP.....8mg/8mg Olmesartan Medoxomil IP .....20mg/40mg	For the treatment of patients with stage II hypertension.	14.08.2020

29.	<p>Glycopyrrolate IP.....9mcg</p> <p>Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate.....4.8mcg</p> <p>Per actuation deliver Inhalation Aerosol</p> <p><b>(In additional Strength)</b></p>	Indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease.	14.08.2020
30.	<p>Didecyl dimethyl Ammonium Chloride.....10.14% w/w</p> <p>N-Alkyl Dimethyl Benzyl Ammonium Chloride.....6.76% w/w</p> <p>Surface Disinfectant</p>	Antimicrobial product for use against Novel coronavirus SARS-Cov-2, the cause of COVID-19.	14.08.2020
31.	<p>Octyl Decyl Dimethyl Ammonium Chloride .....6.510% w/w</p> <p>Dioctyl Dimethyl Ammonium Chloride.....2.604% w/w</p> <p>Didecyl Dimethyl Ammonium Chloride.....3.906% w/w</p> <p>Alkyl dimethyl Benzyl Ammonium Chloride.....8.680% w/w</p> <p>Surface Disinfectant</p>	Antimicrobial product for use against Novel Coronavirus SARS-Cov-2, the cause of COVID-19.	14.08.2020
32.	<p>Each tablet contains:</p> <p>Vildagliptin.....50mg/50mg</p> <p>Metformin Hydrochloride (Sustained Release) IP.....500mg/1000mg</p>	For the treatment of type_II diabetes mellitus when single drug therapy along with diet, exercise do not result in adequate glycemic control.	18.08.2020
33.	<p>Film coated bilayered tablet contains:</p> <p>Azelnidipine .....8mg/8mg</p> <p>Telmisartan.....40mg/80mg</p>	For treatment of Stage-II Hypertension.	19.08.2020

34.	<p>Each vial contains:</p> <p>Amoxicillin Sodium IP (sterile) eq. to Amoxicillin.....125mg</p> <p>Potassium Clavulanate IP (sterile) eq. to Clavulanate.....25mg</p> <p><b>Injection</b></p>	For the treatment of bacterial infections.	19.08.2020
35.	<p>Each film coated tablets contains:</p> <p>Efonidipine Hydrochloride Ethanolate .....20mg/20mg</p> <p>Metoprolol Succinate (Extended Release)...25mg/50mg</p>	It is indicated for the management of Stage - II Hypertension.	25.08.2020
36.	<p>Each uncoated bilayered tablets contains:</p> <p>Atorvastatin Calcium IP eq. to Atorvastatin.....10mg/20mg</p> <p>Clopidogrel Bisulphate IP eq. to Clopidogrel .....75mg/75mg</p> <p><b>(In additional dosage form)</b></p>	Post coronary intervention and acute syndrome.	23.09.2020
37.	<p>Each Dispersible tablets contains:</p> <p>Lamivudine USP.....60mg</p> <p>Abacavir Sulphate USP...120mg</p>	Indicated in the treatment of HIV-1 infection in children.	06.10.2020
38.	<p>Each tablet contains:</p> <p>Tenofovir Alafenamide Fumarate ..... 25mg</p> <p>Emtricitabine.....200mg</p> <p><b>(In additional Indication)</b></p>	Indicated for use in high risk adults and adolescents weighing at least 35kg for PrEP to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex.	12.10.2020
39.	<p>Each 1.8ml solution for injection contains:</p> <p>Lignocaine Hydrochloride Ph. Eur...36mg</p> <p>Adrenaline Tartrate Ph. Eur.....0.0225mg</p>	It is a local anaesthetic indicated for the local and loco-regional anaesthesia in dental surgery in adults and in children and adolescents aged 4 to 18 years of age.	12.10.2020

		It is appropriate for procedures of long durations and when there is a risk of significant bleeding into the operative field.	
40.	Each 1.7ml solution for injection: Articaine Hydrochloride EP.....68mg Adrenaline Tartrate EP.....0.0300mg	It is a local anaesthetic indicated for the local and loco-regional anaesthesia in dental procedures in adults. It is intended for adults, adolescents and in children over 4 years old.	14.10.2020
41.	Each Actuation delivers (Ex-actuator) contains: Glycopyrrolate IP .....9.0mcg Formoterol Fumarate dihydrate IP eq. to Formoterol Fumarate.....4.8mcg Inhalation Aerosol <b>(In additional strength)</b>	Indicated for the long term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease.	26.10.2020
42.	Each Film Coated Tablets contains: Rosuvastatin Calcium IP eq. to Rosuvastatin .....20mg Clopidogrel Bisulphate IP eq. to Clopidogrel .....75mg	Post coronary intervention and acute coronary syndrome.	27.11.2020
43.	Each Film Coated Tablets contains: Remogliflozin Etabonate.....100mg Vildagliptin.....50mg	It is indicated in adults aged 18 years and older with type 2 diabetes mellitus: <ul style="list-style-type: none"> <li>To improve glycaemic control when Metformin and one of mono-components of Fixed dose combination of Remogliflozin Etabonate &amp; Vildagliptin do not provide adequate glycaemic control.</li> <li>When already being treated with the free combination of Remogliflozin Etabonate &amp; Vildagliptin.</li> </ul>	27.11.2020

44.	Each Film Coated Tablets contains:  Ivabradine Hydrochloride eq. to Ivabradine + Metoprolol Tartrate IP (7.5mg+25mg, 5mg +50mg, 5mg+25mg & 7.5mg+50mg)	For the symptomatic treatment of chronic stable angina pectoris substitution therapy in adult patients with normal sinus rhythm already controlled by Metoprolol and Ivabradine taken concomitantly at the same dose level.	27.11.2020
45.	Each Film Coated Tablets contains:  Metoprolol Succinate IP eq. to Metoprolol Tartrate (as extended release)+ Chlorthalidone IP + Telmisartan IP (47.5mg eq. to 50mg + 6.25mg + 40mg & 23.75mg eq. to 25mg + 6.25mg+ 40mg)	It is indicated for the treatment of patients with uncontrolled essential hypertension and stable coronary artery disease (CAD)	21.12.2020
46.	Each Film Coated Tablets contains:  Carvedilol IP.....3.125mg  Ivabradine Hydrochloride eq. to Ivabradine.....5mg	It is indicated for as substituted therapy in adult patients with normal sinus rhythm already controlled by Ivabradine and carvedilol taken concomitantly at the same doses level for:  I. The symptomatic treatment of chronic stable angina pectoris in coronary artery disease patients  II. The treatment of chronic heart failure (II-IV NYHA-class) with systolic dysfunction.	30.12.2020

**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.