

FIXED DOSE COMBINATIONS APPROVED BY DCG (I) From 1st January 2021 to 31st December 2021

S.No	FDC	Indication	Approval Date								
1.	Each gram contains: Adapalene EP.....0.3% w/w Benzoyl Peroxide EP.....2.5% w/w Topical Gel (Additional Strength)	For the cutaneous treatment of Acne vulgaris, when comedones, numerous papules and pustules are present.	08.01.2021								
2.	Each modified release bilayered tablet contains: S (-) Metoprolol Succinate eq. to S (-) Metoprolol Tartrate (as extended release) + Telmisartan IP (Immediate Release) (25 mg + 20 mg & 25mg + 40 mg)	For the treatment of essential hypertension.	18.01.2021								
3.	Zinc Citrate Trihydrate eq. to Zinc10mg Ascorbic Acid IP1000mg Effervescent tablets	For the treatment of Vitamin C and Zinc deficiency.	01.02.2021								
4.	Each Capsules contains: Atorvastatin Calcium IP eq. to Atorvastatin.....40mg Aspirin IP75mg (As one gastro-resistant tablet) (Additional Strength)	Treatment of dyslipidemia associated with atherosclerotic arterial disease with risk of myocardial infarction, stroke, or peripheral vascular disease.	05.02.2021								
5.	Each 20ml vial contains: Ceftazidime pentahydrate eq. to Ceftazidime2gm Avibactam Sodium eq. to Avibactam.....0.5gm Powder for concentrate for solution for infusion	<ul style="list-style-type: none"> • Complicated Intra-abdominal infections (cIAI) • Complicated Urinary tract infections (cUTI), including pyelonephritis • Hospital-acquired pneumonia (HAP) including ventilator associated pneumonia (VAP) with susceptible gramnegative microorganisms. Treatment of patients with bacteremia that occurs in association with, or is suspected to be associated with, any of the infections listed above.	12.02.2021								
6.	Each uncoated tablet contains: Azelnidipine IP + Chlorthalidone IP (8mg + 6.25mg & 8mg+12.5mg)	For the treatment of essential hypertension.	19.02.2021								
7.	Composition of Amino acid Solution 8% solution for intravenous infusion (Pack size 500ml in Glass bottle) Per 1000ml solution for infusion contains:	For supply of amino acids as part of a parenteral nutrition regimen in serve forms of hepatic insufficiency with and without hepatic encephalopathy when oral or enteral nutrition is impossible or insufficient or contraindicated.	19.02.2021								
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8.	<p>Each tablet contains:</p> <p>Benidipine Hydrochloride JP + Telmisartan IP (4mg + 40mg & 4mg + 80mg)</p>	For the treatment of hypertension	26.02.2021																												
9.	<p>Composition of Amino acid Solution for intravenous infusion (Pack size 100ml, 250ml, 500ml in Glass bottle)</p> <p>Per 1000ml solution for infusion contains:</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Quality</th> </tr> </thead> <tbody> <tr> <td>L-isoleucine Ph. Eur</td> <td>5.10 g</td> </tr> <tr> <td>L-leucine Ph. Eur.</td> <td>10.30 g</td> </tr> <tr> <td>L-lysine monoacetate corresponding to L-lysine USP</td> <td>10.01 g 7.1 g</td> </tr> <tr> <td>L-methionine Ph. Eur.</td> <td>2.80 g</td> </tr> <tr> <td>N-acetyl-L-cysteine Corresponding to L-Cysteine Ph. Eur.</td> <td>0.50 g 0.37 g</td> </tr> <tr> <td>L-phenylalanine Ph. Eur.</td> <td>3.80 g</td> </tr> <tr> <td>L-threonine Ph. Eur.</td> <td>4.80 g</td> </tr> <tr> <td>L-tryptophan Ph. Eur.</td> <td>1.90 g</td> </tr> <tr> <td>L-valine Ph. Eur.</td> <td>6.20 g</td> </tr> <tr> <td>L-arginine Ph. Eur.</td> <td>4.90 g</td> </tr> <tr> <td>L-histidine Ph. Eur.</td> <td>4.30 g</td> </tr> </tbody> </table>	Active Ingredients	Quality	L-isoleucine Ph. Eur	5.10 g	L-leucine Ph. Eur.	10.30 g	L-lysine monoacetate corresponding to L-lysine USP	10.01 g 7.1 g	L-methionine Ph. Eur.	2.80 g	N-acetyl-L-cysteine Corresponding to L-Cysteine Ph. Eur.	0.50 g 0.37 g	L-phenylalanine Ph. Eur.	3.80 g	L-threonine Ph. Eur.	4.80 g	L-tryptophan Ph. Eur.	1.90 g	L-valine Ph. Eur.	6.20 g	L-arginine Ph. Eur.	4.90 g	L-histidine Ph. Eur.	4.30 g	Balanced supply of protein elements in acute and chronic renal insufficiency as well as during peritoneal and hemodialysis treatment.	15.03.2021				
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12.	<p>Each extended release tablet contains:</p> <p>Pseudoephedrine Hydrochloride IP...120mg Fexofenadine Hydrochloride IP.....60mg</p> <p>(Additional Dosage form)</p>	It is indicated for the relief of symptoms associated with allergic rhinitis in adults and children 12 years of age and older.	19.03.2021																								
13.	<p>Each Film coated bilayered tablets contains: Mirabegron (in extended release) + Solifenacin Succinate (50mg + 5mg & 25mg + 5mg)</p>	It is indicated for the treatment of overactive bladder (OAB)	08.04.2021																								
14.	<p>Each 10ml liquid sachet contains: Sodium Hyaluronate BP.....1.24% Chondroitin Sulfate Sodium BP....3.12% Poloxamer IP (407).....2.7% Oral Liquid</p>	For the treatment of symptoms of Gastro Esophageal Reflux Disease (GERD)	09.04.2021																								
15.	<p>Each pack (200 ml) contains:</p> <p>Zinc Sulphate Monohydrate IP0.0110g Sodium Citrate IP.....0.5800g Potassium chloride IP.....0.3000g Sodium Chloride IP.....0.5200g Dextrose Anhydrous IP.....2.7000g</p>	For oral rehydration in various etiology	15.04.2021																								
16.	<p>Each Film Coated tablets contains:</p> <p>L-Tyrosine USP.....60mg Histidine Hydrochloride Monohydrate BP eq. to Histidine.....76mg L-Tryptophan USP.....46mg L-Threonine USP.....106mg L-Lysine Acetate USP.....210mg Calcium-DL-2-hydroxy-4(methylthio) Butyrate (α-Ketoanalogue to Methionine Calcium salt) IH.....118mg Calcium-3-Methyl-2 Oxo-Butyrate (α-Ketoanalogue to Valine Calcium salt) IH.....172mg</p>	Prevention and treatment of damages due to faulty of 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	18.05.2021																								

	<p>Calcium-2-Oxo-3-Phenylpropionate (α-Ketoanalogue to Phenylalanine Calcium salt) IH.....136mg</p> <p>Calcium-4-Methyl-2-Oxo-Valerate (α-Ketoanalogue to Leucine Calcium salt) IH.....202mg</p> <p>Calcium-3-methyl-2-Oxo-Valerate (α-Ketoanalogue to Isoleucine Calcium salt) IH.....134mg</p>		
17.	<p>Each 5ml sustained release oral suspension contains:</p> <p>Dextromethorphan Polistirex eq. to Dextromethorphan Hydrobromide IP 30mg</p> <p>ChlorpheniraminePolistirex eq. to Chlorpheniramine Maleate IP4mg</p> <p>Methyl Paraben IP10mg</p> <p>Propyl paraben IP1mg</p>	For the temporary relief of cough, due to throat irritation, sneezing and running nose.	23.06.2021
18.	<p>Each tablet contains:</p> <p>RemogliflozinEtabonate.....100mg</p> <p>Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin10mg</p>	<p>It is indicated in adults aged 18 years and older with type 2 diabetes mellitus:</p> <ul style="list-style-type: none"> To improve glycaemic control when Metformin and one of mono-components of fixed dose combination of RemogliflozinEtabonate& Teneligliptin do not provide adequate glycaemic control, When already being treated with the free combination of RemogliflozinEtabonate& Teneligliptin. 	28.06.2021
19.	<p>Each capsule contains:</p> <p>Tamsulosin Hydrochloride IP (as prolonged release pellets)0.4mg</p> <p>Tadalafil IP (as film coated tablet).....5mg</p>	Substitution therapy in treatment of benign prostatic hyperplasia and erectile dysfunction in patients who are already taking Tamsulosin and Tadalafil concomitantly.	02.07.2021
20.	<p>Each hard gelatin capsule contains:</p> <p>Rosuvastatin Calcium IP eq. to Rosuvastatin.....20mg (as film coated immediate release tablet)</p> <p>Choline Fenofibrate IP eq. to Fenofibric acid (as delayed release tablet).....135mg</p>	For the treatment of mixed dyslipidemia	06.07.2021
21.	<p>Each 1 g contains:</p> <p>Lincomycin Hydrochloride.....0.222g</p> <p>Spectinomycinsulphate.....0.445g</p>	<p>Poultry: For prevention and treatment of Chronic Respiratory Disease(CRD)/airsacculitis caused by Mycoplasma spp. And CCRD (Complicated Chronic Respiratory Disease) associated with Mycoplasma and coliform infections ofpoultry susceptible to the combination of lincomycin and spectinomycin.</p> <p>Swine(pigs): For the treatment of swine dysentery, bacterial enteritis caused by Ecoli or Salmonella spp., porcine proliferative</p>	09.07.2021

		<p>enteropathy (Ileitis) caused by Lawsonia intracellularis and infectious arthritis caused by organisms susceptible to the combination of lincomycin and spectinomycin.</p> <p>[This drug combination will be used for therapeutic purpose (not for the growth promotion purpose) considering the growing concern of Antimicrobial resistance]</p>	
22.	<p>Each tablets contains:</p> <p>Dydrogesterone IP.....2.5mg</p> <p>Estradiol EP.....0.5mg</p>	For the treatment of Hormone replacement therapy (HRT) in estrogen deficiency in postmenopausal women with a uterus	16.07.2021
23.	<p>Each spray delivers contains:</p> <p>Fluticasone Furoate.....27.5mcg</p> <p>Oxymetazoline Hydrochloride IP...50mcg</p> <p>Composition:</p> <p>Fluticasone Furoate.....0.028%w/w</p> <p>Oxymetazoline Hydrochloride IP.....0.050%w/w</p> <p>Benzalkonium Chloride solution IP.....0.030%w/w</p>	Indicated for the treatment of symptoms of allergic rhinitis with nasal congestion	16.07.2021
24.	<p>Each film coated tablet contains:</p> <p>Dextromethorphan Hydrobromide IP.....10mg</p> <p>Phenylephrine Hydrochloride IP.....5mg</p> <p>Chlorpheniramine Maleate IP.....2mg</p>	Indicated for relief from the symptoms of common cold and nasal congestion and associated fever due to allergic reactions.	16.07.2021
25.	<p>Each Combipack contains:</p> <p>One Tablet of Netupitant 300mg (each film coated) and</p> <p>One tablet of Palonosetron Hydrochloride USP eq. to Palonosetron 0.5mg (each uncoated tablet)</p>	<ul style="list-style-type: none"> For the prevention of acute and delayed nausea and vomiting associated with highly emetogenic Cisplatin-based cancer chemotherapy. For the prevention of acute and delayed nausea and vomiting associated with moderate emetogenic cancer chemotherapy in adults. 	29.07.2021
26.	<p>Composition of Hydroxyl Ethyl Starch 6% Solution for infusion (Pack Size-250ml, 500ml)</p> <p>Per 1000ml solution for infusion contains:</p> <p>Poly (O-2-hydroxyethyl) starch....60.00g</p> <p>Sodium Chloride Ph. Eur.9.00g</p> <p>Other Excipients:</p> <p>Sodium hydroxide Ph. Eur. Hydrochloride acid Ph. Eur., Water for injections Ph. Eur.</p> <p>Electrolytes: Na+, Cl- 154 mmol, 154 mmol</p>	For the treatment and prophylaxis of hypovolaemia in adults and children. It is not a substitute for red blood cells or coagulation factors in plasma.	29.07.2021
27.	<p>Magnesium chloride Hexahydrate 0.3gm + Potassium chloride 0.3gm + Sodium chloride 6.02gm + Sodium acetate Trihydrate 4.63gm</p>	For the treatment and prophylaxis of hypovolaemia in adults and children. It is not	30.07.2021

	+ Poly (O-2-hydroxyethyl) starch 60gm per 1000ml solution for infusion (Pack size 250ml & 500ml)	a substitute for red blood cells or coagulation factors in plasma.	
28.	<p>i. Sodium Alginate IP 250mg + Sodium Bicarbonate IP 106.5mg + Calcium Carbonate IP 187.5mg chewable tablet</p> <p>ii. Sodium Alginate IP 250mg + Sodium Bicarbonate IP 106.5mg + Calcium Carbonate IP 162.5mg per 5ml suspension</p>	Heartburn and Indigestion	05.08.2021
29.	<p>Each ml contains:-</p> <p>Ropivacaine Hydrochloride IP Eq. to anhydrous Ropivacaine Hydrochloride.....7.5mg Dextrose (Monohydrate) IP.....80mg Water for Injections IP.....q.s</p>	For the patients undergoing lower limb orthopedic surgeries under Spinal Anesthesia.	13.08.2021
30.	<p>Each Film Coated Tablet contains:-</p> <p>Lamivudine IP.....300mg Dolutegravir Sodium eq. to Dolutegravir.....50mg</p>	Indicated as a complete regimen for the treatment of human immunodeficiency virus type1 (HIV-1) infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per ml) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components.	13.08.2021
31.	<p>Each hard gelatin capsule contains:-</p> <p>Atorvastatin Calcium IP Eq. to Atorvastatin.....40mg ClopidogrelBisulphate IP Eq. to Clopidogrel.....75mg (Additional Strength)</p>	For the treatment of dyslipidemia associated with atherosclerotic arterial disease with risk of myocardial infarction, stroke or peripheral vascular disease	13.08.2021
32.	<p>Each Film Coated tablet contains:-</p> <p>Isoniazid IP.....300mg Rifampentine.....300mg (Additional Indication)</p>	For the treatment of latent tuberculosis infection caused by Mycobacterium tuberculosis in patients who are at risk of progression to tuberculosis disease (including those in close contact with active tuberculosis patients, recent conversion to a positive tuberculin skin test, HIV-infected patients, or those with pulmonary fibrosis on radiograph)	06.09.2021
33.	<p>Each 10 ml contains:-</p> <p>Sodium Alginate IP.....500mg Sodium Bicarbonate IP.....213mg Calcium Carbonate IP.....325mg Oral Suspension</p>	Heartburn and indigestion	07.09.2021
34.	1. Solution for Infusion 1000ml (NutriflexPeri)Upper Chamber	Supply of the daily requirement of energy, amino acids, electrolytes, and fluids during	13.09.2021

	<p>contains (400mI): Isoleucine 2.34gm + Leucine 3.13gm + Lysine Hcl 2.84gm as Lysine 2.27gm + Methionine 1.96gm + Phenylalanine 3.51gm + Threonine 1.82gm + Tryptophan 0.57gm + Valine 2.60gm + Arginine Monoglutamate 4.98gm as Arginine 2.70gm + Glutamic Acid 2.28gm + Histidine HCl Monohydrate 1.69gm as Histidine 1.25gm + Alanine 4.85gm + Aspartic Acid 1.50gm + Glutamic Acid 1.22gm + Glycine 1.65gm + Proline 3.40gm + Serine 3.00gm + Magnesium Acetate Tetrahydrate 0.86gm + Sodium Acetate Trihydrate 1.56gm + Potassium Dihydrogen Phosphate 0.78gm + Potassium Hydroxide 0.52gm + Sodium Hydroxide 0.50gm</p> <p>Lower Chamber Contains (600mI): Glucose Monohydrate 88.0gm as Anhydrous Glucose 80gm + Sodium Chloride 0.17gm + Calcium Chloride Dihydrate 0.37gm</p>	Parenteral nutrition for patients with mild to moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.	
35.	<p>1. Solution for Infusion 1000ml (Nutriflex Plus) Upper chamber contains (400ml): Isoleucine 2.82 gram (gm) + Leucine 3.76gm + Lysine Hydrochloride 3.41gm as Lysine 2.73gm + Methionine 2.35gm + Phenylalanine 4.21gm + Threonine 2.18gm + Tryptophan 0.68gm + Valine 3.12gm + Arginine monohydrate 5.98gm as Arginine 3.24gm and Glutamic acid 2.74gm + Histidine hydrochloride monohydrate 2.03gm as Histidine 1.50 gm + Alanine 5.82gm + Aspartic acid 1.8gm + Glutamic acid 1.470gm + Glycine 1.98 gm + Proline 4.08gm + Serine 3.60gm + Magnesium acetate tetrahydrate 1.23gm + Sodium acetate trihydrate 1.56gm + Sodium Dihydrogen Phosphate Dihydrate 3.12gm + Potassium Hydroxide 1.40gm + Sodium Hydroxide 0.23gm</p> <p>Lower chamber contains (600ml): Glucose monohydrate 165.0gm as anhydrous glucose 150gm + Calcium chloride dihydrate 0.53gm</p> <p>2. Solution for Infusion 2000ml Upper chamber contains (800ml): Isoleucine 5.64 (gram) gm + Leucine 7.52gm + Lysine Hydrochloride 6.82gm as Lysine 5.46gm +</p>	Supply of the daily requirement of energy, amino acids, electrolytes, and fluids during Parenteral nutrition for patients with mild to moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.	13.09.2021

	<p>Methionine 4.7gm + Phenylalanine 8.42 gm + Threonine 4.36gm + Tryptophan 1.36gm + Valine 6.24gm + Arginine Monoglutamate 11.96gm as Arginine 6.48gm and Glutamic acid 5.48gm + Histidine hydrochloride monohydrate 4.06gm as Histidine 3.00 gm + Alanine 11.64gm + Aspartic acid 3.60gm + Glutamic acid 2.94gm + Glycine 3.96 gm + Proline 8.16gm + Serine 7.20gm + Magnesium acetate tetrahydrate 2.46gm + Sodium acetate trihydrate 3.12gm + Sodium Dihydrogen Phosphate Dihydrate 6.24gm + Potassium Hydroxide 2.80gm + Sodium Hydroxide 0.46gm</p> <p>Lower chamber contains (1200ml): Glucose monohydrate 330.0gm as anhydrous glucose 300gm + Calcium chloride dihydrate 1.06gm</p>		
36.	<p>Each Film Coated Tablets contains:</p> <p>RemogliflozinEtabonate + Vildagliptin + Metformin Hydrochloride IP (100mg + 50mg + 500mg & 100mg + 50mg + 1000mg)</p>	<p>It is indicated as an adjunct to diet and exercise in adults aged 18 years and older with type 2 diabetes mellitus:</p> <ul style="list-style-type: none"> • To improve glycaemic control when Metformin and one of other twomonocomponents of RemogliflozinEtabonate&Vildagliptindo not provide adequate glycaemic control. • When already being treated with the free combination of Metformin, Remogliflozin&Vildagliptin. 	21.09.2021
37.	<p>Each Kit contains:</p> <p>A) 14 nos. Rivaroxaban tablets 2.5mg Each film coated tablet contains: Rivaroxaban.....2.5mg</p> <p>B) 07 nos. Aspirin tablets 75mg Each gastro resistant tablet contains: Aspirin IP.....75mg</p>	<p>Rivaroxaban in combination with Aspirin is indicated to reduce the risk of major cardiovascular events (Cardiovascular (CV) death, myocardia infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).</p>	01.10.2021
38.	<p>Each hard gelatin capsule contains: Pregabalin IP + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed release pellets) (75mg + 20mg, 50mg + 20mg & 75mg + 30mg)</p>	<p>For the treatment of Neuropathic pain</p>	25.10.2021
39.	<p>Each uncoated bilayered tablet contains: -</p> <p>Efonidipine Hydrochloride Ethanolate (as immediate release)40mg S (-) Metoprolol Succinate eq. to S (-) Metoprolol Tartrate (as prolonged release).....25mg</p>	<p>It is indicated for the management of hypertension.</p>	26.10.2021
40.	<p>Each 10 ml contains: Sodium Alginate IP1000mg Potassium Hydrogen Carbonate Ph. Eur.....200mg Oral Suspension</p>	<p>To treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or withdrawal of acid suppressing therapy.</p>	01.11.2021

41.	Each 5 gram contains: Sildenafil Citrate IP eq. to Sildenafil ...100mg Dapoxetine Hydrochloride eq. to Dapoxetine.....60mg Oral Jelly (In Additional Dosage form)	For the treatment of co-existing erectile dysfunction and premature ejaculation in men 18-64 years of age.	09.11.2021
42.	Clindamycin Phosphate USP ...1.2% Benzoyl Peroxide USP5% topical gel	For the treatment of Acne Vulgaris	09.11.2021
43.	Each film coated tablet contains:- Sitagliptin Phosphate eq. to Sitagliptin IP + Metformin Hydrochloride IP (as an extended-release form) (100mg +1000mg & 100mg + 500mg)	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.	11.11.2021
44.	Each Capsule contains: Aspirin (eneteric coated pellets form)...75mg Atorvastatin (As pellets form).....20mg	For the treatment of dyslipidemia associated with atherosclerotic arterial disease with risk of myocardial infarction, stroke or peripheral vascular disease.	23.11.2021
45.	Each film coated tablets contains:- Amlodipine Besylate USP Eq. to Amlodipine.....10mg Olmesartan Medoxomil USP40mg (In Additional Strength)	<ol style="list-style-type: none"> 1. For the treatment of hypertension alone or with other antihypertensive agents. 2. To use as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals. 	25.11.2021
46.	Each ml contains:- Levobupivacaine Hydrochloride eq. to Levobupivacaine.....5mg Dextrose (Monohydrate) IP.....80mg Water for injections IP.....Q.S	For spinal anesthesia in adults patients	26.11.2021
47.	Each ml contains: Brinzolamide IP.....10mg Timolol Maleate IP eq. to Timolol.....5mg Potassium Sorbate IP.....0.47%w/v (as preservative) Ophthalmic Suspension	Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.	09.12.2021

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.

