

**FIXED DOSE COMBINATIONS APPROVED BY DCG (I) From 1<sup>st</sup> January 2021 to 30<sup>th</sup> June 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 <b>(Additional Strength)</b>	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 Zinc .....10mg Ascorbic Acid IP .....1000mg 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 IP .....75mg (As one gastro-resistant tablet) <b>(Additional Strength)</b>	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 Ceftazidime .....2gm Avibactam Sodium eq. to Avibactam.....0.5gm <b>Powder for concentrate for solution for infusion</b>	<ul style="list-style-type: none"> <li>• Complicated Intra-abdominal infections (cIAI)</li> <li>• Complicated Urinary tract infections (cUTI), including pyelonephritis</li> <li>• Hospital-acquired pneumonia (HAP) including ventilator associated pneumonia (VAP) with susceptible gram negative microorganisms.</li> </ul> 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) <b>Per 1000ml solution for infusion contains:</b>	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 &amp; 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><b>Per 1000ml solution for infusion contains:</b></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><b>(Additional Dosage form)</b></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:</p> <p>Mirabegron (in extended release) + Solifenacin Succinate (50mg + 5mg &amp; 25mg + 5mg)</p>	It is indicated for the treatment of overactive bladder (OAB)	08.04.2021																										
14.	<p>Each 10ml liquid sachet contains:</p> <p>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 IP ....0.0110g 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</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																										

	Calcium-DL-2-hydroxy-4(methylthio) Butyrate ( $\alpha$ -Ketoanalogue to Methionine Calcium salt) IH.....118mg Calcium-3-Methyl-2 Oxo-Butyrate ( $\alpha$ -Ketoanalogue to Valine Calcium salt) IH.....172mg Calcium-2-Oxo-3-Phenylpropionate ( $\alpha$ -Ketoanalogue to Phenylalanine Calcium salt) IH.....136mg Calcium-4-Methyl-2-Oxo-Valerate ( $\alpha$ -Ketoanalogue to Leucine Calcium salt) IH.....202mg Calcium-3-methyl-2-Oxo-Valerate ( $\alpha$ -Ketoanalogue to Isoleucine Calcium salt) IH.....134mg		
17.	Each 5ml sustained release oral suspension contains: Dextromethorphan Polistirex eq. to Dextromethorphan Hydrobromide IP 30mg Chlorpheniramine Polistirex eq. to Chlorpheniramine Maleate IP .....4mg Methyl Paraben IP .....10mg Propyl paraben IP .....1mg	For the temporary relief of cough, due to throat irritation, sneezing and running nose.	23.06.2021

**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.**