

FIXED DOSE COMBINATIONS APPROVED BY DCG (I) Nov 2024 to Mar 2025

S. NO.	Name of FDC	Indication	Date of approval
1.	Linagliptin 2.5mg + Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin 5mg film coated tablet	For the treatment in patients with type 2 Diabetes Melitus Inadequately Controlled on Metformin Monotherapy.	25-11-24
2.	Dapagliflozin Propanediol Monohydrate IP eq. to Dapagliflozin + Gliclazide IP + Metformin Hydrochloride IP (10mg + 30mg + 500mg & 10mg + 60mg + 500mg) film coated bilayered tablets	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes melitus inadequately controlled with metformin Monotherapy	25-11-24
3.	Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Metoprolol Succinate IP eq. to Metoprolol Tartrate (Extended Release) (10mg + 23.75mg eq. to 25mg & 10mg + 47.50mg eq. to 50mg) film coated bilayer tablets	It is indicated in patients with heart Failure with Reduced Ejection Fraction (HFrEF)	27-11-24
4.	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Bisoprolol Fumarate IP (10mg + 1.25mg & 10mg + 2.5mg) film coated tablets	Heart failure with Reduced Ejection Fraction (HFrEF)	13-12-24
5.	Empagliflozin + Linagliptin + Metformin Hydrochloride (as extended release) (10mg + 5mg + 1000mg & 25mg + 5mg + 1000mg) film coated tablets	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.	14-01-2025
6.	L-Alanyl L-Glutamine 20gram (L-Alanine USP 8.2 & L-Glutamine USP 13.46gram) + Sodium Chloride 0.9gram per 100ml injection (Pack size Non PVC Bag and PVC Bag 100ml and 50ml)	It is indicated for the treatment of short term fluid replacement after trauma.	12-02-25
7.	Glycopyrronium (As Glycopyrrolate IP) 12.5mcg + Formoterol Fumarate Dihydrate IP 6mcg inhaler	It is indicated as a maintenance bronchodilator treatment to relief symptoms in adults patients with chronic obstructive pulmonary disease (COPD).	05-03-25
8.	Aztreonam 1.5g + Avibactam Sodium 0.5g eq. to Avibactam Sodium approximately 44.6mg Powder for Concentrate for Solution for Infusion	For the treatment of the following infection in adult patients- Complicated intra abdominal infection, Hospital acquired pneumonia, including ventilator associated pneumonia, Complicated urinary tract infection, including pyelonephritis. It is also indicated for the treatment of infection due to aerobic Gram negative organisms i adult patients with limited treatment options. Consideration should be given to	05-03-25

		official guidance on the appropriate use of antibacterial agents.	
9.	Vilanterol trifenate eq. to Vilanterol 12.5mcg + Glycopyrrolate IP eq. to Glycopyrronium 25mcg + Fluticasone Furoate Ph. Eur. 100mcg metered dose inhalation (120 Metered doses)	For the maintenance treatment of asthma in patients aged 18 years and older	05-03-2025
10.	Vilanterol trifenate eq. to Vilanterol 25mcg + Glycopyrrolate IP eq. to Glycopyrronium 50mcg + Fluticasone Furoate Ph. Eur. 200mcg capsules	For the maintenance treatment of asthma in patients aged 18 years and older	19-03-2025

Note 1: It may be stated that the above list of FDCs are 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.