

	Availability in market	Strength	Approval date	Indication according to CDSCO	Dosage	Comment	NLEM 2022	WHO Model List	USFDA	BNF
Analgesics										
Paracetamol	Yes	650 mg as a Sustained release preparation	1996	Not mentioned	Not available	Worldwide the concern is to restrict the dose of paracetamol to 325 mg. Now 650 mg is a best-selling strength in India. This strength escapes price control	No	No	No	No
Nimesulide + Paracetamol	Yes	100 mg nimesulide + 500 mg paracetamol	No evidence of approval	Not mentioned on site	Not available	Unsafe combination as nimesulide should not be combined with any other NSAID, because of risk of hepatotoxicity Combination with nimesulide escapes price control	No	No	No	No
Diazepam + Paracetamol	?	5 mg Diazepam + 500 mg Paracetamol	October 1977	Not mentioned on site	Not available	Bizarre FDC of benzodiazepine and NSAID. Should have been removed from website. No review information	No	No	No	No
Antibiotics										
Doxycycline + Lactobacillus 5 billion	Yes	Doxycycline 100 mg + Lactobacillus 5 billion spores	12.11.2007	Indication: "For adult patients prone to intrabdominal bacterial infection & Antibiotic associated diarrhoea"	Not available	Also available at Lactobacillus 60 million cells. Other combinations of doxycycline available in the market: with tinidazole, chymotrypsin, and serratiopeptidase not	No	No	No	No

						listed on CDSCO. Combinations more than 2 times expensive than single ingredient doxycycline. Combination with Lactobacillus escapes price control				
Ceftriaxone + sulbactam	Yes	NA	8.12.2005	NA Composition: Dosage: NA Indication: "For LRTI"	Not available	Widely sold FDC in India. No similar combination approved in any well-regulated market. Combination with sulbactam puts ceftriaxone outside price control	No	No	No	No
Ceftriaxone + sulbactam + EDTA	Yes	Not mentioned	Not mentioned in list of new drugs approved in 2011, but mentioned in list of FDCs	Drug combination not mentioned in CDSCO website	Not mentioned	No well-designed RCT to support its use. Pharmacologists and microbiologists have raised concern. [45, 61]. However, it sells in even leading hospitals. While DCGI is silent on this FDC, it has banned Meropenem + EDTA.[62]	No	No	No	No
Proton pump inhibitors										
Pantoprazole + Domperidone	Yes	20 mg+ 10 mg	Approval Date: 24/12/2004	Type: NA Dosage: NA Indication: "By RMP- for the treatment of gastroesophageal reflux diseases	Not mentioned	This is a very widely used FDC in India for dyspepsia and for prolonged duration. Proton Pump Inhibitors can reduce iron absorption, increase risk of C.difficile diarrhea, be a risk factor for fractures	No	No	Domperidone is not licensed for use in US	Domperidone only recommended for short duration treatment of nausea and vomiting.

				(GERD) not responding to pantoprazole”.		and kidney disease. Domperidone increases risk of arrhythmias in patients with cardiac disease.				
<i>CDSCO: Central Drugs Standards Control Organisation; NLEM: National List of Essential Medicines, 2022; WHO Model list of Essential Medicines; US FDA: United States Food and Drug Administration; BNF: British National Formulary; FDC: Fixed Dose Combinations; RMP: Registered Medical Practitioner.</i>										

Supplementary Table. Regulatory approvals by CDSCO -rationale and comparison with regulatory status in other parts of the world and presence of medicines or their FDCs in lists of essential medicines.

Source of information on Indian FDC approvals: CDSCO. Available from: <https://cdscoonline.gov.in/CDSCO/cdscoDrugs>