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File No. 4-01/2023-DC (Misc. 3)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

11 APR 2025

To,
All State/ UT's Drugs Controllers

Subject: Manufacturing and marketing of unapproved FDC's - regarding.

Sir/ Madam,

With reference to the letter issued by this office vide F.No. 4-01/2013-DC (Misc13-PSC) dated 15.01.2013, wherein concerns were raised regarding the grant of manufacturing licenses for sale of the Fixed Dose Combination (FDC) drugs that fall under the definition of a "New Drug" in the country without due approval from Drugs Controller General (India). The same concern has been raised from time to time and multiple letters have been issued to the respective SLA's that granted permission for manufacturing & marketing of unapproved FDC's. The recent such letter was issued on 28.02.2025.

With reference to the above subject, it has come to the notice of this Directorate that certain Fixed Dose Combination (FDC) drugs have been licensed for manufacture, sale, and distribution without prior evaluation of safety and efficacy as per the provision of NDCT Rules 2019 under the Drugs & Cosmetics Act 1940. This poses a serious risk to public health and safety.

The approval of such unapproved FDC's compromises patient safety and may lead to adverse drug reactions, drug interactions, and other health hazards due to the absence of scientific validation. Upon issuance of show cause notices to the manufacturers, they have stated that these licenses were granted by the respective Drug Licensing Authorities and have not violated any Rules. This has resulted in a lack of uniform enforcement of the provision of NDCT Rules 2019 under the Drugs & Cosmetics Act 1940 across the country.

In view of the above, all the State and Union Territory Drug Controllers are requested to review their approval process for such FDC's and ensure strict compliance of the provisions of the Act and Rules. Public health and safety must remain the top priority.

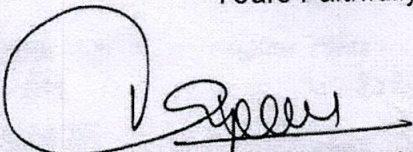
A list of unapproved FDC's which were earlier licensed by State/ Union Territory Drug Controllers for manufacture, sale, and distribution without evaluation of safety & efficacy by CDSCO and later on cancelled by Drug Licensing Authorities (SLAs) or voluntarily surrendered by manufacturers following the issuance of show cause notices is annexed for reference.

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Accordingly, all the State/ UT Drugs Controllers are requested to ensure that the FDC's in annexure & any other unapproved FDC's shall not be allowed for manufacture, sale, & distribution in the country and also conduct the investigation & take necessary action as per the provision of NDCT Rules 2019 under the Drugs & Cosmetics Act 1940 and the same shall be intimated to this office.

This matter may be treated as **urgent & serious**.

Yours Faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy forwarded to:-

1. All Zonal/Sub Zonal Offices of CDSCO
2. US (D), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
3. Website of CDSCO

List of Unapproved FDCs with Cancelled / Surrendered Product Permission

Sr. No.	Name of FDC
1.	Combipack of Each film coated extended release tablet contains: Mirabegron 25mg and Each film coated tablet contains: Solifenacin Succinate 5mg
2.	Nefopam Hydrochloride 30mg + Paracetamol 325mg tablets
3.	Metformin Hydrochloride IP 500mg (as extended release form) + Glimepiride IP 3mg + Dapagliflozin Propanediol Monohydrate IP eq. to Dapagliflozin 10mg film coated bilayered tablets
4.	FDC of: (i) Dextromethorphan Hydrobromide IP 10mg + Phenylephrine Hydrochloride IP 5mg per 5ml Syrup & (ii) Diphenhydramine Hydrochloride IP 12.5mg + Phenylephrine Hydrochloride IP 5mg per 5ml Syrup
5.	Cilnidipine IP 20mg + Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate 50mg film coated Bilayered tablet
6.	Ketoconazole IP 2.0%w/w + Neomycin Sulphate IP 0.5%w/w + Idochlorhydroxyquinoline IP 1%w/w + Tolnaftate IP 1%w/w + Clobetasol Propionate IP 0.05%w/w cream
7.	Dehydroepiandrosterone SR 75mg + Melatonin BP 3mg + Ubidecarenone (Coenzyme Q 10) BP 100mg capsules
8.	Cefixime IP 200mg + Ofloxacin IP 200mg + Lactic acid bacillus 60 million spores tablets
9.	Aluminium Hydroxide Gel IP eq. to Aluminium Hydroxide 365mg + Magnesium Hydroxide Paste 1 USP eq. to Magnesium Hydroxide 80mg + Simethicone USP 100mg + Deglycyrrhizinated Liquorice eq. to Liquorice 400mg per 5ml oral suspension
10.	Alpha amylase IP(1:800):28.125mg (fungal Diastase derived from <i>Apergillus oryzae</i>) Digest not less than 22.5g of cooked starch, Papain IP 15mg + Anise Oil I.P 1mg + Caraway oil IP 1mg + Cinnamon Oil BP 1mg + Dill oil BP 1mg syrup
11.	Omega-3 fatty acids BP 300mg Eq. to EPA 90mg Eq. to DHA 60mg + Wheat germ oil BP 100mg + Green tea extracts Eq. to Polyphenols 25mg + Zinc sulphate monohydrate IP eq. to elemental zinc 12.5mg + Biotin BP 5mg + Lutein USP 5mg + Zeaxanthin 1mg + Copper sulphate pentahydrate BP Eq. to elemental copper 1mg + Selenium Dioxide USP Eq. to elemental selenium 75mcg soft gelatin capsules
12.	Pregabalin (SR) IP 75mg + Nortriptyline HCl IP 10mg + Vitamin D3 IP 2000IU + Mecobalamin IP 1500mcg tablet
13.	Acebrophylline (SR) 200mg + Montelukast Sodium IP 10mg + Fexofenadine Hydrochloride IP 120mg tablet
14.	Dehydroepiandrosterone 75mg (as sustained release) + Folic Acid IP 4.5mg tablet
15.	Dyhydroepiandrostrone 75mg + Melatonin BP 5mg + Ubidecarenone BP 100mg tablet

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16.	Sertraline Hydrochloride IP eq. to Sertraline 50mg + Clonazepam IP 0.5mg tablets
17.	Sertraline Hydrochloride IP eq. to Sertraline 50mg + Clonazepam IP 0.25mg tablets
18.	Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As Immediate Release Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Immediate Release Pellets) & Aspirin IP 150mg (As Gastro-Resistant Pellets) Capsule
19.	Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As Immediate Release Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Immediate Release Pellets) & Aspirin IP 150mg (As Gastro-Resistant Pellets) Capsule
20.	Tamsulosin Hydrochloride IP 0.4mg & Finasteride IP 5mg Tablet
21.	Metoprolol Succinate USP 23.75 mg eq. to Metoprolol Tartrate 25mg and Ramipril IP 2.5mg Tablet
22.	Bisoprolol Fumarate IP 5mg & Cilnidipine IP 10mg tablets
23.	Chlorpheniramine Maleate IP 4mg + Codeine Phosphate IP 10mg + Sodium Citrate IP 75mg Syrup
24.	Rifaximin BP 200mg & Metronidazole Benzoate IP Eq. to Metronidazole 400mg Tablets
25.	Cefixime (as Trihydrate) IP eq. to Anhydrous Cefixime 200mg + Azithromycin Dihydrate IP eq. to Anhydrous Azithromycin 250mg + Lactic Acid Bacillus 60 million spores film coated tablets
26.	Norfloxacin IP 125mg + Metronidazole Benzoate IP eq. to Metronidazole 120mg + Simethicone IP 10mg suspension
27.	Cyproheptadine HCl IP 4mg + Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 5mg uncoated tablet
28.	Meropenem 1gm + EDTA for injection Injection
29.	Glimepiride IP 1mg & Metformin HCL IP 500mg Tablet
30.	Glimepiride IP 2mg, Metformin Hydrochloride IP (As Sustained Release form) 500mg and Voglibose IP 0.3mg Tablet
31.	Metformin Hydrochloride IP (As Prolonged-Release) 500mg & Voglibose IP 0.2mg Tablet
32.	Ofloxacin IP 50mg, Ornidazole IP 125mg and Racecadrotil IP 15mg syrup
33.	Ambroxol Hydrochloride IP 20mg + Dextromethorphan Hydrobromide IP 10mg + Chlorpheniramine Maleate IP 2mg per 5ml syrup
34.	Ketoconazole IP 2.0%w/w + Iodochlorhydroxyquinoline IP 1%w/w + Tolnaftate IP 1%w/w + Clobetasol Propionate IP 0.05%w/w + Neomycin Sulphate IP 0.10%w/w cream base
35.	Meropenem 1000mg + Avibactam (Sterile) IP eq. to Avibactam 500mg Injection