

F. No. 04-146/2007-DC (Part-I)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road,
New Delhi

Dated: 27/8/2021

To,
All State/UT Drugs Controller

Subject:- Procedure to be followed for regularisation of FDCs (Fixed Dose Combinations) declared as rational in respect to 294 FDCs by the DTAB which were licensed to manufacture and market by State Licensing Authority (SLA) without prior approval from DCG(I)-regarding.

Sir,

This is in continuation to this Directorate letter of even number dated 27.02.2019 and 08.09.2020 whereby a detailed pathway was issued for obtaining permission from this Directorate in respect of 83 FDCs and subsequently 03 FDCs declared as rational.

As per the report of DTAB dated 13.04.2021 and recommendations of subcommittee of DTAB as approved, 31 more FDCs have been considered as **rational** under 294 FDCs category. The list of these 31 FDCs is enclosed as **Annexure - A**.

All the manufacturers who are already holding licenses from State Licensing Authorities for such FDCs and did not obtain NOC from DCG (I) are required to submit their applications to this Directorate at the earliest within 06 months.

In view of above, you are requested to direct all concerned stakeholders for submission of application in Form CT-21 as per the defined pathway for clearance of the cases. You are also requested to ensure that product license in respect of these 31 FDCs are issued after the approval of DCG(I) in favour of the applicant.

Yours faithfully,



(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to:-

1. PS to JS(R), Ministry of Health and family Welfare, Nirman Bhawan, New Delhi
2. CDSCO Zonal and Sub-Zonal offices
3. Drug Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE/Indian Drug/Pharmaceuticals Association Forum
4. Website of CDSCO

Annexure - A

| S. No. | Name of the FDC | Recommendations |
|---------------|--|---|
| 1. | Amoxicillin+ Cloxacillin+ Lactic acid bacillus | Rational. |
| 2. | Amoxycillin+ Clavulanic acid+ Lactic acid bacillus | Rational. |
| 3. | Amoxycillin+ Lactic acid bacillus | Rational. |
| 4. | Amoxycillin+ Lactobacillus acidophilus+ Flucloxacillin Sodium | Rational. |
| 5. | Ampicillin+ Cloxacillin+ Lactic acid bacillus | Rational. |
| 6. | Ampicillin+ Lactic acid bacillus | Rational. |
| 7. | Calcium dobesilate+ Lignocaine+ Hydrocortisone | Rational for short term use. |
| 8. | Cefadroxy+ Lactic acid bacillus | Rational |
| 9. | Cefdinir+ Lactic acid bacillus | Rational |
| 10. | Cefixime+ Lactic acid bacillus | Rational |
| 11. | Cefixime+ Lactobacillus+ Dicloxacillin | Rational if Dicloxacillin is in sustained release form in twice daily doses schedule and Indication of the FDC should be restricted to skin & soft tissue infections. |
| 12. | Cefpodoxime prozetil+ Lactic acid bacillus | Rational |
| 13. | Cefpodoxime+ Cloxacillin+ Lactobacillus | Rational if Cloxacillin is in sustained release form in twice daily doses schedule and Indication of the FDC should be restricted to skin & soft tissue infections. |
| 14. | Cefprozil+ Lactobacillus | Rational |
| 15. | Cepodoxime+ Cloxacillin+ Lactic acid bacillus | Rational if Cloxacillin is in sustained release form in twice daily doses schedule and Indication of the FDC should be restricted to skin & soft tissue infections. |
| 16. | Dicyclomine+ Ranitidine | Rational |
| 17. | Domperidone+ Paracetamol | Rational. FDC is indicated for management of acute migraine. |
| 18. | Domperidone+ Paracetamol+ Tramadol | Rational provided that dose of paracetamol is 325mg. FDC is indicated for management of acute migraine. |
| 19. | Doxycycline+ Lactobacillus | Rational |
| 20. | Drotaverine+ Nimesulide | Rational. FDC is indicated for dysmenorrhoea. |
| 21. | Drotaverine+ Paracetamol | Rational. FDC is indicated for dysmenorrhoea. |
| 22. | Lincomycin+ Lactobacillus | Rational |
| 23. | Ofloxacin+ Lactic acid bacillus | Rational |
| 24. | Ondansetron+ Ranitidine | Rational |
| 25. | Torsemide+ Spironolactone | Rational |
| 26. | Allantoin+Dimethicone + Methylparaben+ Propylparaben | Rational |
| 27. | Aloe vera+Vit-e acetate | Rational if FDC is in cream and lotion dosage form only. |
| 28. | Aloe+ Tocopherol | Rational if FDC is in cream and lotion dosage form only. |
| 29. | Aloevera+Glycerine+PEG 100 stearate+Vit E | Rational if FDC is in cream and lotion dosage form only. |
| 30. | Ampicillin+Flucloxacillin Sodium Salt | Rational |
| 31. | Ampicillin+Flucloxacillin Sodium Salt+ Lactobacillus Acidophilus | Rational |