

**OFFICE OF THE STATE DRUGS CONTROLLER
DRUGS & FOOD CONTROL ORGANIZATION
J&K (JAMMU / SRINAGAR)**

PUBLIC NOTICE

The Central Government (Ministry of Health & Family Welfare) in exercise of the powers conferred by Section 26A of the Drugs & Cosmetics Act, 1940 (23 Of 1940) has issued notifications which command prohibition of 14 below mentioned Fixed Dose Combinations (FDC) (**Manufacture for sale, sale or distribution**) for the reason that Empowered Expert Committee has recommended that there is no therapeutic justification for such FDCs & the FDC may involve risk to Human Beings :

S.No	Drug Fixed Dose Combination	Notification Dated 02.06.2023 vide S.O
1	Nimesulide+ Paracetamol dispersible tablets	2394(E)
2	Amoxicillin+ Bromhexine	2395(E)
3	Pholcodine+ Promethazine	2396(E)
4	Chlorpheniramine maleate + Dextromethorphan + Guaiphenesin + Ammonium Chloride + Menthol	2397(E)
5	Chlopheniramine Maleate + Codeine Syrup	2398(E)
6	Ammomium Chloride + Bromhexine + Dextromethorphan	2399(E)
7	Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol	2400(E)
8	Dextromethorphan + Chlorpheniramine + Guaiphenesin + Ammonium Chloride	2401(E)
9	Paracetamol + Bromhexine + Phenylephrine + Chlorpheniramine + Guaiphenesin	2402(E)
10	Salbutamol + Bromhexine	2403(E)
11	Chlorpheniramine + Codeine Phosphate + Menthol Syrup	2404(E)
12	Phenytoin + Phenobarbitone sodium	2405(E)
13	Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol (100mg + 40mg + 2.5mg + 0.9mg) , (125mg + 55mg + 4mg + 1mg) , (110mg + 46mg + 3mg + 0.9mg) & (130mg + 55mg + 3mg + 0.5mg) per 5ml syrup	2406(E)
14	Salbutamol + Hydroxyethyltheophylline (Etofylline) + Bromhexine	2407(E)

All the Stake Holders are hereby informed through the medium of this Notice not to deal with manufacture for sale, sale or distribution of above FDCs with immediate effect. The stocks of such medicinal preparations / formulations should be recalled through the supply chain and disposed of as per prescribed norms.

Any firm / person found manufacturing / supplying the above said FDCs shall invite action under the provisions of the Drugs and Cosmetics Act, 1940 and Rules there under.

The product permissions (**Manufacture for sale or distribution granted by the Licensing Authority**) of the above FDCs granted in favor of Manufacturing Units located within the Union Territory of J&K may be treated as cancelled with immediate effect.

Sd/

(Lotika Khajuria)
State Drugs Controller
Drug & Food Control Organization
J&K

No. : DFO/D-168/966-988

Dated : 09.06.2023

Copy To :

1. Secretary to Government , Health and Medical Education Department, Civil Secretariat , J&K for favour of information.
2. Drugs Controller General of India, FDA Bhawan, Kotla Road, Delhi for favour of information.
3. Director SKIMS, Srinagar for favor of information & necessary action at the level of Drugs Prescribing Authorities.
4. Principal Medical College, Jammu / Srinagar for information & necessary action at the level of Drugs Prescribing Authorities.
5. Principal Medical Colleges Doda / Kathua / Baramulla / Anantnag / Handwara / Udhampur / Rajouri for information & necessary action at the level of Drugs Prescribing Authorities.
6. Director Health Services, Jammu / Srinagar for information & necessary action at the level of Drugs Prescribing Authorities.
7. Director Family Welfare MCH & Immunization J&K Jammu for information.
8. Managing Director , Jammu & Kashmir Medical Supplies Corporation Ltd for information & necessary action.
9. **Joint Director Information Jammu / Kashmir with the request to get the Public Notice published in leading daily locals of the UT on top most priority in the larger public interest.**
10. **Deputy Drugs Controller, Jammu / Kashmir for information and necessary compliance. Further, requested to instruct sub-ordinate**

offices to display the said Notice over Notice Boards in their respective offices.

11. All ADCs _____ for information and necessary compliance.
12. M/s Saytech Technologies with the request to upload this Notice over the home page of official website of this Organization.