The manufacture, sale and distribution of the below mentioned formulations has been prohibited by the Central Government, Ministry of Health & Family Welfare, Government of India due to the reason that the use of these drugs is likely to involve risk to human beings or the said products do not have the therapeutic value, claim or purported to claimed for them or contain ingredients and in such quantity for which there is no therapeutic justification:-

1. Amidopyrin.
2. Fixed dose combinations of Vitamins with anti-inflammatory agents and tranquilizers
3. Fixed dose combinations of atropine in Analgesics and anti-pyretics.
4. Fixed dose combinations of Strychnine and Caffeine in tonics.
5. Fixed dose combinations of Yohimbin and Strychnine with Testosterone and Vitamins.
7. Fixed dose combinations of sodium Bromide/ chloral Hydrate with other drugs.
8. Phenacetin.
10. Fixed dose combinations of Penicillin with Sulphonamides.
11. Fixed dose combinations of Vitamins with Analgesics
12. Fixed dose combinations of Tetracycline with Vitamin C.
13. Fixed dose combinations of Hydroxyquinoline group of drugs except preparations meant for external use.
14. Fixed dose combinations of corticosteroids with any other drug for internal use.
15. Fixed dose combinations of Chloramphenicol with any other drug for internal use.
17. Fixed dose combinations of Fixed dose combinations of Vitamins with Anti-T.B. Drugs except combination of Isoniazid with Pyridoxin Hydrochloride (Vitamin B6.)
18. Penicillin skin/eye ointment
20. Nialamide.
22. Methapyrilene, its salts.
23. Methaqualone.
26. Combinations of Anabolic steroids with other drugs.
27. Fixed dose combination of Oestrogen and Progestin(other than oral contraceptives) containing per tablet Oestrogen content of more than 50 mcg,(equivalent to Ethenyl Estradiol) and progestin content of more than 3mg (equivalent to Norethysterone Acetate and all fixed dose combination injectable preparations containing synthetic Oestrogen and progesterone.
29. Fixed dose combination of Pyrazinamide with other anti tubercular drugs except combination of Pyrazinamide with Rifampicin and INH as per recommended daily dose given below: - Minimum Maximum.
Rifampicin 450 mg 600 mg
INH 300 mg 300 mg
Pyrazinamide 1000 mg 1500 mg.

30. Fixed dose combination of histamine H2 – receptor antagonists with antacids except those combinations approved by the Drugs Controller, India.

31. The patent and proprietary medicines of fixed dose combinations of essential oils with alcohol having a percentage higher than 20% proof except preparations given in the Indian Pharmacopoeia.

32. All Pharmaceutical preparations containing Chloroform exceeding 0.5% w/w or whichever is appropriate.

33. Fixed dose combination of Ethambutol with INH other than the following:
   INH Ethambutol 200 mg 600 mg. 300 mg. 800 mg.

34. Fixed dose combination containing more than one antihistamine.

35. Fixed dose combination of anthelmintic with cathartic/purgative except for piperazine.

36. Fixed dose combination of salbutamol or any other bronchodilator with centrally acting antitussive and/or antihistaminic.

37. Fixed dose combination of laxatives and/or anti-spasmodic drugs in enzyme preparations.

38. Fixed dose combination of Metaclopramide with other drugs except for preparations containing Metaclopramide and aspirin/paracetamol.

39. Fixed dose combination of centrally acting antitussive with antihistamine having high atropine like activity in expectorants.

40. Preparations claiming to combat cough associated with asthma containing centrally acting anti-tussive and/or other antihistamine.

41. Liquid oral tonic preparations containing and/or other phosphates and/or central nervous system stimulant and such preparations containing alcohol more than 20% proof.

42. Fixed dose combination containing Pectin and/or Kaolin with any drug which is systemically absorbed from GI tract except for combinations of Pectin and/or Kaolin with drugs not systemically absorbed.

43. Chloral Hydrate as a drug.

44. Dover’s Powder I.P.

45. Dover’s Powder Tablets I.P.

46. Anti diarrhoeal formulations containing Kaolin or Pectin or Attapulgite or activated charcoal.

47. Anti diarrhoeal formulations containing Phthalyl sulphathiazole or Sulphaguanidine or Succinyl Sulphathiazole.

48. Anti diarrhoeal formulations Neomycin or Streptomycin or Dihydrostreptomycin including their respective salts and esters.

49. Liquid oral anti-diarrhoeals or any other dosage form for paediatric use containing Diphenoxylate or Loparamide or Atropine or Belladonna including their salts or esters or metabolites Hyoscyamine or their extracts or their alkaloids.

50. Liquid oral anti-diarrhoeals or any other dosage form for paediatric use containing halogenated hydroxyquinolines.

51. Fixed dose combination or anti-diarrhoeals with electrolytes.

52. Patent and Proprietary Oral Rehydration Salts other than those conforming to the following parameters:
   (a) Patent and Proprietary Oral Rehydration Salts on reconstitution to one liter shall contain: -
      Sodium – 50 to 90 millimoles.
      Total osmolarity – not more than 290 millimoles.
      Dextrose: Sodium molar ratio- not less than 1:1 and not more than 3:1.
   (b) Patent and Proprietary cereal based Oral Rehydration Salts on reconstitution to one liter shall contain: -
      Sodium – 50 to 90 millimoles.
      Total osmolarity – not more than 290 millimoles.
Precooked rice - equivalent to not less than 50 gms. And not more than 80 gms. As total replacement of dextrose.
(c) Patent and Proprietary Oral Rehydration Salts (ORS) may contain aminoacids in addition to Oral Rehydration Salts conforming to the parameters specified above and labeled with the indication “For Adult Choletric Diarrhoea only.”
(d) Patent and Proprietary Oral Rehydration Salts shall not contain Mono or Polysaccharides or saccharine sweetening agent.

53  Fixed dose combination of Oxyphenbutazone or Phenylbutazone with any other drug.
54  Fixed dose combination of Analgin with any other drug.[The words ‘other than anti-spasmodics’ omitted by G.O.I. notification no. 405(E) dt.03.06.1999.]
55  Fixed dose combination Dextropropoxyphene with any other drug other than anti-spasmodics and/or non-steroidal anti-inflammatory drugs (NSAIDS).
56  Fixed dose combination of a drug, standards of which are specified in the Second Schedule to the said Act with an Ayurvedic, Siddha or Unani drug.
57  Mepacrine Hydrochloride (Quinacrine and its salts) in any dosage form for use for female sterilization or contraception.
58  Fenfluramine and Dexfenfluramine.
59  Fixed dose combinations of diazepam and Diphenhydramine Hydrochloride.
60  Parenteral Preparations containing Fixed dose combination of Streptomycin with Penicillin’s
61  Fixed dose combination of Vitamin B1 B6 and B12 for Human Use.
62  Fixed dose combination of Hemoglobin in any form (Natural or Synthetic)
63  Fixed dose combination of Pancreatin or Pancrelipase containing amylase, protease and lipase with any other enzyme.
64  Fixed dose combinations of Nitrofurantoin and Trimethoprim
65  Fixed dose combination of Phenobarbitone with any anti histaminic drugs
66  Fixed dose combination of Phenobarbitone with Hyoscin and/or Hyoscyamine.
67  Fixed dose combination of Phenobarbitone with Ergotamine and/or Belladonna
68  Fixed dose combination of Haloperidol with any anti cholinergic agent including Propentheline Bromide
69  Fixed dose combination of Nalidixic acid with any anti-ameobics including Metronidazole
70  Fixed dose combination of Loparamide Hydrochloride with Furazolidine
71  Fixed dose combination of Cyproheptadine with lysine or Peptone.
72  Astemizole for Human Use
73  Terfinadine for Human Use
74  Phenoformin for Human Use
75  Rofecoxib and its formulation for Human Use
76  Valdecoxib and its formulation for Human Use
77  Diclofenac and its formulation for Veterinary use
78  Artemisine or its derivatives like Artesunates, Artemther or Combination containing any of the items.
79  Nimesulide formulations for Human Use in children below 12 years of age.
80  Cisapride and its formulations for Human Use
81  Phenypropanolamine and its formulations for Human Use (Notification stayed by Madras High Court).
82  Human Placental Extract and its formulations for Human Use Except
   a) Its Topical Application for wound Healing and
   b) Injections for pelvic inflammatory disease
83  Sibutramine and its formulations for Human Use
84  R- Sibutramine and its formulations for Human Use
Rosiglitazone and its formulations for Human Use

The general public and the stake holders particularly retail outlets and practitioners are requested not to sell or prescribe the said medicines in the larger interest of end users.

Sd/-
(Satish Gupta)
Controller,
Drug & Food Control Organization,
J&K, Jammu

Copy to the:-
1. Commissioner/Secretary to Government, Health & Medical Education Department, Jammu for favour of information.
2. Drugs Controller General (India), Directorate General of Health Services, FDA Bhavan, Kotla Road, New Delhi.
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