[1]SCHEDULE V

[See rule 124-B]

Standards for patent or proprietary medicines.

1. [2][* * *]

[3]2. Standards for patent or proprietary medicines, containing vitamins:

Patent or proprietary medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain the vitamins in quantities not less than and not more than those specified below in single or in two divided daily doses, namely: -

(See Table)

[4]3 [5][* * *]

[6][4. General Standards for Different Categories of Patent or Proprietary Medicines. -

In the case of Pharmaceutical products containing several active ingredients, the selection shall be such that the ingredients do not interact with one another and do not affect the safety and therapeutic efficacy of the product. The combination shall not also lead to analytical difficulties for the purpose of assaying the content of such ingredient separately. The substances added as additives shall be innocuous, shall not affect the safety or therapeutic efficacy of the active ingredients, and shall not affect the assays and identity tests in the amount present.

Subject to the provisions of these rules, patent or proprietary medicines shall comply with the following standards, namely: -

1. Patent or proprietary medicines shall comply with the general requirements of the dosage from under which it falls as given in the Indian Pharmacopoeia. If the dosage form is not included in the Indian Pharmacopoeia, but is included in any other pharmacopoeia, prescribed for the purpose of the Second Schedule to the Act, it shall comply with the general requirements

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[1] Added under G.S.R. No. 665, dated 28-5-1977 (Govt. of India Notification No. X. 11014/2/77-D & MS, dated 6-5-1977).

[2] Omitted as per G.O.I. Notification No. GSR 59(E) dt 22.1.1992.,

[3] Added under G.S.R. No. 930, published in the Gazette of India, Pt. II, Sec. 3, Sub-Sc. (i),
dtd 22-7-1978. (G.O.I. Notification No. X. 11013/2/77-DMS & PFA dated 13th July, 1978.)

[4]and [5] Paragraph 3 inserted by G.O.I. Notification No. GSR 331(E) dt 8.5.1984 and omitted as per G.O.I. Notification No. GSR 59(E) dt 22.1.1992.

[6] Inserted as per G.O.I. Notification No. GSR 792(E) dt 17.9.1987.

of the dosage of such pharmacopoeia. Without prejudice to the generality of the foregoing requirements, general requirements shall include compliance with colour consistency, clarity, stability, freedom from contamination with foreign matter or fungal growth, defects like chipping and capping of tablets, cracking of the coating, mottled appearance and other characteristic defects that can be perceived by visual inspection.

2. Without prejudice to the generality of the following paras, dosage forms of patent or proprietary medicines shall comply with the following requirements, namely:-

a) Tablets: Medicines shall comply with requirements for tablets as laid down in the Indian Pharmacopoeia. The nature of coating shall be indicated on the label. Permitted colours may, however, be added and declared on the label. Nature of tablets, such as uncoated, sugar coated or film coated, shall be declared on the label.

b) Capsules : Medicines shall comply with the requirements for capsules laid down in the Indian Pharmacopoeia. However, the capsules shall be free from distortion or shape, dis-colouration and other physical defects like leakage of power from joints, pinholes or cracks in the capsules;

c) Liquid oral dosage forms: Emulsions and suspensions shall disperse uniformly on shaking. Homogeneous solutions shall contain no sediments. The volume of the product (net content) in the container shall be not less than the labeled volume. The limit for ethanol content of pharmaceutical products shall be not less than 90 per cent and not more than 110 per cent of the labeled contents.

d) Injections: Medicines shall comply with the requirements for injections as laid down in the Indian Pharmacopoeia.

e) Ointments: Medicines shall comply with the requirements for injections as laid down in the Indian Pharmacopoeia.

3. The contents of active ingredients, other than vitamins, enzymes and antibiotics, in patent or proprietary medicines shall be not less than 90 per cent and not more than 110 per cent of the labeled content; however, for enzymes and vitamins, only for lower limit of 90 per cent shall apply. In all dry formulations containing antibiotics, the limit shall be 90 to 130 per cent of the labeled contents and in case of liquid antibiotic formulations, the limit shall be 90 to 140 per cent of labeled contents.

Fiducial limits for error for microbiological assay of antibiotics may be estimated depending upon the design of assay procedure. Methods, used for assaying active ingredients shall employ the same basic principles and shall use same organisms as given in the latest edition of the Indian Pharmacopoeia or shall follow any other methods as approved by the authority competent to grant licence to manufacture.

4. All patent or proprietary medicines containing aspirin shall be subjected to "Free Salicylic Acid Test" and the limit of such acid shall be 0.75 per cent. Except in case of soluble type aspirin in which case the limit of such acid shall be 3 per cent.

5. Patent or proprietary medicine to be tested under the provisions of Rule 121-A for pyrogen shall be tested by injecting into rabbits not less than the human dose of the medicine based on body weight of a 60 kg. human being. Methodology selected shall be indicated in the protocol but the dose shall be not greater than 5 times the human dose based on body weight of 60 kg for man.

6. In injectable patent or proprietary medicines, the test for freedom from toxicity, shall be performed as described in the Indian Pharmacopoeia. Dose selected shall be indicated in the protocol but the dose shall not be less than five times the human dose based on body weight of 60 kg. human being.]