[31][SCHEDULE V

[*See* Rule 124-B]

STANDARDS FOR PATENT OR PROPRIETARY MEDICINES

[31a]1. [* * *]

[32][2. *Standards for patent or proprietary medicines, containing vitamins.*- Patents or proprietary medicins 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:-

Vitamin	Unit	Patent or proprietary medicines containing vitamins for prophylactic use.	Patent or proprietary medicienes containing vitamins for therapeutic use. Patent or proprietary medicienes containing vitamins for therapeutic use.	Patent or proprietary medicines containing vitamins for paediatric use	
		Per	daily dose	(in single dose or in two divided doses)	
		For adults			
1	2	3	4	5	6
Vitamin A	I.U.	Not less than 1,600 and not more than 2,500.	Not less than 5,000 and not more than 10,000.	Not less than 750 and not more than 3,000.	Not less than 1,500 and not more than 5,000.

Vitamin D	I.U.	Not less than 100 and not more than 200.	Not less than 400 and not more than 1,000	Not less than 200 and not more than 400.	Not less than 100 and not more than 400.
Vitamin B1	mg.	Not less than 1 and not more than 2.	Not less than 4.5 and not more than 10.	Not less than 0.5 and not more than 1.	Not less than 1 and not more than 4.5.
Vitamin B6	mg.	Not less than 0.5 and not more than 1.5.	Not less than 1.5 and not more than 3.	Not less than 0.5 and not more than 1.5.	Not less than 1 and not more than 3.
Niacinamide	mg.	Not less than 15 and not more than 26.	Not less than 45 and not more than 100.	Not less than 5 and not more than 15.	Not less than 10 and not more than 40.
d-Pantothenic acid or its salts and pathenol.	mg.	Not less than 1 and not more than 5.	Not less than 5 and not more than 50.	Not less than 1 and not more than 3.	Not less than 2.5 and not more than 10.
Folic Acid	mcg.	Not less than 50 and not more than 300.	Not less than 1,000 and not more than 1,500.	Not less than 25 and not more than 100.	Not less than 100 and not more than 500.

Vitamin B12	mcg.	Not less than 0.5 and not more than 1.0	Not less than 5 and not more than 15.	Not less than 1 and not more than 3.	Not less than 1 and not more than 5.
Vitamin C	mg.	Not less than 25 and not more than 50.	Not less than 75 and not more than 150.	Not less than 20 and not more than 40.	Not less than 30 and not more than 80.
Vitamin E	I.U.	Not less than 5 and not more than 10.	Not less than 15 and not more than 25.	Not less than 2.5 and not more than 10.	Not less than 5 and not more than 20.

Note 1. – Patent or proprietary medicines containing vitamins intended for prophylactic, therapeutic or paediatric use shall bear on the label the words "For Prophylactic Use", "For Therapeutic Use" or "For Paediatric Use" as the case may be. In the cases of paediatric preparations the age of the infant or the child for whose use it is intended, shall be given in addition to the particulars required to be given under these rules.

Note 2. – The above standards shall not apply to any preparation containing a single vitamin only and also to any preparation containing vitamins intended for parenterals use :

Provided, however, that in the case of patent or proprietary medicines containing vitamins which are intended for the treatment of certain specific conditions or diseases, the Licensing Authority specified in clause (b) or Rule 21, may permit the addition of vitamins therein in relaxation of the limits specified above, if satisfactory evidence is produced in justification of such relaxation.]

[32a][3. [31a][* * *]

[32b][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 assayg the content of such ingredient separately. The substances added as additives shall be innocuous, shall not affect the safety or therapeutic of the active ingredients, and shall not affect the assay and dentity 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 form under which it falls as given in the Indian Pharmacopoeia. If the dosage form is not included in the Indian Pharmacopoeia, but is incuded in any other pharmacopoeia, prescribed for the purpose of the Second Schedule to the Act, it shall comply with the general requirements of the dosage of such pharmacopeia. Without prejudice to the generality of the foregoing requirements, general requirements shall include compliance with colour cosistency, clarity, stability, freedom from contamination with foreign matter or fungal growth, defects like cipping and capping of tablets, cracking of the coating, mottled appearance and other characterstic 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, howerver, be added and declared on the label. Nature of tablets, such as uncoated, sugar coated or filmcoated, shall also be declared on the label.

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(b) Capsules: Medicines shall comply with the requirements for capsules laid down in the Indian Pharmacopoeia. However, the capsules shall be free from distortion of shape, discolouration 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 disposed uniformly on shaking. Homogeneous solutions shall contain no sedments. The volume of the product (net content) in the container shall be not less than the labelled 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 labelled 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 ointments as laid down in Indian Pharmacopeia.

3. The content 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 labelled content; hwever, 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 labelled contents and in case of liquid antibiotic formulations, the limit shall be 90 to 140 per cent of labelled contents.

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

4. All patent or proprietary medicines containing 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 and limits shall be based on the method recorded in the Indian Pharmacopeia. Dose 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 medicine, 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.]