[PART XI

medicine based on body weight of a 60 kg. human being. Methodology and limits shall be based on the method recorded in the Indian Pharmacopoeia. 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 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.]

[1][***]

[2][SCHEDULE X

(*See* rules 23, 61, 75, 97 and 105-A)

Amobarbital	Glutethimide	Methylphenobarbital
Amphetamine	[3][Ketamine hydrochloride]	Pentobarbital
Barbital	Meprobamate	Phencylidine
Cyclobarbital	Methamphetamine	Phenometrazine
Dexamphetamine	[4][***]	[5][***]
Ethchlorvynol	Methylphenidate	Secobarbital

Notes.—1. Any stereiosometric form of the substance specified in this Schedule, any salt of the substance and preparation containing such substances are also covered by this Schedule.

2. Preparations containing the above substances are also covered by this Schedule:

Provided, however, preparations containing Meprobamate [5][* * *] in combination with other drugs may be exempted by the licensing authority specified in clause (*b*) of rule 21, from the provisions of this Schedule, if satisfactory evidence is adduced that these preparations are not liable to be misused.]

[6][SCHEDULE Y

[*See* rules 122-A, 122-B, 122-D, 122-DA, 122-DAA and 122-E]

REQUIREMENTS AND GUIDELINES FOR PERMISSION TO IMPORT AND/OR MANUFACTURE OF NEW DRUGS FOR SALE OR TO UNDERTAKE CLINICAL TRIALS

1. *Application for permission.*—(1) Application for permission to import or manufacture new drugs for sale or to undertake clinical trials shall be made in Form 44 accompanied with following data in accordance with the appendices, namely:—

(*i*) chemical and pharmaceutical information as prescribed in Item 2 of Appendix I;

(*ii*) animal pharmacology data as prescribed in Item 3 of Appendix I and Appendix IV;

(*a*) specific pharmacological actions as prescribed in Item 3.2 of Appendix I, and demonstrating, therapeutic potential for humans shall be described according to

1. Schedule W omitted by G.S.R. 94(E), dated 8-2-2000 (w.e.f. 8-2-2000). Earlier it was inserted by G.S.R. 27(E), dated 17-1-1981 (w.e.f. 1-8-1981).
2. Inserted by G.S.R. 462(E), dated 22-6-1982 (w.e.f. 22-6-1982).
3. Inserted by G.S.R. 724(E), dated 7-11-2013 (w.e.f. 7-11-2013).
4. Certain words omitted by G.S.R. 647(E), dated 28-10-1998 (w.e.f. 28-10-1998).
5. Certain words omitted by G.S.R. 673(E), dated 27-10-1993 (w.e.f. 27-10-1993).
6. Substituted by G.S.R. 32(E), dated 20-1-2005 (w.e.f. 20-1-2005).