Drugs (Specifications) Rules, 1978

Notification S.R.O. 1080 (1)/78: In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Govern moist is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, .namely :--

1. Short title and commencement: (1) These rules may bc called the Drugs (Specifications) Rules, 1978.
(2) They shall come into force at once.

2. Specifications: The specifications for the classes of drugs specified in column 1 of the schedule shall be those specified against those drugs in column 2 of the schedule.

SCHEDULE
Specifications for Drugs

Class of drug	Specifications to be compiled with
1. Drugs bearing reference on the lebelling to any of the publications specified under sub-clause t (ii) of clause (z) of Section 3.	Specifications given in the publication referred to on the labelling.
2. Drugs included in the recent editions of any of the following publications but not bearing any reference to such publication :- (a) the international Pharmacopoeia or such other specifications as published by the World Health Organisation, (b) the European Pharmacopoeia, (c) the United States Pharmacopoeia, (d) the British Pharmacopoeia, (e) the British Pharmaceutical Codex. (f) the United States .National Formulary.	Specifications as approved by the Registration Board for this purpose and if no such approval is available the specifications given in the said publications in the same order of preference as given in column 1.
3. Veterinary drugs	Specifications as approved by the Registration Board for this purpose and if no such approval is available, the specification given in the current edition of British Veterinary Codex and, if a drug is not included in the current edition and is included in an earlier edition the specification proscribed in that edition.
4. Drugs other than those falling under serial number 1, 2 or 3 above.	Specifications as approved by the Registration Board for specification are available the ingredients and their quantities displayed in the labelling which shall be tested and analysed by the Government Analyst or the Federal Drug Laboratory or such other laboratory as may have been specified to be the laboratory for the purpose of sub-section (5) of section 22.
5. Ophthalmic preparations	In addition to the requirements, if any, set out above, ophthalmic preparations shall meet the following requirement:- A-Ophthalmic Solutions and Suspensions; Ophthalmic solutions and suspensions shall-- (a) be sterile except in case of those ophthalmic

solutions and suspensions which are not specifically required to comply with the test for 'Sterility' in the Pharmacopocia;

(b) contain one or more suitable substances as preservatives to prevent the growth of micro-organisms
Provided that solutions in used surgery shall not have any preservative and be packed in single dose containers;

(c). be free from foreign matter:

(d) be contained in bottles made of either neutral glass or soda glass specially treated to reduce the amount of alkali released when in contact with aqueous liquids or in suitable plastic containers which would not in any way be incompatible with the solution and the droppers to be supplied with the containers shall be made of neutral glass or of suitable plastic material and when supplied separately shall be packed in sterile cellophane or other suitable packings; and

B-- Ophthalmic Ointment Ophthalmic Ointment shall--

(a) be sterile;
(b) be free from foreign matter.