Legal Definitions of Schedules to Rules

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Following are the schedules to the rules:

A – Proforma for application for the licenses, issue and renewal of licenses, for sending memoranda under the Act.

B – Rates of fee for test or analysis by the Central Drugs Laboratory or the Government Analyst.

C– List of biological and special products whose import, sale, distribution, and manufacture are governed by special provisions.

C1 – List of other special products whose import, sale, distribution, and manufacture are governed by special provisions.

D – List of drugs exempted from the provisions of import of drugs.

E1 – List of poisonous substances under the Ayurvedic (including Siddha) and Unani systems of medicine.

F (i) – Space, equipment, and supplies required for a blood bank.

(ii) – Minimum requirement for grant of license to procure blood components from whole human blood.

F1 Part I – Provisions applicable to the production of bacterial and viral vaccines.

Part II – Provisions applicable to the production of all sera from living animals.

Part III – Provisions applicable to the manufacture and standardization of diagnostic agents (bacterial origin).

F2 – Standards for surgical dressings.

F3 – Standards for sterilised umbilical tapes.

FF – Standards for ophthalmic preparations.

G – List of substances to be used only under medical supervision and which are to be labelled accordingly. H – List of prescription drugs.

J – Diseases or ailments which a drug may not prevent or cure.

K – Drugs exempted from certain provisions of the manufacture of drugs.

M – Good Manufacturing Practices (GMP) requirements of factory premises, plants, and equipment.

M1 – Requirements of factory premises, etc., for manufacture of homeopathic preparations.

M2 – Requirements of factory premises for the manufacture of cosmetics.

M3 – Requirements of factory premises for the manufacture of medical devices.

N– List of minimum equipment for efficient running of a pharmacy.

O – Standards for disinfectant fluids.

P – Life periods of drugs.

P1 – Pack sizes of drugs.

Q – Part I – List of dyes, colours and pigments permitted in cosmetics and soaps.

Part II – List of colours permitted in soaps.

R – Standards for condoms made of rubber latex intended for single use and other mechanical contraceptives.

R1 – Standards for medical devices.

S – Standards for cosmetics.

T – Requirements of factory premises and hygienic conditions for Ayurvedic (including Siddha) and Unani drugs.

U – Particulars to be shown in manufacturing, raw material, and analytical records of drugs.

U1 – Particulars to be shown in manufacturing, raw material, and analytical records of cosmetics.

V – Standards for patent or proprietary medicines.

W – List of drugs to be marketed under generic names only.

X – List of drugs whose import, manufacture, sale, labelling, and packaging are governed by special provisions.

Y – Requirements and guidelines on clinical trials for import and manufacture of new drugs.