THE DRUGS AND COSMETICS RULES, 1945

as corrected up to the 30th November, 2004

DEPARTMENT OF HEALTH
NOTIFICATION

New Delhi, the 21st December 1945

No. F. 28-10/45-H (1). –In exercise of the powers conferred by Sections 6(2), [1][12, 33 and 33N] of the Drugs and Cosmetics Act, 1940 (XXIII of 1940), the Central Government is pleased to make the following Rules:—

RULES

PART I–PRELIMINARY

1. *Short title, extent and commencement*. —*(1)* These Rules may be called the Drugs and Cosmetics Rules, 1945.

[2]*(2)* They extend to the whole of India.

2. *Definitions*.— In these Rules, unless there is anything repugnant in the subject or context—

(a) "the Act" means the Drugs and Cosmetics Act, 1940 (XXIII of 1940) as amended from time to time;

[3]*(b)* "Central Licence Approving Authority" means the Drugs Controller, India, appointed by the Central Government.

(c) "Director" means the Director of the Central Drugs Laboratory;

(d) "From" means a form set forth in Schedule A;

[4]*(dd)* Homoeopathic medicines include any drug which is recorded in Homoeopathicproving or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such Homoeopathic medicines but does not include a medicine which is administered by parenteral route.

(e) "Laboratory" means the Central Drugs Laboratory;

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[1]Amended by G.O.I. Notification No.G.S.R. 370(E) dated 07-04-1994
[2]Amended by G.O.I Notification No.G.S.R. 358 dated 15-3-1975 (Govt. of India Notification No. X 11011/3/72-D & MS dated 5-3-1975).
[3]Amended by G.O.I. Notification No. G.S.R. 923(E) dated 14-12-1992
[4]Added under Government of India Notification No. F. 1-59 / 68-D, dated 19th Nov. 1969.

[1][*(ea)* "registered Homeopathic medical practitioner" means a person who is registered in the Central Register or State Register of Homeopathy;]

[2][*(ee)* "Registered medical practitioner" means a person–

(i) holding a qualification granted by an authority specified or notified under Section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified In the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or

(ii) registered or eligible for registration in a medical register of a State meant for the registration of persons practicing the modern scientific system of medicine [3]excluding the Homoeopathic system of medicine; or

(iii) registered in a medical register, [3]other than a register for the registration of Homoeopathic practitioner, of a State, who although not falling within sub-clause (i) or sub-clause (ii) declared by a general or special order made by the State Government in this behalf as a person practicing the modern scientific system of medicine for the purposes of this Act; or

(iv) registered or eligible for registration in the register of dentists for a State under the Dentists Act, 1948 (16 of 1948); or

(v) who is engaged in the practice of veterinary medicine and who possesses qualification approved by the State Government.

[4]*(f)*'retail sale' means a sale [5][whether to a hospital, or dispensary, or a medical, educational or research institute or to any other person] other than a sale by way of wholesale dealing;

[5]*(g)* 'sale by way of wholesale dealing' means sale to a person for the purpose of selling again and includes sale to a hospital, dispensary, medical, educational or research institution.

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[1]Ins by G.O.I Notification No. G.S.R 680 (E) dated 5-12-1980
[2]Added by Government of India, Notification No. F. 1-22 / 59-D, dated 9 th April, 1960.
[3]Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5 th June, 1972).
[4]Amended or added under Government of India Notification No. F. 1-3/51-DS., Dated 15 th October, 1954.
[5]Amended by G.O.I. Notification No. G.S.R 681 (E) dated 6-6-1988

[1]*(h)* "Schedule" means a Schedule to these Rules.

[2]*(i)*State Government in relation to a Union Territory means the Administrator thereof.

(j)'Poisonous substance' means a substance specified in Schedule E.

PART II—THE CENTRAL DRUGS LABORATORY

3. *Functions*.—It shall be the function of the Laboratory—

*(i)*to analyse or test such samples of drugs as may be sent to it under sub-section (2) of Section 11, or under sub-section (4) of Section 25 of the Act;

(ii) [2]***

(iii) to carry out such other duties as may be entrusted to it by the Central Government or, with the permission of the Central Government, by a State Government after consultation with the Drugs Technical Advisory Board.

[3]**3A***(1)*The functions of the Laboratory in respect of the following drugs or classes of drugs shall be carried out at the Central Research Institute, Kasauli, and the functions of the Director in respect of the said drugs or classes of drugs shall be exercised by the Director of the said Institute :—

(1) Sera

(2) Solution of serum proteins intended for injection

(3) Vaccines

(4) Toxins

(5) Antigens

(6) Anti-toxins

(7) Sterilized surgical ligature and sterilized surgical suture.

(8) Bacteriophages.

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[1]Amended by Government of India Notification No. F.28-10/45-H (1), dated 31st March 1957.
[2]Amended or omitted by Government of India Notification No. F-1-16/57-D, dated 15th June, 1957.
[3]Amended by Government of India Notification No. F. 4-1 / 60-D, dated 15th May, 1961