THE DRUGS RULES, 1945
[21st December, 1945]

In exercise of the powers conferred by sections 6(2), 12, 33 and 33(N) of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government is pleased to make the following Rules:

PART I
PRELIMINARY

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

(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 (23 of 1940), as amended from time to time;

(aa) "biopharmaceutical classification system" means a system used to classify drugs on the basis of solubility and permeability, classified as category I-high solubility and high permeability, category II-low solubility and high permeability, category III-high solubility and low permeability, and category IV-low solubility and low permeability;]

(b) "Central Licence Approving Authority" means the Drugs Controller, India, or the Joint Drugs Controller (India) or the Deputy Drugs Controller (India) appointed by the Central Government;

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

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

(dd) "Homoeopathic medicines" include any drug which is recorded in Homoeopathic provings 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
ophthalmic and ear/nose preparations containing antibiotics and/or steroids) are also covered by this Schedule.

3. The inclusion of a substance in this Schedule does not imply or convey that the substance is exempted from the provisions of Rule 122A/122B.]

4[4. The salts, esters, derivatives and preparations containing ’[steroids or Hydroquinone] for topical or external use shall also be covered under this Schedule.

'5. Notwithstanding anything contained in these rules, the provisions of rule 65 and rule 97 in respect or drugs specified from serial number 538 to serial number 551 inserted vide Notification number G.S.R. 277(E), dated 23rd March, 2018 published in the Gazette of India, Extraordinary, Part II, Section (3), Sub-section (i) shall be on voluntary basis for a period commencing on the day on which this notification shall come into force and ending on the 31st March, 2019 and thereafter shall be mandatory.]

2\[SCHEDULE III (See rules 65 and 97)

1. Alprazolam 17. Ceftriaxone 33. Meropenem
2. Balofloxacin 18. Chlordiazepoxide 34. Midazolam
11. Cefotaxime 27. Ethionamide 43. Sparfloxacin
12. Cefpirome 28. Feropenem 44. Thiacetazone
13. Cefpodoxime 29. Gemifloxacin 45. Tramadol
16. Ceftizoxime 32. Levofoxacin

SCHEDULE I
(Omitted)

SCHEDULE J