

***THE DRUGS RULES, 1945¹**

[21st December, 1945]

In exercise of the powers conferred by ¹[sections 6(2), 12, 33 and 33(N)] of the Drugs ²[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 ³[***] Rules, 1945.

(2) They extend to the whole of India ³[***].

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;

⁶[(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;] ⁷[(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;

⁸[(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 of 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 HI (See rules 65 and 97)**

1. Alprazolam	17. Ceftriaxone	33. Meropenem
2. Balofloxacin	18. Chlordiazepoxide	34. Midazolam
3. Buprenorphine	19. Clofazimine	35. Moxifloxacin
4. Capreomycin	20. Codeine	36. Nitrazepam
5. Cerdinir	21. Cycloserine	37. Pentazocine
6. Cefditoren	22. Diazepam	38. Prulifloxacin
7. Cefepime	23. Diphenoxylate	39. Pyrazinamide
8. Cefetamet	24. Doripenem	40. Rifabutin
9. Cefixime	25. Ertapenem	41. Rifampicin
10. Cefoperazone	26. Ethambutol Hydrochloride	42. Sodium Para-aminosalicylate
11. Cefotaxime	27. Ethionamide	43. Sparfloxacin
12. Cefpirome	28. Feropenem	44. Tniacetazone
13. Cefpodoxime	29. Gemifloxacin	45. Tramadol
14. Ceftazidime	30. Imipenem	46. Zolpidem ³ [47. Oxytocin]
15. Ceftibuten	31. Isoniazid	⁴ [48. Tapentadol]
16. Ceftizoxime	32. Levofloxacin	

SCHEDULE I

(Omitted)

SCHEDULE J