

***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;

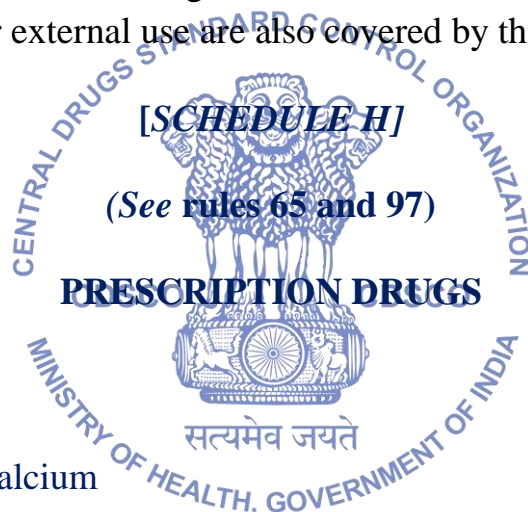
(d) "Form" means a Form set forth in Schedule A;

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

Doxylamine Succinate
Isothipendyl
Mebhydrolin Napadisylate
Meclozine
Phenindamine
Pheniramine
Promethazine
Thenalidine
Triprolidine

Substances being tetra-N-Subs. derivatives of Ethylene Diamine or Prophylenediamine.

Note.—Preparations containing the above substances excluding those intended for topical or external use are also covered by this Schedule.]



1. Abacavir
2. Abciximab
3. Acamprosate Calcium
4. Acebutol Hydrochloride
5. Aclarubicin
6. Albendazole
7. Alclometasone Dipropionate
8. Actilyse
9. Acyclovir
10. Adenosine
11. Adrenocorticotrophic Hormone (Acth)
12. Alendronate Sodium
13. Aliopurinol
14. Alphachymotrypsin
15. ****
16. Alprostadi
17. Amantadine Hydrochloride

18. Amifostine
19. Amikacin Sulphate
20. Amiloride Hydrochloride
21. Amineplene
22. Aminoglu tethimide
23. Aminosalicyclic Acid
24. Amiodarone Hydrochloride
25. Amitriptyline
26. Amlodipine Besylate
27. Amoscanate
28. Amoxopine
29. Amrinone Lactate
30. Analgin
31. Androgenic Anabolic, Oestrogenic & Progestational Substances
32. Antibiotics
33. Apraclonidine
34. Aprotinin
35. Organic Compound of Arsenic
36. Arteether
37. Artemether
38. Artesunate
39. Articaïne Hydrochloride
40. Atenolol
41. Atracurium Besylate Injection
42. Atorvastatin
43. Auranofin
44. Azathioprine
45. Aztreonam
46. Bacampicillin
47. Baclofen
48. Balsalazide
49. Bambuterol
50. Barbituric Acid
51. Basiliximab
52. Benazepril Hydrochloride
53. Benidipine Hydrochloride



54. Benserazide Hydrochloride
55. Betahistine Dihydrochloride
56. Bethanidine Sulphate
57. Bezafibrate
58. Bicalutamide
59. Biclotymol
60. Bifonazole
61. Bimatoprost
62. Biperiden Hydrochloride
63. Biphenyl Acetic Acid
64. Bitoscanate
65. Bleomycin
66. Primonidine Tartrate
67. Bromhexine Hydrochloride
68. Bromocriptine Mesylate
69. Budesomde
70. Bulaquine
71. Bupivacaine Hydrochloride
72. Bupropion
73. Buspirone
74. Butenafine Hydrochloride
75. Butorphanol Tartrate
76. Cabergoline
77. Calciumdobesilate
78. Candesartan
79. Capecitabine
80. Captopril
81. Carbidopa
82. Carbocisteine
83. Carboplatin
84. Carboquone
85. Carisoprodol
86. L-Camitine
87. Carteolol Hydrochloride
88. Carvedilol
89. Cefadroxyl
90. Cefatoxime Sodium



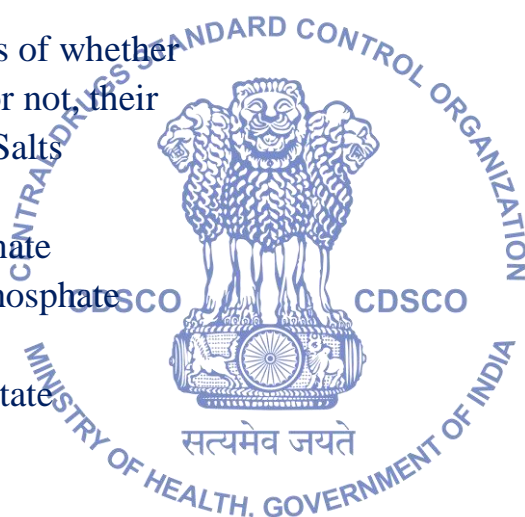
91. Cefazolin Sodium
92. ****
93. ****
94. ****
95. ****
96. ****
97. ****
98. ****
99. Cefuroxime
100. Celecoxib
101. Centchroman
102. Centbutindole
103. Centpropazine
104. Cetirizine Hydrochloride
105. ****
106. Chlormezanone
107. ****
108. Chlorpromazine
109. Chlorzoxazone
- no. Ciclopirox Olamine CDSCO
111. Cimetidine
112. Cinnarizine
113. Ciprofloxacin Hydrochloride सत्यमेव जयते
Monohydrate / Lactate
114. Cisplatin
115. Citalopram Hydrobromide
116. Clarithromycin
117. Clavulanic Acid
118. Clidinium Bromide
119. Clindamycin
120. Clobazam
121. Clobetasol Propenat
122. Clobetasone 17-Butyrate
123. ****
124. Clofibrate
125. Clonazepam
126. Clonidine Hydrochloride



127. Clopamide
128. Clopidogrel Bisulphate
129. Clostebol Acetate
130. Clotrimazole
131. Clozapine
132. ****
133. Colchicine
134. Corticosteroids
135. Cotrimoxazole
136. Cyclandelate
137. Cyclosporins
138. Daclizumab
139. Danazole
140. Dapsone
141. Desloratadine
142. Desogestrol
143. Dexrazoxane
144. Dextranomer
145. ****
146. Dextropropoxyphene
147. ****
148. Diazoxide
149. Diclofenac Sodium/Potassium/Acid
150. Dicyclomin Hydrochloride
151. Didanosine
152. Digoxine
153. Dilazep Hydrochloride
154. Diltiazem
155. Dinoprostone
156. ****
157. Dipivefrin Hydrochloride
158. Di-sodium Pamidronate
159. Disopyramide
160. Docetaxel
161. Domperidone
162. Donepezil Hydrochloride
163. Dopamine Hydrochloride



164. Dothiepin Hydrochloride
165. Doxapram Hydrochloride
166. Doxazosin Mesylate
167. Doxepin Hydrochloride
168. Doxorubicin Hydrochloride
169. Drotrecogin-Alpha
170. Ebastine
171. Econazole
172. Efavirenz
173. Enalapril Meleate
174. Enfenamic Acid
175. Epinephrine
176. Epirubicine
177. Eptifibatide
178. Ergot, Alkaloids of whether
Hydrogenated or not, their
Homologues, Salts
179. Esomeprazole
180. Estradiol Succinate
181. Estramustine Phosphate
182. Etanercept
183. Ethacridine Lactate
184. ****
185. Ethamsylate
186. Ethinyloestradiol
187. T**]
188. Etidronate Disodium
189. Etodolac
190. Etomidate
191. Etoposide
192. Exemestane
193. Fanciclovir
194. Famotidine
195. Fenbendazole
196. Fenofibrate
197. Fexofenadine
198. Finasteride



199. Flavoxate Hydrochloride
200. 5-Fluorouracil
201. Fludarabine
202. Flufenamic Acids
203. Flunarizine Hydrochloride
204. Fluoxetine Hydrochloride
205. Flupenthixol
206. Fluphenazine Enanthate and Decanoate
207. Flurazepam
208. Flurbiprofen
209. Flutamide
210. Fluticasone Propionate
211. Fluvoxamine Maleate
212. Formestane
213. Fosfestril Sodium
214. Fosinopril Sodium
215. Fossphenytoin Sodium
216. Fotemustine
217. Gabapentin
218. Galanthamine Hydrobromide
219. Gallamine, its Salts, its Quaternary Compound
220. Gancyclovir
221. Ganirelix
222. Gatifloxacin
223. Gemcitabine
224. Gemfibrozil
225. Gemtuzumab
226. Genodeoxycholic Acid
227. Gliclazide
228. Glimepiride
229. Glucagon
230. Glycopyrrolate
231. Glydiazinamide
232. Goserelin Acetate
233. Granisetron
234. Guanethidine



235. Gugulipid
236. Halogenated Hydroxyquinolines
237. Haloperidol
238. Heparin
239. Hepatitis B. Vaccine
240. Hyaluronidase
241. Hydrocortisone 17-Butyrate
242. Hydrotalcite
243. Hydroxyzine
244. Ibuprofen
245. Idebenone
246. Indapamide
247. Imipramine
248. Indinavir Sulphate
249. Indomethacin
250. Insulin Human
251. Interferon
252. Intravenous Fat Emulsion
253. Iobitridol
254. Iohexol
255. Iopamidol
256. Iomeprol
257. Iopromide
258. Irbesartan
259. Irinotecan Hydrochloride
260. Iron Preparation for Parenteral use
261. Isepamicine
262. Isocarboxide
263. Isoflurane
264. Isonicotnic Acid Hydrazine and other
Hydragine Derivatives of Isonicotnic Acid
265. Isosorbide Dinitrate/Mononitrate
266. Isotretinoin
267. Isoxsuprine
268. Itopride
269. ****
270. Ketoconazole



271. Ketoprofen
272. Ketorolac Tromethamine
273. Labetalol Hydrochloride
274. Lacidipine
275. Lamivudine
276. Lamotrigine
277. Latanoprost
278. Lefunomide
279. Lercanidipine Hydrochloride
280. Letrozole
281. Leuprolide Acetate
282. Levamesole
283. Levarterenol
284. Levobunolol
285. Levocetirizine
286. Levodopa
287. ****
288. Levovist
289. Lidoflazine
290. Linezplid
291. Lithium Carbonate
292. Lofepamine Decanoate
293. Loperamide
294. Lorazepam
295. Losartan Potassium
296. Loteprednol
297. Lovastatin
298. Loxapine
299. Mebendazole
300. Mebeverine Hydrochloride
301. Medroxy Progesterone Acetate
302. Mefenamic Acid
303. Mefloquine Hydrochloride
304. Megestrol Acetate
305. Meglumine Iocarmate
306. Melagenina
307. Melitracen Hydrochloride



308. Meloxicam
309. Mephenesin, its Esters
310. Mephentermine
311. ****
312. Mesterolone
313. Metaxalone
314. Methicillin Sodium
315. Methocarbamol
316. Methotraxate
317. Metoclopramide
318. Metoprolol Tartrate
319. Metrizamide
320. Metronidazole
321. Mexiletine Hydrochloride
322. Mianserin Hydrochloride
323. Miconazole
324. ****
325. Mifepristone
326. Milrinone Lactate
327. Miltefosine
328. Minocycline
329. Minoxidil
330. Mirtazapine
331. Misoprostol
332. Mitoxantrone Hydrochloride
333. Mizolastine
334. Moclobemide
335. Mometasone Furoate
336. Monteiukast Sodium
337. Morphazinamide Hydrochloride
338. Mosapride
339. ****
340. Mycophenolate Mofetil
341. Nadifloxacin
342. Nadolol
343. Nafarelin Acetate
344. Nalidixic Acid



345. Naproxen
346. Narcotic Drugs listed in Narcotic Drugs & Psychotropic Substances Act, 1985
347. Natamycin
348. Nateglinide
349. N-butyl-2-cyanoacrylate
350. Nebivolol
351. Nebumetone
352. Nelfinavir Mesilate
353. Netilmicin Sulphate
354. Nevirapine
355. Nicergoline
356. Nicorandil
357. Nifedipine
358. Nimesulide
359. Nimustine Hydrochloride
360. ****
361. Nitroglycerin
362. Noreth Isterone Enanthate
363. Norfloxacin
364. Octylonium Biomiae
365. Ofloxacin
366. Olanzapine
367. Omeprazole
368. Omidazole
369. Orphenadrine
370. Orthoclone Sterile
371. Oxazepam
372. Oxazolidine
373. Oxcarbazepine
374. Oxethazaine Hydrochlorid
375. Oxiconazole
376. Oxolinic Acid
377. Oxprenolol Hydrochloride
378. Oxybutynin Chloride
379. Oxyfedrine
380. Oxymetazoline



381. Oxyphenbutazone
382. ****
383. Ozothine
384. Paclitaxel
385. Pancuronium Bromide
386. Pantoprazole
387. Para-Amino Benzene Sulphonamide, its Salts & Derivatives
388. Para-Amino Salicylic Acid, its Salts, its Derivatives
389. Parecoxib
390. Paroxetine Hydrochloride
391. D-Penicillamine
392. ****
393. Pentoxifylline
394. Peplomycin
395. Phenelzine Sulphate
396. Phenobarbital
397. Phenothiazine, Derivatives of and Salts of its Derivatives
398. Phenylbutazone
399. Pimozide
400. Pindolol
401. Pioglitazone Hydrochloride
402. Piracetam
403. Piroxicam
404. Pituitary Gland, Active Principles of, not otherwise specified in this Schedule and their Salts
405. Polidocanol
406. Polyestradiol Phosphate
407. Poractant Alfa
408. Praziquantel
409. Prednisolone
410. Prednisolone Stearoylglycolate
411. Prenoxdiazin Hydrochloride
412. Promazine Hydrochloride



413. Promegestone
414. Propafenon Hydrochloride
415. Propanolol Hydrochloride
416. Propofol
417. Protristylone Hydrochloride
418. ****
419. Pyrvinium
420. Quetiapine Fumerate
421. Quinapril
422. Quiniaine Sulphate
423. Rabeprazole
424. Racecadotril
425. Raloxifene Hydrochloride
426. Ramipril Hydrochloride
427. Ranitidine
428. Rauwolfia, Alkaloids of, their Salts,
Derivatives of the Alkaloids of Rauwolfia
429. Reboxetine
430. Repaglinide
431. Reproterol Hydrochloride
432. Rilmenidine
433. Riluzone
434. Risperidone
435. Ritonavir
436. Ritodrine hydrochloride
437. Rituximab
438. Rivastigmine
439. Rocuronium bromide
440. Ropinirole
441. Rosoxacin.
442. Rosiglitazone melete
443. Salbutamol sulphate
444. Salicyl-azo-sulphapyridine
445. Salmon calcitonin
446. Saquinavir
447. Satranidazole
448. Secnidazole



449. Septopal beads & chains
450. Serratiopeptidase
451. Sertraline hydrochloride
452. Sibutramine hydrochloride
453. Sildenafil citrate
454. Simvastatin
455. Sirolimus
456. Sisomicin sulphate
457. S-neominophagen
458. Sodiumpico sulphate
459. Sodium cromoglycate
460. Sodium hyaluronate
461. Sodium valproate
462. Sodium and maglumine
iothalamates
463. Somatostatin
464. Somatotropin
465. Sotalol
466. 2[Sparfloxacin]
467. Spectinomycin hydrochloride
468. Spironolactone
469. Stavudine
470. Sucralfate
471. Sulphadoxine
472. Sulphamethoxine
473. Sulphamethoxypyridazine
474. Sulphaphenazole
475. Sulpiride
476. Sulprostone hydrochloride
477. Sumatriptan
478. Tacrine hydrochloride
479. Tamsulosin hydrochloride
480. Trapidil
481. Tegaserod maleate
482. Teicoplanin
483. Telmisartan
484. Temozolamide



485. Terazosin
486. Terbutaline sulphate
487. Terfenadine
488. Terizidone
489. Terlipressin
490. Testosteroneun decoanoate
491. Teratolol hydrochloride
492. Thalidomide
493. 2[Thiacetazone]
494. Thiocolchicoside
495. Thiopropazate, its salts
496. Thymogene
497. Thymosin-alpha1
498. Tiaprofenic acid
499. Tibolone
500. Timolol maleate
501. Tinidazole
502. Tizanidine
503. Tabramycin
504. Tolfenamic acid
505. Topiramate
506. Topotecan hydrochloride
507. 2[Tramadolhydrochloride]
508. Tranexamic acid
509. Tranylcyproamine, its salts
510. Trazodone
511. Tretinoin
512. Trifluoperazine
513. Trifluoperidol hydrochloride
514. Triflusal
515. Trimetazidine dihydrochloride
516. Trimipramine
517. Tripotassium dicitrate bismuthate
518. Tromantadine hydrochloride
519. Urokinase
520. Valsartan
521. Vasopressin



- 522. Vecuronium bromide
- 523. Venlafaxine hydrochloride
- 524. Verapamil hydrochloride
- 525. Verteporfin
- 526. Vincristine sulphate
- 527. Vinblastine sulphate
- 528. Vindesine sulphate
- 529. Vinorelbine tatrare
- 530. Xipamide
- 531. Zidovudine hydrochloride
- 532. Ziprasidone hydrochloride
- 533. Zoledronic acid
- 534. 2[Zolpidem]
- 535. Zopiclone
- 536. Zuclopenthixol
- 537. Etizolam]
- 538. Alclometasone
- 539. Beclomethasone
- 540. Betamethasone
- 541. Desonide
- 542. Desoximetasone
- 543. Dexamethasone
- 544. Diflorasone diacetate
- 545. Fluocinonide
- 546. Huocinolone acetonide
- 547. Halobetasol propionate
- 548. Halometasone
- 549. Methylprednisone
- 550. Prednicarbate
- 551. Triamcinolone acetonide



Note: —1. Preparations exempted under proviso to para 2 of Note to Schedule X shall also be covered by this Schedule.

2. The salts, esters, derivatives and preparations containing the above substances excluding those intended for topical or external use (except

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