

**DRUGS AND COSMETICS (2<sup>ND</sup> AMENDMENT) RULES, 2006**  
**MINISTRY OF HEALTH AND FAMILY WELFARE**  
**(Department of Health)**  
**NOTIFICATION**

New Delhi, the 16th March, 2006

**G.S.R. 160(E).**— Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 24<sup>th</sup> February, 2005, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number G.S.R. 105(E), dated the 24th February, 2005, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on 25<sup>th</sup> February, 2005;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government.

Now, therefore, in exercise of the powers conferred by Sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the **Drugs and Cosmetics (2<sup>nd</sup> Amendment) Rules, 2006.**

*[Published in the Gazette of India (extraordinary) Part-II, section 3, sub-section (i) vide G.S.R. 160(E), dated 16th March, 2006.]*

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, for Schedule H, the following Schedule shall be substituted, namely:—

**SCHEDULE-H**  
(See Rules 65 and 97)  
**PRESCRIPTION DRUGS**

- |   |   |
|---|---|
| <b>1</b><br>1. ABACAVIR<br>2. ABCIXIMAB<br>3. ACAMPROSATE CALCIUM<br>4. ACEBUTOL HYDROCHLORIDE<br>5. ACLARUBICIN<br>6. ALBENDAZOLE<br>7. ALCLOMETASONE DIPROPIONATE<br>8. ACTILYSE<br>9. ACYCLOVIR<br>10. ADENOSINE<br>11. ADRENOCORTICOTROPHIC<br>HORMONE (ACTH) | 12. ALENDRONATE SODIUM<br>13. ALLOPURINOL<br>14. ALPHACHYMOTRYPSIN<br>15. ALPRAZOLAM<br>16. ALPROSTADIL<br>17. AMANTADINE HYDROCHLORIDE<br>18. AMIFOSTINE<br>19. AMIKACIN SULPHATE<br>20. AMILORIDE HYDROCHLORIDE<br>21. AMINEPTINE<br>22. AMINOGLUTETHIMIDE<br>23. AMINOSALICYLIC ACID<br>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. ARTICAINE HYDROCHLORIDE  
40. ATENOLOL

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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. BUDESONIDE  
70. BULAQUINE

71. BUPIVA CAINE HYDROCHLORIDE  
72. BUPROPION  
73. BUSPIRONE  
74. BUTENAFINE HYDROCHLORIDE  
75. BUTORPHANOL TARTRATE  
76. CABERGOLINE  
77. CALCIUM DOBESILATE  
78. CANDESARTAN  
79. CAPECITABINE  
80. CAPTOPRIL  
81. CARBIDOPA  
82. CARBOCISTEINE  
83. CARBOPLATIN  
84. CARBOQUONE  
85. CARISOPRODOL  
86. L-CARNITINE  
87. CARTEOLOL HYDROCHLORIDE  
88. CARVEDILOL  
89. CEFADROXYL  
90. CEFATOXIME SODIUM  
91. CEFAZOLIN SODIUM  
92. CEFDINIR  
93. CEFEPIME HYDROCHLORIDE  
94. CEFETAMET PIVOXIL  
95. CEFPIROME  
96. CEFPODOXIME POXETIL  
97. CEFTAZIDIME PENTAHYDRATE  
98. CEFTIZOXIME SODIUM  
99. CEFUROXIME  
100. CELECOXIB  
101. CENTCHROMAN  
102. CENTBUTINDOLE  
103. CENTPROPAZINE  
104. CETIRIZINE HYDROCHLORIDE  
105. CHLORDIAZEPOXIDE  
106. CHLORMEZANONE  
107. *Omitted vide GSR 790 (E) dated  
29.10.2009*  
108. CHLORPROMAZINE  
109. CHLORZOXAZONE  
110. CICLOPIROX OLAMINE  
111. CIMETIDINE  
112. CINNARIZINE  
113. CIPROFLOXACIN  
HYDROCHLORIDE  
MONOHYDRATE / LACTATE  
114. CISPLATIN  
115. CITALOPRAM HYDROBROMIDE  
116. CLARITHROMYCIN  
117. CLAVULANIC ACID  
118. CLIDINIUM BROMIDE

119. CLINDAMYCIN  
 120. CLOBAZAM  
 121. CLOBETASOL PROPENATE  
 122. CLOBETASONE 17-BUTYRATE  
 123. CLOFAZIMINE  
 124. CLOFIBRATE  
 125. CLONAZEPAM  
 126. CLONIDINE HYDROCHLORIDE  
 127. CLOPAMIDE  
 128. CLOPIDOGREL BISULPHATE  
 129. CLOSTEBOL ACETATE  
 130. CLOTRIMAZOLE  
 131. CLOZAPINE  
 132. CODEINE  
 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. *Omitted vide GSR 790 (E) dated 29.10.2009*  
 146. DEXTROPROPOXYPHENE  
 147. DIAZAPAM  
 148. DIAZOXIDE  
 149. DICLOFENAC  
     SODIUM/POTASSIUM/ACID  
     **3**  
 150. DICYCLOMIN HYDROCHLORIDE  
 151. DIDANOSINE  
 152. DIGOXINE  
 153. DILAZEP HYDROCHLORIDE  
 154. DILTIAZEM  
 155. DINOPROSTONE  
 156. DIPHENOXYLATE, ITS SALTS  
 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. ECONOZOLE  
 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. ETHAMBUTOL HYDROCHLORIDE  
 185. ETHAMSYLATE  
 186. ETHINYLOESTRADIOL  
 187. ETHIONAMIDE  
 188. ETIDRONATE DISODIUM  
 189. ETODOLAC  
 190. ETOMIDATE  
 191. ETOPOSIDE  
 192. EXEMESTANE  
 193. FAMCICLOVIR  
 194. FAMOTIDINE  
 195. FENBENDAZOLE  
 196. FENOFIBRATE  
 197. FEXOFENADINE  
 198. FINASTERIDE  
 199. FLAVOXATE HYDROCHLORIDE  
 200. 5-FLUOROURACIL  
 201. FLUDARABINE  
 202. FLUFENAMIC ACIDS  
 203. FLUNARIZINE HDROCHLORIDE  
 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. HYDROCORISONE 17-BUTYRATE  
242. HYDROTALCITE  
243. HYDROXIZINE  
244. IBUPROFEN  
245. IDEBENONE  
246. IINDAPAMIDE  
247. IMIPRAMINE  
248. INDINAVIR SULPHATE  
249. INDOMETHACIN  
250. INSULIN HUMAN  
251. INTERFERON  
252. INTRAVENOUS FAT EMULSION  
253. IOBITRIDOL  
254. IOHEXOL  
255. IOPAMIDOL  
4  
256. IOMEPROL  
257. IOPROMIDE  
258. IRBESARTAN  
259. IRINOTECAN HYDROCHLORIDE

260. IRON PREPARATION FOR  
PARENTERAL USE  
261. ISEPAMICINE  
262. ISOCARBOXSIDE  
263. ISOFLURANE  
264. ISONICOTNIC ACID HYDRAZINE  
AND OTHER-HYDRAGINE  
DERIVATIVES OF ISONICOTINIC  
ACID  
265. ISOSORBIDE DINITRATE/  
MONONITRATE  
266. ISOTRETINOIN  
267. ISOXSUPRINE  
268. ITOPRIDE  
269. KETAMINE HYDROCHLORIDE  
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. LEVOFLOXACIN  
288. LEVOVIST  
289. LIDOFLAZINE  
290. LINEZPLID  
291. LITHIUM CARBONATE  
292. LOFEPRAMINE 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. MEROPENAM  
 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. MIDAZOLAM  
 325. MIFEPRISTONE  
 326. MILRINONE LACTATE  
 327. MILTEFOSINE  
 328. MINOCYCLINE  
 329. MINOXIDIL  
 330. MIRTAPAZINE  
 331. MISOPROSTOL  
 332. MITOXANTRONE  
     HYDROCHLORIDE  
 333. MIZOLASTINE  
 334. MOCLOBEMIDE  
 335. MOMETASONE FUROATE  
 336. MONTELUKAST SODIUM  
 337. MORPHAZINAMIDE  
     HYDROCHLORIDE  
 338. MOSAPRIDE  
 339. MOXIFLOXACIN  
 340. MYCOPHENOLATE MOFETIL  
 341. NADIFLOXACIN  
 342. NADOLOL  
 343. NAFARELIN ACETATE  
 344. NALIDIXIC ACID  
 345. NAPROXEN  
 346. NARCOTICS 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. NITRAZEPAM  
     **5**  
 361. NITROGLYCERIN  
 362. NORETH ISTERONE ENANTHATE  
 363. NORFLOXACIN  
 364. OCTYLONIUM BROMIDE  
 365. OFLOXACIN  
 366. OLANZAPINE  
 367. OMEPRAZOLE  
 368. ORNIDAZOLE  
 369. ORPHENADRINE  
 370. ORTHOCLONE STERILE  
 371. OXAZEPAM  
 372. OXAZOLIDINE  
 373. OXCARBAZEPINE  
 374. OXETHAZAINE HYDROCHLORIDE  
 375. OXICONAZOLE  
 376. OXOLINIC ACID  
 377. OXPRENOLOL HYDROCHLORIDE  
 378. OXYBUTYNIN CHLORIDE  
 379. OXYFEDRINE  
 380. OXYMETAZOLINE  
 381. OXYPHENBUTAZONE  
 382. OXYTOCIN  
 383. OZOTHINE  
 384. PACLITAXEL  
 385. PANCURONIUM BROMIDE  
 386. PANTOPRAZOLE  
 387. PARA-AMINO BENZENE  
     SULPHONAMIDE, ITS SALTS &  
     DERIVATIVES  
 388. PARP-AMINO SALICYLIC ACID,  
     ITS SALTS, ITS DERIVATIVES  
 389. PARECOXIB  
 390. PAROXETINE HYDROCHLORIDE  
 391. D-PENICILLAMINE  
 392. PENTAZOCINE  
 393. PENTOXIFYLLINE  
 394. PEPLEOMYCIN  
 395. PHENELZINEH SULPHATE  
 396. PHENOBARBITAL

397. PHENOTHIAZINE, DERIVATIVES  
 OF AND SALTS OF ITS  
 DERIVATIVES  
 398. PHENYLBUTAZINE  
 399. PIMOZIDE  
 400. PINDOLOL  
 401. PIOGLITAZONE  
 HYDROCHLORIDE  
 402. PIRACETAM  
 403. PIROXICAM  
 404. PITUITORY GLAND, ACTIVE  
 PRINCIPLES OF, NOT OTHERWISE  
 SPECIFIED IN THIS SCHEDULE  
 AND THEIR SALTS  
 405. POLIDOCANOL  
 406. POLYESTRADIOL PHOSPHATE  
 407. PORACTANT ALFA  
 408. PRAZIQUANTEL  
 409. PREDNIMUSTINE  
 410. PREDNISOLONE  
 STEAROYLGLYCOLATE  
 411. PRENOXDIAZIN  
 HYDROCHLORIDE  
 412. PROMAZINE HYDROCHLORIDE  
 413. PROMEGESTONE  
 414. PROPAFENON HYDROCHLORIDE  
 415. PROPANOLOL HYDROCHLORIDE  
 416. PROPOFOL  
 417. PROTRISTYLINE  
 HYDROCHLORIDE  
 418. PYRAZINAMIDE  
 419. PYRVINIUM  
 420. QUETIAPINE FUMERATE  
 421. QUINAPRIL  
 422. QUINIDINE SULPHATE  
 423. RABEPRAZOLE  
 424. RACECADOTRIL  
 425. RALOXIFENE HYDROCHLORIDE  
 426. RAMIPRIL HYDROCHLORIDE  
 427. RANITIDINE  
 428. RAUWOLFIA, ALKALOIDS OF,  
 THEIR SALTS, DERIVATIVES OF  
 THE ALKALOIDS OR 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 MELEATE  
 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. SODIUM PICOSULPHATE  
 459. SODIUM CROMOGLYCAT  
 460. SODIUM HYALURONATE  
 461. SODIUM VALPROATE  
 462. SODIUM AND MAGLUMINE  
 IOTHALAMATES  
 463. SOMATOSTATIN  
 6  
 464. SOMATOTROPIN  
 465. SOTALOL  
 466. 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



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|-----------------------------------|---|
| 485. TERAZOSIN                    | 513. TRIFLUPERIDOL<br>HYDROCHLORIDE       |
| 486. TERBUTALINE SULPHATE         | 514. TRIFLUSAL                            |
| 487. TERFENADINE                  | 515. TRIMETAZIDINE<br>DIHYDROCHLORIDE     |
| 488. TERIZIDONE                   | 516. TRIMIPRAMINE                         |
| 489. TERLIPRESSIN                 | 517. TRIPOTASSIUM DICITRATE<br>BISMUTHATE |
| 490. TESTOSTERONE<br>UNDECOANOATE | 518. TROMANTADINE<br>HYDROCHLORIDE        |
| 491. TERATOLOL HYDROCHLORIDE      | 519. UROKINASE                            |
| 492. THALIDOMIDE                  | 520. VALSARTAN                            |
| 493. THIACETAZONE                 | 521. VASOPRESSIN                          |
| 494. THIOCOLCHICOSIDE             | 522. VECURONIUM BROMIDE                   |
| 495. THIOPROPAZATE, ITS SALTS     | 523. VENLAFAXINE HYDROCHLORIDE            |
| 496. THYMOGENE                    | 524. VERAPAMIL HYDROCHLORIDE              |
| 497. THYMOSIN-ALPHA 1             | 525. VERTEPORFIN                          |
| 498. TIAPROFENIC ACID             | 526. VINCRISTINE SULPHATE                 |
| 499. TIBOLONE                     | 527. VINBLASTINE SULPHATE                 |
| 500. TIMOLOL MALEATE              | 528. VINDESINE SULPHATE                   |
| 501. TINIDAZOLE                   | 529. VINORELBINE TATRATE                  |
| 502. TIZANIDINE                   | 530. XIPAMIDE                             |
| 503. TABRAMYCIN                   | 531. ZIDOVUDINE HYDROCHLORIDE             |
| 504. TOLFENAMIC ACID              | 532. ZIPRASIDONE HYDROCHLORIDE            |
| 505. TOPIRAMATE                   | 533. ZOLEDRONIC ACID                      |
| 506. TOPOTECAN HYDROCHLORIDE      | 534. ZOLPIDEM                             |
| 507. TRAMADOL HYDROCHLORIDE       | 535. ZOPICLONE                            |
| 508. TRANEXAMIC ACID              | 536. ZUCLOPENTHIXOL                       |
| 509. TRANYLCYPROMINE, ITS SALTS   |   |
| 510. TRAZODONE                    |   |
| 511. TRETINOIN                    |   |
| 512. TRIFLUPERAZINE               |   |

**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.”

**Foot Note-** The Principal Rules were published in the Official Gazette vide notification No. F. 28-10/45-H (1) dated 21.12.1945 and last amended vide No. G.S.R. 790 (E) dated 29.10.2009.