

DRUGS AND COSMETICS (2ND AMENDMENT) RULES, 2006
MINISTRY OF HEALTH AND FAMILYWELFARE
(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 24th 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 25th 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 (2nd 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

- | | |
|---|------------------------------|
| 1 | |
| 1. ABACAVIR | 12. ALENDRONATE SODIUM |
| 2. ABCIXIMAB | 13. ALLOPURINOL |
| 3. ACAMPROSATE CALCIUM | 14. ALPHACHYMOTRYPSIN |
| 4. ACEBUTOL HYDROCHLORIDE | 15. ALPRAZOLAM |
| 5. ACLARUBICIN | 16. ALPROSTADIL |
| 6. ALBENDAZOLE | 17. AMANTADINE HYDROCHLORIDE |
| 7. ALCLOMETASONE DIPROPIONATE | 18. AMIFOSTINE |
| 8. ACTILYSE | 19. AMIKACIN SULPHATE |
| 9. ACYCLOVIR | 20. AMILORIDE HYDROCHLORIDE |
| 10. ADENOSINE | 21. AMINEPTINE |
| 11. ADRENOCORTICOTROPHIC HORMONE (ACTH) | 22. AMINOGLUTETHIMIDE |
| | 23. AMINOSALICYLIC 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. ARTICAIN HYDROCHLORIDE
40. ATENOLOL
- 2**
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
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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. LOTE Prednol
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. MIRTAZAPINE
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
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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. PRAZIQUNTEL
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 CROMOGLYCATO
460. SODIUM HYALURONATE
461. SODIUM VALPROATE
462. SODIUM AND MAGLUMINE
IOTHALAMATES
463. SOMATOSTATIN
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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
HYDROCHLORIDE |
| 486. TERBUTALINE SULPHATE | 514. TRIFLUSAL |
| 487. TERFENADINE | 515. TRIMETAZIDINE
DIHYDROCHLORIDE |
| 488. TERIZIDONE | 516. TRIMIPRAMINE |
| 489. TERLIPRESSIN | 517. TRIPOTASSIUM DICITRATE
BISMUTHATE |
| 490. TESTOSTERONE
UNDECOANOATE | 518. TROMANTADINE
HYDROCHLORIDE |
| 491. TERATOLOL HYDROCHLORIDE | 519. UROKINASE |
| 492. THALIDOMIDE | 520. VALSARTAN |
| 493. THIAACETAZONE | 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. VINOURELBINE 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.