

DRUGS AND COSMETICS (2ND 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 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. 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. ALLOPURINOL
14. ALPHACHYMOTRYPSIN
15. ALPRAZOLAM
16. ALPROSTADIL
17. AMANTADINE HYDROCHLORIDE
18. AMIFOSTINE
19. AMIKACIN SULPHATE
20. AMILORIDE HYDROCHLORIDE
21. AMINEPTINE
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. ARTICAINA HYDROCHLORIDE
40. ATENOLOL

41.	ATRACURIUM BESYLATE INJECTION	96.	CEFPODOXIME POXETIL
42.	ATORVASTATIN	97.	CEFTAZIDIME PENTAHYDRATE
43.	AURANOFIN	98.	CEFTIZOXIME SODIUM
44.	AZATHIOPRINE	99.	CEFUROXIME
45.	AZTREONAM	100.	CELECOXIB
46.	BACAMPICILLIN	101.	CENTCHROMAN
47.	BACLOFEN	102.	CENTBUTINDOLE
48.	BALSALAZIDE	103.	CENTPROPАЗINE
49.	BAMBUTEROL	104.	CETIRIZINE HYDROCHLORIDE
50.	BARBITURIC ACID	105.	CHLORDIAZEPOXIDE
51.	BASILIXIMAB	106.	CHLORMEZANONE
52.	BENAZEPRIL HYDROCHLORIDE	107.	CHLORPHENIRAMINE MALEATE
53.	BENIDIPINE HYDROCHLORIDE	108.	CHLORPROMAZINE
54.	BENSERAZIDE HYDROCHLORIDE	109.	CHLORZOXAZONE
55.	BETAHISTINE DIHYDROCHLORIDE	110.	CICLOPIROX OLAMINE
56.	BETHANIDINE SULPHATE	111.	CIMETIDINE
57.	BEZAFIBRATE	112.	CINNARIZINE
58.	BICALUTAMIDE	113.	CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE / LACTATE
59.	BICLOTYMOЛ	114.	CISPLATIN
60.	BIFONAZOLE	115.	CITALOPRAM HYDROBROMIDE
61.	BIMATOPROST	116.	CLARITHROMYCIN
62.	BIPERIDEN HYDROCHLORIDE	117.	CLAVULANIC ACID
63.	BIPHENYL ACETIC ACID	118.	CLIDINIUM BROMIDE
64.	BITOSCANATE	119.	CLINDAMYCIN
65.	BLEOMYCIN	120.	CLOBAZAM
66.	PRIMONIDINE TARTRATE	121.	CLOBETASOL PROPENATE
67.	BROMHEXINE HYDROCHLORIDE	122.	CLOBETASONE 17-BUTYRATE
68.	BROMOCRIPTINE MESYLATE	123.	CLOFAZIMINE
69.	BUDESONIDE	124.	CLOFIBRATE
70.	BULAQUINE	125.	CLONAZEPAM
71.	BUPIVA CAINE HYDROCHLORIDE	126.	CLONIDINE HYDROCHLORIDE
72.	BUPROPION	127.	CLOPAMIDE
73.	BUSPIRONE	128.	CLOPIDOGREL BISULPHATE
74.	BUTENAFINE HYDROCHLORIDE	129.	CLOSTEBOL ACETATE
75.	BUTORPHANOL TARTRATE	130.	CLOTRIMAZOLE
76.	CABERGOLINE	131.	CLOZAPINE
77.	CALCIUM DOBESILATE	132.	CODEINE
78.	CANDESARTAN	133.	COLCHICINE
79.	CAPECITABINE	134.	CORTICOSTEROIDS
80.	CAPTOPRIL	135.	COTRIMOXAZOLE
81.	CARBIDOPA	136.	CYCLANDELATE
82.	CARBOCISTEINE	137.	CYCLOSPORINS
83.	CARBOPLATIN	138.	DACLIZUMAB
84.	CARBOQUONE	139.	DANAZOLE
85.	CARISOPRODOL	140.	DAPSONE
86.	L-CARNITINE	141.	DES LorATADINE
87.	CARTEOLOL HYDROCHLORIDE	142.	DESOGESTROL
88.	CARVEDILOL	143.	DEXRAZOXANE
89.	CEFADROXYL	144.	DEXTRANOMER
90.	CEFATOXIME SODIUM	145.	DEXTROMETHORPHAN HYDROMIDE
91.	CEFAZOLIN SODIUM	146.	DEXTROPROPOXYPHENE
92.	CEFDINIR	147.	DIAZAPAM
93.	CEFEPIME HYDROCHLORIDE	148.	DIAZOXIDE
94.	CEFETAMET PIVOXIL	149.	DICLOFENAC SODIUM/POTASSIUM/ACID
95.	CEFPiROME		

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| 150. | DICYCLOMIN HYDROCHLORIDE | 203. | FLUNARIZINE HDROCHLORIDE |
| 151. | DIDANOSINE | 204. | FLUOXETINE HYDROCHLORIDE |
| 152. | DIGOXINE | 205. | FLUPENTHIXOL |
| 153. | DILAZEP HYDROCHLORIDE | 206. | FLUPHENAZINE ENANTHATE AND
DECANOATE |
| 154. | DILTIAZEM | 207. | FLURAZEPAM |
| 155. | DINOPROSTONE | 208. | FLURBIPROFEN |
| 156. | DIPHENOXYLATE, ITS SALTS | 209. | FLUTAMIDE |
| 157. | DIPIVEFRIN HYDROCHLORIDE | 210. | FLUTICASONE PROPIONATE |
| 158. | DI-SODIUM PAMIDRONATE | 211. | FLUVOXAMINE MALEATE |
| 159. | DISOPYRAMIDE | 212. | FORMESTANE |
| 160. | DOCETAXEL | 213. | FOSFESTRIL SODIUM |
| 161. | DOMPERIDONE | 214. | FOSINOPRIL SODIUM |
| 162. | DONEPEZIL HYDROCHLORIDE | 215. | FOSSPHENYTOIN SODIUM |
| 163. | DOPAMINE HYDROCHLORIDE | 216. | FOTEMUSTINE |
| 164. | DOTHIEPIN HYDROCHLORIDE | 217. | GABAPENTIN |
| 165. | DOXAPRAM HYDROCHLORIDE | 218. | GALANTHAMINE HYDROBROMIDE |
| 166. | DOXAZOSIN MESYLATE | 219. | GALLAMINE, ITS SALTS, ITS QUATERNARY
COMPOUND |
| 167. | DOXEPIN HYDROCHLORIDE | 220. | GANCYCLOVIR |
| 168. | DOXORUBICIN HYDROCHLORIDE | 221. | GANIRELIX |
| 169. | DROTRECOGIN-ALPHA | 222. | GATIFLOXACIN |
| 170. | EBASTINE | 223. | GEMCITABINE |
| 171. | ECONOZOLE | 224. | GEMFIBROZIL |
| 172. | EFAVIRENZ | 225. | GEMTUZUMAB |
| 173. | ENALAPRIL MELEATE | 226. | GENODEOXYCHOLIC ACID |
| 174. | ENFENAMIC ACID | 227. | GLICLAZIDE |
| 175. | EPINEPHRINE | 228. | GLIMEPIRIDE |
| 176. | EPIRUBICINE | 229. | GLUCAGON |
| 177. | EPTIFIBATIDE | 230. | GLYCOPYRROLATE |
| 178. | ERGOT, ALKALOIDS OF WHETHER
HYDROGENATED OR NOT, THEIR
HOMOLOGOUES, SALTS | 231. | GLYDIAZINAMIDE |
| 179. | ESOMEPRAZOLE | 232. | GOSERELIN ACETATE |
| 180. | ESTRADIOL SUCCINATE | 233. | GRANISETRON |
| 181. | ESTRAMUSTINE PHOSPHATE | 234. | GUANETHIDINE |
| 182. | ETANERCEPT | 235. | GUGULIPID |
| 183. | ETHACRIDINE LACTATE | 236. | HALOGENATED HYDROXYQUINOLINES |
| 184. | ETHAMBUTOL HYDROCHLORIDE | 237. | HALOPERIDOL |
| 185. | ETHAMSYLATE | 238. | HEPARIN |
| 186. | ETHINYLOESTRADIOL | 239. | HEPATITIS B. VACCINE |
| 187. | ETHIONAMIDE | 240. | HYALURONIDASE |
| 188. | ETIDRONATE DISODIUM | 241. | HYDROCORISONE 17-BUTYRATE |
| 189. | ETODOLAC | 242. | HYDROTALCITE |
| 190. | ETOMIDATE | 243. | HYDROXIZINE |
| 191. | ETOPOSIDE | 244. | IBUPROFEN |
| 192. | EXEMESTANE | 245. | IDEBENONE |
| 193. | FAMCICLOVIR | 246. | IINDAPAMIDE |
| 194. | FAMOTIDINE | 247. | IMIPRAMINE |
| 195. | FENBENDAZOLE | 248. | INDINAVIR SULPHATE |
| 196. | FENOFIBRATE | 249. | INDOMETHACIN |
| 197. | FEXOFENADINE | 250. | INSULIN HUMAN |
| 198. | FINASTERIDE | 251. | INTERFERON |
| 199. | FLAVOXATE HYDROCHLORIDE | 252. | INTRAVENOUS FAT EMULSION |
| 200. | 5-FLUOROURACIL | 253. | IOBITRIDOL |
| 201. | FLUDARABINE | 254. | IOHEXOL |
| 202. | FLUFENAMIC ACIDS | 255. | IOPAMIDOL |

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. 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

361.	NITROGLYCERIN	412.	PROMAZINE HYDROCHLORIDE
362.	NORETH ISTERONE ENANTHATE	413.	PROMEGESTONE
363.	NORFLOXACIN	414.	PROPAFENON HYDROCHLORIDE
364.	OCTYLONIUM BROMIDE	415.	PROPANOLOL HYDROCHLORIDE
365.	OFLOXACIN	416.	PROPOFOL
366.	OLANZAPINE	417.	PROTRISTYLINE HYDROCHLORIDE
367.	OMEPRAZOLE	418.	PYRAZINAMIDE
368.	ORNIDAZOLE	419.	PYRVINIUM
369.	ORPHENADRINE	420.	QUETIAPINE FUMERATE
370.	ORTHOCLONE STERILE	421.	QUINAPRIL
371.	OXAZEPAM	422.	QUINIDINE SULPHATE
372.	OXAZOLIDINE	423.	RABEPRAZOLE
373.	OXCARBAZEPINE	424.	RACECADOTRIL
374.	OXETHAZAINE HYDROCHLORIDE	425.	RALOXIFENE HYDROCHLORIDE
375.	OXICONAZOLE	426.	RAMIPRIL HYDROCHLORIDE
376.	OXOLINIC ACID	427.	RANITIDINE
377.	OPRENOLOL HYDROCHLORIDE	428.	RAUWOLFIA, ALKALOIDS OF, THEIR SALTS, DERIVATIVES OF THE ALKALOIDS OR RAUWOLFIA
378.	OXYBUTYNIN CHLORIDE	429.	REBOXETINE
379.	OXYFEDRINE	430.	REPAGLINIDE
380.	OXYMETAZOLINE	431.	REPROTEROL HYDROCHLORIDE
381.	OXYPHENBUTAZONE	432.	RILMENIDINE
382.	OXYTOCIN	433.	RILUZONE
383.	OZOTHINE	434.	RISPERIDONE
384.	PACLITAXEL	435.	RITONAVIR
385.	PANCURONIUM BROMIDE	436.	RITODRINE HYDROCHLORIDE
386.	PANTOPRAZOLE	437.	RITUXIMAB
387.	PARA-AMINO BENZENE SULPHONAMIDE, ITS SALTS & DERIVATIVES	438.	RIVASTIGMINE
388.	PARP-AMINO SALICYLIC ACID, ITS SALTS, ITS DERIVATIVES	439.	ROCURONIUM BROMIDE
389.	PARECOXIB	440.	ROPINIROLE
390.	PAROXETINE HYDROCHLORIDE	441.	ROSOXACIN
391.	D-PENICILLAMINE	442.	ROSIGLITAZONE MELEATE
392.	PENTAZOCINE	443.	SALBUTAMOL SULPHATE
393.	PENTOXIFYLLINE	444.	SALICYL-AZO-SULPHAPYRIDINE
394.	PEPLEOMYCIN	445.	SALMON CALCITONIN
395.	PHENELZINEH SULPHATE	446.	SAQUINAVIR
396.	PHENOBARBITAL	447.	SATRANIDAZOLE
397.	PHENOTHIAZINE, DERIVATIVES OF AND SALTS OF ITS DERIVATIVES	448.	SECNIDAZOLE
398.	PHENYLBUTAZINE	449.	SEPTOPAL BEADS & CHAINS
399.	PIMOZIDE	450.	SERRATIOPEPTIDASE
400.	PINDOLOL	451.	SERTRALINE HYDROCHLORIDE
401.	PIOGLITAZONE HYDROCHLORIDE	452.	SIBUTRAMINE HYDROCHLORIDE
402.	PIRACETAM	453.	SILDENAFIL CITRATE
403.	PIROXICAM	454.	SIMVASTATIN
404.	PITUITORY GLAND, ACTIVE PRINCIPLES OF, NOT OTHERWISE SPECIFIED IN THIS SCHEDULE AND THEIR SALTS	455.	SIROLIMUS
405.	POLIDOCANOL	456.	SISOMICIN SULPHATE
406.	POLYESTRADIOL PHOSPHATE	457.	S-NEOMINOPHAGEN
407.	PORACTANT ALFA	458.	SODIUM PICOSULPHATE
408.	PRAZIQUANTEL	459.	SODIUM CROMOGLYCATE
409.	PREDNIMUSTINE	460.	SODIUM HYALURONATE
410.	PREDNISOLONE STEAROYLGLYCOLATE	461.	SODIUM VALPROATE
411.	PRENOXDIAZIN HYDROCHLORIDE	462.	SODIUM AND MAGLUMINE IOTHALAMATES
		463.	SOMATOSTATIN

464.	SOMATOTROPIN	519.	UROKINASE
465.	SOTALOL	520.	VALSARTAN
466.	SPARFLOXACIN	521.	VASOPRESSIN
467.	SPECTINOMYCIN HYDROCHLORIDE	522.	VECURONIUM BROMIDE
468.	SPIRONOLACTONE	523.	VENLAFAXINE HYDROCHLORIDE
469.	STAVUDINE	524.	VERAPAMIL HYDROCHLORIDE
470.	SUCRALFATE	525.	VERTEPORFIN
471.	SULPHADOXINE	526.	VINCRISTINE SULPHATE
472.	SULPHAMETHOXINE	527.	VINBLASTINE SULPHATE
473.	SULPHAMETHOXYPYRIDAZINE	528.	VINDESINE SULPHATE
474.	SULPHAPHENAZOLE	529.	VINORELBINE TATRATE
475.	SULPIRIDE	530.	XIPAMIDE
476.	SULPROSTONE HYDROCHLORIDE	531.	ZIDOVUDINE HYDROCHLORIDE
477.	SUMATRIPTAN	532.	ZIPRASIDONE HYDROCHLORIDE
478.	TACRINE HYDROCHLORIDE	533.	ZOLEDRONIC ACID
479.	TAMSULOSIN HYDROCHLORIDE	534.	ZOLPIDEM
480.	TRAPIDIL	535.	ZOPICLONE
481.	TEGASEROD MALEATE	536.	ZUCLOPENTHIXOL
482.	TEICOPLANIN		
483.	TELMISARTAN		
484.	TEMOZOLAMIDE		
485.	TERAZOSIN		
486.	TERBUTALINE SULPHATE		
487.	TERFENADINE		
488.	TERIZIDONE		
489.	TERLIPRESSIN		
490.	TESTOSTERONE UNDECOANOATE		
491.	TERATOLOL HYDROCHLORIDE		
492.	THALIDOMIDE		
493.	THIACETAZONE		
494.	THIOLCHICOSIDE		
495.	THIOPROPAZATE, ITS SALTS		
496.	THYMOGENE		
497.	THYMOSIN-ALPHA 1		
498.	TIAPROFENIC ACID		
499.	TIBOLONE		
500.	TIMOLOL MALEATE		
501.	TINIDAZOLE		
502.	TIZANIDINE		
503.	TABRAMYCIN		
504.	TOLFENAMIC ACID		
505.	TOPIRAMATE		
506.	TOPOTECAN HYDROCHLORIDE		
507.	TRAMADOL HYDROCHLORIDE		
508.	TRANEXAMIC ACID		
509.	TRANLYCYPROMINE, ITS SALTS		
510.	TRAZODONE		
511.	TRETINOIN		
512.	TRIFLUPERAZINE		
513.	TRIFLUPERIDOL HYDROCHLORIDE		
514.	TRIFLUSAL		
515.	TRIMETAZIDINE DIHYDROCHLORIDE		
516.	TRIMIPRAMINE		
517.	TRIPOTASSIUM DICITRATE BISMUTHATE		
518.	TROMANTADINE HYDROCHLORIDE		

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."

[No. X-11014/3/2004-DMS & PFA]

RITA TEOTIA, Jt. Secy.

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. 26(E) dated 19.1.2006.
