

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. APRACLOPIDINE
34. APROTININ
35. ORGANIC COMPOUND OF ARSENIC
36. ARTEETHER
37. ARTEMETHER
38. ARTESUNATE
39. ARTICAINE 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.	CENTPROPAZINE
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.	BICLOTYMOLOL	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.	CLOTTRIMAZOLE
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.	DESLOXATADINE
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		

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 HOMOLOGUES, 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	308.	MELOXICAM
257.	IOPROMIDE	309.	MEPHENESIN, ITS ESTERS
258.	IRBESARTAN	310.	MEPHENTERMINE
259.	IRINOTECAN HYDROCHLORIDE	311.	MEROPENAM
260.	IRON PREPARATION FOR PARENTERAL USE	312.	MESTEROLONE
261.	ISEPAMICINE	313.	METAXALONE
262.	ISOCARBOXSIDE	314.	METHICILLIN SODIUM
263.	ISOFLURANE	315.	METHOCARBAMOL
264.	ISONICOTNIC ACID HYDRAZINE AND OTHER-HYDRAGINE DERIVATIVES OF ISONICOTINIC ACID	316.	METHOTRAXATE
265.	ISOSORBIDE DINITRATE/ MONONITRATE	317.	METOCLOPRAMIDE
266.	ISOTRETINOIN	318.	METOPROLOL TARTRATE
267.	ISOXSUPRINE	319.	METRIZAMIDE
268.	ITOPRIDE	320.	METRONIDAZOLE
269.	KETAMINE HYDROCHLORIDE	321.	MEXILETINE HYDROCHLORIDE
270.	KETOCONAZOLE	322.	MIANSERIN HYDROCHLORIDE
271.	KETOPROFEN	323.	MICONAZOLE
272.	KETOROLAC TROMETHAMINE	324.	MIDAZOLAM
273.	LABETALOL HYDROCHLORIDE	325.	MIFEPRISTONE
274.	LACIDIPINE	326.	MILRINONE LACTATE
275.	LAMIVUDINE	327.	MILTEFOSINE
276.	LAMOTRIGINE	328.	MINOCYCLINE
277.	LATANOPROST	329.	MINOXIDIL
278.	LEFUNOMIDE	330.	MIRTAZAPINE
279.	LERCANIDIPINE HYDROCHLORIDE	331.	MISOPROSTOL
280.	LETROZOLE	332.	MITOXANTRONE HYDROCHLORIDE
281.	LEUPROLIDE ACETATE	333.	MIZOLASTINE
282.	LEVAMESOLE	334.	MOCLOBEMIDE
283.	LEVARTERENOL	335.	MOMETASONE FUROATE
284.	LEVOBUNOLOL	336.	MONTELUKAST SODIUM
285.	LEVOCETIRIZINE	337.	MORPHAZINAMIDE HYDROCHLORIDE
286.	LEVODOPA	338.	MOSAPRIDE
287.	LEVOFLOXACIN	339.	MOXIFLOXACIN
288.	LEVOVIST	340.	MYCOPHENOLATE MOFETIL
289.	LIDOFLAZINE	341.	NADIFLOXACIN
290.	LINEZPLID	342.	NADOLOL
291.	LITHIUM CARBONATE	343.	NAFARELIN ACETATE
292.	LOFEPRAMINE DECANOATE	344.	NALIDIXIC ACID
293.	LOPERAMIDE	345.	NAPROXEN
294.	LORAZEPAM	346.	NARCOTICS DRUGS LISTED IN NARCOTIC DRUGS & PSYCHOTROPIC SUBSTANCES ACT, 1985
295.	LOSARTAN POTASSIUM	347.	NATAMYCIN
296.	LOTEPREDNOL	348.	NATEGLINIDE
297.	LOVASTATIN	349.	N-BUTYL-2-CYANOACRYLATE
298.	LOXAPINE	350.	NEBIVOLOL
299.	MEBENDAZOLE	351.	NEBUMETONE
300.	MEBEVERINE HYDROCHLORIDE	352.	NELFINAVIR MESILATE
301.	MEDROXY PROGESTERONE ACETATE	353.	NETILMICIN SULPHATE
302.	MEFENAMIC ACID	354.	NEVIRAPINE
303.	MEFLOQUINE HYDROCHLORIDE	355.	NICERGOLINE
304.	MEGESTROL ACETATE	356.	NICORANDIL
305.	MEGLUMINE IOCARMATE	357.	NIFEDIPINE
306.	MELAGENINA	358.	NIMESULIDE
307.	MELITRACEN HYDROCHLORIDE	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.	PRAZQUANTEL	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
 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
 485. TERAZOSIN
 486. TERBUTALINE SULPHATE
 487. TERFENADINE
 488. TERIZIDONE
 489. TERLIPRESSIN
 490. TESTOSTERONE UNDECOANOATE
 491. TERATOLOL HYDROCHLORIDE
 492. THALIDOMIDE
 493. THIACETAZONE
 494. THIOCOLCHICOSIDE
 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. TRANYLCYPROMINE, 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

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 TATRATE
 530. XIPAMIDE
 531. ZIDOVUDINE HYDROCHLORIDE
 532. ZIPRASIDONE HYDROCHLORIDE
 533. ZOLEDRONIC ACID
 534. ZOLPIDEM
 535. ZOPICLONE
 536. ZUCLOPENTHIXOL

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.
