THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES RULES, 1985[1]

In exercise of the powers conferred by section 9, read with section 76 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following rules, namely:—

CHAPTER 1

PRELIMINARY

1. Short title and commencement.—(1) These rules may be called the Narcotic Drugs and Psychotropic Substances Rules, 1985.

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

2. Definitions.—In these rules, unless the context otherwise requires,—

(a) "the Act," means the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985);

(b) "Appellate Authority" means any authority to whom an appeal may lie under any provision of these rules;

[3][(c) "Chemical Examiner" means the Chemical Examiner or Deputy Chief Chemist or Shift Chemist or Assistant Chemical Examiner, Government Opium and Alkaloid Works, Neemuch or, as the case may be, Ghazipur;]

(d) "Chief Controller of Factories" means the Chief Controller of Government Opium and Alkaloid Factories;

[4][(da) "Controller of Drugs" means the officer appointed as the controlling authority by the State Government under rule 50 of the Drugs and Cosmetics Rules, 1945 made under the Drugs and Cosmetics Act, 1940 (23 of 1940);]

(e) "crop year" means the period beginning on and from the 1st October of any year to the 30th September of the following year;

[4][(ea) "Firm" means a company, body corporate, proprietorship firm, partnership firm, limited liability partnership firm, association of persons;]

[4][[(eb) "Form" means a Form oppended to these Rules;]

(f) "General Manager" means the General Manager, Government Opium and Alkaloid Works, Neemuch or, as the case may be, Ghazipur;

(g) "issuing authority" means the Narcotic Commissioner or any other officer who may be authorised in this behalf by the Central

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1. *Vide* G.S.R. 837(E), dated 14th November, 1985, published in the Gazette of India, Extra., Pt. II, Sec. 3(i), dated 14th November, 1985.
2. Came into force on 14-11-1985.
3. Subs. G.S.R. 82, dated 14th February, 1995, for clause (c) (w.e.f. 25-2-1995).
4. Ins. by G.S.R. 359(E), dated 5th May, 2015 (w.e.f. 5-5-2015).

Sl. No.	International non-proprietary names	Other non-proprietary names	Chemical name
90.	METAMFETAMINE	methamphetamine RACEMATE	(±)-N-μ-dimethylphenethylamine mecnate
91.		delta-9-***tetrahydrocannabinol and stereochemical variants	(6a-R, 10aR)-6a, 7, 8, 10a-tetrahydro-6, 6, 9-trimethyl-3-penty 611-dibenzo [b-d] pyran-OI
92.	BUPRENORPHINE		21, cyclopropyl-7-μ-[(S)-I-hydroxy-1-2, 2-trimethyl-propyl]6, 14-endo-ethano-6-7,8, 14-tetra-hydrooripavine
93.	BUTALBITAL		5-allyl-5-isobutylbarbituric acid
94	CATHINE	(+)-norpseudo-ephedrine	(+)-(R)-μ-[(R)-I-aminoethyl] benzyl alcohol
95.	ALLOBARBITAL	MEFENOREX	5,5-diallybarbituric acid
96.	ETILAMFETAMINE	N-ethylamphetamine	N-ethyl-μ-methylphenethylamine
97.	FENCAMEFAMIN		N-ethyl-3-phenly-2-norbornanmine
98.	FENPROPOREX		(±)-3-[(μ-methyphenethy) amino] propioxitrile
99.	MEFENOREX		N(3 chloropropyl)-a-methylphenethylamine
100.	MIDAZOLAM		8-chloro-6-a-(o-fluorophenyl)-1-methyl-4H-imidazol [1, 5-a] [1,4] benzodiazepine
101.	PEMOLINE		2-amino-5-phenyl-2-oxazolin-4-one(-2-imino-5-phenyl-4-oxazolidinone)
102.	PYROVAERONE		4-methyl-2-(1-pyrrolidinyl) valerophenone
103.	SECBUTABARBITAL		5-sec-butyl-5-ethylbarbituric acid
104.	VINYLBITAL		5-(1-methylbutyl)-5vinylbarbituric acid
105.		rutobarbital	5-butyl-5-ethylbarbituric acid]
[1][105A.	ETRYPTAMINE		(3-(2-aminobutyl) indole)
105B.	METHCATHINONE		(2-(methylamino)-1 phenylpropan-1-one)
105C.	ZIPEPROL		(a-(a-methoxybenzyl)-4 (b methoxyphenethyl)-1-(piperazineethanol)
105D.	AMINOREX		(2-amino-5-phenyl-2-oxazoline)
105E.	BROTIZOLAM		(2-bromo-4-)0-chlorophenyl)-9-methyl-6H-thieno (3,2-f)-s-triazolo [4,3,-a} {1,4} diazepine)
105F.	MESOCARB		(3-(μ-methylphenethyl-N-henylerbamoyl) Sydnone imine].
[2][106.			2C-B (4-bromo-2, 5 dimethoxyphenethylamine)
107.			4-MTA (a* Methyl-4-Mthyl thiophenethylamine)
108.			GHB (r-Hydroxybutyric Acid)
109.			Zolpidem (INN)]
[3][110.			amineptine (7-[(10, 11-dihydro-5H-dibenzo [a, d] cyclo hepten-5-yl) amino] heptanoic acid)]
[4][110A.	KETAMINE		2-(2-cholorphenyl)-2-(methyl amino) cyclohexanone]
[5][110B.	MEPHEDRONE	4-methylmethcathinone (4-MMC) 4-methylephedrone	(RS-2-methylamino-1-(4-methylphenyl) propan-1-one]

[6][111.] Salts and preparations of above.

1. Added by S.O. 39(E), dated 12th January, 1996.
2. Ins. by G.S.R. 475(E), dated 11th June, 2003.
3. Ins. by G.S.R. 1(E), dated 2nd January, 2004.
4. Ins. by G.S.R. 311(E), dated 10th February, 2011.
5. Ins. by G.S.R. 376(E), dated 5th February, 2015.
6. Serial No. 110 re-numbered as 111 by G.S.R. 1(E), dated 2nd January, 2004.

Government for issuing a licence under Chapter V of these rules or issuing an import certificate or export authorisation under Chapter VI of these rules in respect of narcotic drugs or psychotropic substances;

(h) "licence" means a licence issued under these rules;

[1][(ha) "Licenced chemist" means a person who has obtained a licence to possess, sell, exhibit or offer for sale or distribution by retail, essential narcotic drugs under these rules;]

[1][(hb) "Licenced dealer" means a person who has obtained a licence to possess, sell, exhibit or offer for sale or distribution by wholesale, essential narcotic drugs under these rules;]

[1][(hc) "medical institution" means a hospital, dispensary, clinic or an institution by whatever name called that offers services or facilities requiring diagnosis, treatment or care of illness, disease, injury, deformity or abnormality, established and administered or maintained by the Government or Municipal Corporation or Municipal Council or Zila Parishad or any person or body of persons;]

[1][(hd) "patent or proprietary medicine" shall have the same meaning as defined in the Drug and Cosmetics Act, 1940 (23 of 1940);]

[1][(he) "prescription" means a prescription given by a registered medical practitioner for the supply of any of the essential narcotic drugs to a patient for medical use in accordance with these rules;]

(i) "Proper Officer", in relation to any function to be performed under these rules, means the officer of Narcotics Department who is assigned those functions by the Narcotics Commissioner;

[1][(ia) "recognised medical institution" means a medical institution recognised as such under these rules;]

[1](ib) "registered medical practitioner" means any person registered as a medical practitioner under the Indian Medical Council Act, 1956 (102 of 1956) or under any law for the registration of medical practitioner for the time being in force, or registered as a dentist under the Dentists Act, 1948 (16 of 1948) or under any law for the registration of dentists for the time being in force and has undergone training in pain relief and palliative care for prescription of essential narcotic drugs for pain relief and palliative care or training in opioid substitution therapy for prescription of essential narcotic drugs for treatment of opioid dependence;]

(j) 'Schedule" means a Schedule annexed to these rules;

(k) words and expressions used herein and not defined, but defined in the Act shall have the meanings respectively assigned to them in the Act.

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1. Ins. by G.S.R. 359(E), dated 5th May, 2015 (w.e.f. 5-5-2015).

COMMENTS

Article(s) seized in connection with an offence may be sent for chemical analysis to any laboratory in the country, which is permitted to do such analysis; *Ram Dayal* v. *Central Narcotics Bureau,* (1993) 3 Crimes 818 (MP) (FB).

CHAPTER II

POWERS OF OFFICERS

3. Delegation of powers.—Subject to such directions as may be given by the Central Government, the Narcotics Commissioner appointed by the Central Government under sub-section (1) of section 5 of the Act, may authorise any officer subordinate to him, to exercise all or any of his powers under these rules.

4. Narcotics Commissioner and other officers to exercise the powers of their subordinates.—The Narcotics Commissioner and such other officer as may be appointed by the Central Government under sub-section (1) of section 5 of the Act may perform all or any of the functions, or exercise any of the powers, assigned under these rules to the officers subordinate to them.

CHAPTER III

OPIUM POPPY CULTIVATION AND PRODUCTION OF OPIUM AND POPPY STRAW

5. Opium poppy cultivation and production of opium or poppy straw.—The opium poppy for production of opium or poppy straw shall not be cultivated save on account of the Central Government and in the tracts notified by it from time to time and in accordance with the conditions of a licence issued by the District Opium Officer under rule 8.

6. Fee for grant of licence.--The licence of cultivation of opium poppy may be granted by the District Opium Officer on payment of a fee of [1][rupees twenty-five].

7. Form of licence for cultivation of the opium poppy.—The licence for cultivation of opium poppy for the production of opium or poppy straw shall be issued in Form No. 1 appended to these rules.

8. Issue of licence.—Subject to the general conditions relating to grant of licence notified by the Central Government*, the District Opium Officer may issue licence to any person for a crop year for cultivation of the opium poppy for production of opium or poppy straw on receipt of an application made by that person in Form No.2 appended to these rules.

9. Licence to specify the area, etc.—The licence for cultivation of opium poppy issued under rule 8 shall specify the area and designate the plots to be cultivated with opium poppy.

10. Designating of Lambardar.—The District Opium Officer may designate one of the cultivators of opium poppy as Lambardar in each village where opium

1. Subs. by G.S.R. 543, dated 24th October, 1994 (w.e.f. 5-11-1994).

* The Central Government has notified the general conditions for grant of licence for cultivation of opium poppy on account of the Central Government during the Opium Crop Year commencing on the 1st day of October, 2005 and ending with the 30th day of September, 2006 (Published in this Volume).

poppy cultivation is permitted, who shall perform such functions and on such terms and conditions as may be specified from time to time by the Narcotics Commissioner.

11. Withholding or cancellation of licence.—(1) An officer higher in rank than the District Opium Officer may, for sufficient reasons to be recorded in writing, withhold or cancel a licence already issued.

(2) No order shall be passed under sub-rule (1) unless the cultivator has been given a reasonable opportunity of showing cause against the said order or is heard in person, if he so desires.

(3) Where opium poppy has been cultivated under a licence which is subsequently withheld, or cancelled, the standing crop, if any, shall be destroyed under the supervision of the proper officer in such manner as may be specified by the Narcotics Commissioner.

12. Procedure with regard to measurement of land cultivated with opium poppy.—(1) All plots of land cultivated with opium poppy in accordance with the licence issued under these rules, shall be measured in metres by the proper officer in the presence of the cultivator concerned and the Lambardar of the village and the concerned cultivator and the Lambardar of the village shall attest the entries made in the records to be maintained by the Lambardar, as may be specified by the Narcotics Commissioner in this behalf, under their signature/ thumb-impression with date, in token of having satisfied themselves regarding the correctness of the measurement.

(2) The measurement conducted by the proper officer shall be subject to such further checks by such officers as may be specified by the Narcotics Commissioner in this behalf.

13. Procedure with regard to preliminary weighment.—(1) The cultivator shall, during the course of harvesting, produce daily before the Lambardar, each day's collection of opium from his crop for weighment.

(2) The Lambardar shall make arrangements to weigh such opium and make necessary entries in the records to be maintained by him as may be specified by the Narcotics Commissioner in this behalf.

(3) The cultivator and the Lambardar shall attest the entries made in such records under their signature/thumb-impression with date, showing the quantity of opium weighed on a particular day.

(4) The proper officer shall conduct check weighment of the opium collected by the cultivators with reference to the entries in the Lambardar's record and indicate his finding therein which shall be attested by him and the Lambardar under their signature with date.

(5) The variations between the quantity of opium produced by the cultivator indicated in the Lambardar's record and as found by the proper officer during his check, shall be inquired into by the proper officer in order to ascertain the liability of the cultivator for punishment under section 19 of the Act.

14. Delivery of opium produced.—All opium, the produce of land cultivated with opium poppy, shall be delivered by the cultivators to the District Opium

Officer or any other officer duly authorised in this behalf, by the Narcotics Commissioner at a place as may be specified by such officer.

15. Opium to be weighed, examined and classified.—All opium delivered by the cultivators to the District Opium Officer or any other officer authorised as aforesaid, shall, in the presence of the concerned cultivator or any person authorised by him and the Lambardar of the village, be weighed, examined and classified according to its quality and consistence and forwarded by the District Opium Officer to the Government Opium Factory in such manner as may be specified by the Narcotics Commissioner.

16. Procedure where cultivator is dissatisfied with classification of opium.—Any cultivator who may be dissatisfied with the classification of his opium done by the officer referred to in rule 15 may have it forwarded by such officer to the Government Opium Factory separately, after having it properly sealed in his presence and in the presence of the concerned Lambardar.

17. Procedure for sending opium suspected to be adulterated.— When opium delivered by a cultivator to the District Opium Officer or any other officer authorised in this behalf, is suspected of being adulterated with any foreign substance, it shall be forwarded to the Government Opium Factory separately, after it is properly sealed in the presence of the cultivator and the concerned Lambardar.

18. Drawing of samples from opium sent to Government Opium Factory under rule 16 or rule 17.—The sealed opium received separately in accordance with rule 16 or rule 17, shall be opened and sample drawn thereof in the presence of the cultivator, if he so desires, to whom, a notice intimating the date and time in this behalf, shall be sent well in advance.

19. Fixation of price of opium.—(1) The Central Government shall, from time to time, fix the price of opium, to be paid to the cultivators, in such manner as it may deem fit.

(2) Such price shall be fixed per kilogram of opium of a standard consistence.

20. Provisional payment of price.—(1) The District Opium Officer shall, having regard to the weight and consistence of opium delivered by individual cultivators, work out the weight of such opium at the standard consistence and determine provisionally the total price payable to such cultivators.

(2) The said officer, shall, pay to the cultivators, ninety per cent. of the price so determined which shall be subject to adjustment against the final price payable to the cultivators to be determined as provided hereinafter.

21. Weighment and examination of the opium at the Government Opium Factory.—The opium forwarded by the District Opium Officer shall be received, weighed, examined, and classified in the Government Opium Factory under the supervision of the General Manager in such manner as may be specified by the Narcotics Commissioner.

22. Confiscation of adulterated opium.—All such opium received separately under rule 17, if found to be adulterated on examination by the Chemical Examiner in the Government Opium Factory may be liable to confiscation by the General Manager.

23. Adjudication of confiscation of adulterated opium.—No such confiscation shall be ordered by the General Manager unless the concerned cultivator is given a reasonable opportunity of showing cause against the proposed order and is heard in person, if he so desires.

24. Determination of final price of opium.—(1) Subject to rule 21, the final price of opium payable to the cultivator shall, having regard to the price fixed by the Central Government under rule 19, be determined by the General Manager on the basis of analysis report of the Chemical Examiner [1][***] and communicated to the concerned District Opium Officer.

(2) The price payable in respect of any opium which is delivered to the District Opium Officer or any other officer authorised in this behalf under rule 14 and is not initially suspected to be adulterated but found to be adulterated on examination in the Government Opium Factory, shall be subject to reduction at such rates as may be specified by the Central Government.

25. Adjustment of cultivators' account and recovery of dues from the cultivators.—The accounts of the cultivators for a particular crop year shall be adjusted by the District Opium Officer at the time of issuing of licences for the subsequent crop year and any balance that may remain due from the cultivators shall be recovered and any amount due to them be paid.

26. Weights and scales.—The weights and scales to be used for weighing the opium at the weighment centres and the Government Opium Factory shall be caused to be examined at the appropriate time by the Deputy Narcotics Commissioner or the General Manager, as the case may be.

27. Cultivation of opium poppy for exclusive production of poppy straw.—The Central Government may, if it considers it expedient so to do, permit cultivation of the opium poppy for the exclusive production of poppy straw in accordance with a licence issued under rule 8 in such tracts and subject to such conditions as may be specified by it, by notification in the Official Gazette in this behalf:

Provided that the poppy straw produced by the cultivators or a result of the cultivation of opium poppy for production of opium, shall be deemed to have been produced under a valid licence issued under rule 8.

28. Appeals to the Deputy Narcotics Commissioner and Narcotics Commissioner.—(1)(a) Any person aggrieved by any decision or order made or passed under these rules relating to refusal, withholding or cancellation of a licence for opium poppy cultivation by an officer of the Narcotics Department, lower in rank than the Deputy Narcotics Commissioner, may appeal to the Deputy Narcotics Commissioner within thirty days from the date of the communication to him of such decision or order.

(b) Notwithstanding anything contained in clause (a), if the decision or order regarding withholding or cancellation of licence for opium poppy cultivation is passed by the Deputy Narcotics Commissioner, such appeal shall lie to the Narcotics Commissioner:

Provided that the Deputy Narcotics Commissioner or, as the case may be, the Narcotics Commissioner may, if he is satisfied that the appellant was prevented

1. Omitted by G.S.R. 82, dated 14th February, 1995 (w.e.f. 25-2-1995).

from submitting his appeal within the time limit specified in clause (a) due to reasons beyond his control, allow such appeal to be presented within a further a period of thirty days.

(2) Every appeal under this rule shall be accompanied by a copy of the decision or order appealed against and shall be in such form and in such a manner as may be specified by the Narcotics Commissioner in this behalf.

29. Appeals to the Chief Controller of Factories.—(1) Any person aggrieved by any decision or order made or passed under rule 21 or rule 23 by the General Manager may appeal to the Chief Controller of Factories within thirty days from the date of the communication to him of such decision or order:

Provided that the Chief Controller of Factories may, if he is satisfied that the appellant was prevented from submitting his appeal within the said time limit due to reasons beyond his control, allow such appeal to be presented within a further period of thirty days.

(2) Every appeal under this rule shall be accompanied by a copy of the decision or order appealed against and shall be in such form and in such manner as may be specified by the Narcotics Commissioner.

30. Procedure for appeal.—(1) The Appellate Authority shall give an opportunity to appellant to be heard, if he so desires.

(2) The Appellate Authority may, at the hearing of an appeal, allow the appellant to go into any ground of appeal not specified in the grounds of appeal, if the Appellate Authority is satisfied that omission of that ground from the grounds of appeal was not wilful or unreasonable.

(3) The Appellate Authority may, after making such further inquiry as may be necessary, pass such orders as he thinks fit confirming, modifying or annulling the decision or order appealed against:

Provided that any order relating to the quantum of adulterated opium to be confiscated in addition to the opium already confiscated under rule 23 shall not be passed unless the appellant has been given a reasonable opportunity of showing cause against the proposed order.

(4) The order of the Appellate Authority disposing of the appeal under this rule shall be in writing and shall state the points for determination, the decision thereon and the reasons for the decision.

(5) On the disposal of the appeal, the Appellate Authority shall communicate the order passed by him to the appellant and the officer who passed the order or made the decision appealed against.

(6) No further appeal or revision shall lie against the order passed by the Appellate Authority under this rule.

CHAPTER IV

MANUFACTURE, SALE AND EXPORT OF OPIUM

31. Manufacture of opium.—Opium shall not be manufactured save by the Central Government Opium Factories at Ghazipur and Neemuch:

Provided that opium mixtures may be manufactured from opium lawfully possessed by a person authorised under the rules made by the State Government for the said purpose.

32. Export of opium.—The export of opium is prohibited save when the export is on behalf of the Central Government.

33. Sale to State Governments or manufacturing chemists.—[1][(1) The sale of opium to the State Governments or manufacturing chemists or the person or entity who has been granted licence under sub-section (2A) of rule 36, as the case may be, shall be only from the Government Opium Factories, located at Neemuch and Ghazipur;

(2) The sale of opium from the Government Opium Factory at Neemuch and Ghazipur to manufacturing chemists or the person or entity who has been granted licence under sub-rule (2A) of rule 36, as the case may be, shall be only under a permit granted by or under the orders of the State Government within whose jurisdiction the chemist or the person or entity resides or has his place of business in the forms prescribed by that Government;]

(3) The permit referred to in sub-rule (2) shall be issued, in quadruplicate and,—

(a) the quadruplicate copy shall be retained by the issuing authority and the remaining copies forwarded to the [2][Government Opium Factories at Neemuch and Ghazipur];

(b) the said factory shall retain the duplicate copy for record, send the original copy with the consignment of opium and return the triplicate copy to the issuing authority after endorsing thereon the quantity actually supplied and the date of despatch.

[3][**33A. Sale of opium derivatives from the Government Opium Factories.**—(1) The Government Opium Factories may sell the opium derivatives only if the buyer produces a valid quota allocation under rule 67E.

(2) Every buyer of a opium derivative under sub-rule (1), shall provide information to the Chief Controller of Factories regarding its utilization, or any other related matter in such form and within such time as may be indicated by the Chief Controller of Factories.]

34. Fixation of sales price of opium.—The price to be charged for opium sold under this Chapter shall be fixed, from time to time, by the Central Government in such manner as it may deem fit.

CHAPTER V

MANUFACTURED DRUGS

35. General prohibition.—The manufacture of crude cocaine, ecgonine and its salts and of diacetyl morphine and its salts is prohibited:

[4][Provided that nothing contained in this rule shall apply in case the drugs are manufactured by Government opium factory or by chemical staff employed under the Central Board of Excise and Customs or any person authorised by the

1. Subs. by G.S.R. 95 (E), dated 4th February, 2004, for sub-rules (1) and (2) (w.e.f. 4-2-2004).
2. Subs. by G.S.R. 95 (E), dated 4th February, 2004, for "Government Opium Factory, Ghazipur" (w.e.f. 4-2-2004).
3. Ins. by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010).
4. Ins. by G.S.R. 350 (E), dated 25th June, 1997 (w.e.f. 27-6-1997).

Narcotics Commissioner by a special licence for purposes mentioned in Chapter VIIA:

Provided further that the Narcotics Commissioner shall consult the Drugs Controller-General of India before issuing a licence under this Chapter.]

36. Manufacture of natural manufactured drugs.—(1) The manufacture of cocaine and its salts is prohibited save the manufacture of cocaine hydrochloride by the chemical staff employed under the Central Board of Excise and Customs from confiscated cocaine.

(2) The manufacture of morphine, codeine, dionine, thebaine, dihydrocodeinone, dihydrocodeine, acetyldihydrocodeine, acetyldihydrocodeinone, dihydromorphine, dihydromorphinone, dihydrohydroxycodeinone, pholocodine and their respective salts is prohibited save by the Government Opium Factory.

[1][(2A) Notwithstanding anything contained in sub-rule (2), the Narcotics Commissioner or such other officer as may be authorized by the Central Government may, on and from the commencement of the Narcotic Drugs and Psychotropic Substances (Amendment) Rules, 2004 grant a licence in Form 3 appended to these rules on such terms and conditions as may be specified in the licence to any person or entity for manufacture of morphine, codeine, dionine, thebaine, dihydrocodeinone, dihydrocodeine, acetyldihydrocodeine, acetyldihydrocodeinone, dihydromorphine, dihydromorphinone, dihydrohydroxycodeinone, pholcodine and their respective salts [2][3][***], if the Central Government determines that such licence is necessary in public interest and is in consonance with India's obligations under International treaties, conventions or protocols];]

[4][(2B) If, in the opinion of the Central Government, the licensee fails to fulfil the purpose for which he is issued a licence under sub-rule (2A) or the terms and conditions of the licence, the Central Government may, after giving the licensee a reasonable opportunity of being heard, cancel the licence.]

(3) The manufacture of medicinal hemp shall be under a licence granted by the State Government on payment of such fees and in accordance with such conditions as may be prescribed by that Government in this behalf.

[4][**36A. Manufacture of natural manufactured drugs from poppy straw.**—(1) Notwithstanding anything contained in rule 36, if the Central Government is of the opinion that it is in public interest to do so, the Narcotics Commissioner or any other officer authorised by the Central Government in this behalf may issue a licence in Form No. 3A on such terms and conditions as may be specified in the licence to manufacture poppy straw concentrate [5][from poppy straw produced from poppy cultivated under a licence issued under rule 8 of these rules].

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1. Ins. by G.S.R. 95(E), dated 4th February, 2004 (w.e.f. 4-2-2004).
2. Added by G.S.R. 736(E), dated 22nd December, 2005 (w.e.f. 22-12-2005).
3. The words "from Indian opium" omitted by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010).
4. Ins. by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010).
5. Subs. by G.S.R. 359(E), dated 5th May, 2015, for "from poppy straw" (w.e.f. 5-5-2015).

(2) The licensee may also manufacture morphine, codeine, thebaine, dionine, dihydrocodeinone, dihydrocodone, acetyldihydrocodeine, acetyldihydrocodeinone, dihydromorphine, dihydromorphinone, dihydrohydroxycodeinone, pholcodeine and their respective salts from the poppy straw concentrate manufactured under sub-rule (1).

(3) If, in the opinion of the Central Government, the licensee fails to fulfil the purpose for which he is issued a licence under sub-rule (1), or the terms and conditions of the licence, the Central Government, may after giving the licensee a reasonable opportunity of being heard, cancel the licence.]

[1][**37. Manufacture of synthetic manufactured drugs.**—Subject to the provisions of rule 36, the manufacture of manufactured drugs notified under sub-clause (b) of clause (xi) of section 2 of the Act including the essential narcotic drugs notified under clause (viiia) of section 2 of the Act (hereafter referred to as the drug) but not including preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess is prohibited save under and in accordance with the conditions of a licence granted by the Narcotics Commissioner or such other officer as may be authorised by the Central Government in this behalf, in Form No. 3 appended to these rules.

Explanation.—For the removal of doubts it is hereby clarified that the licence to manufacture a preparation containing any manufactured drug and including the preparation notified as essential narcotic drugs under clause (viiia) of section 2 of the Act shall be regulated under the rules made by the State Government under section 10 of the Act.]

[2][**38. Application for licence.**—(1) Every application for a licence or for renewal thereof under the proviso to rule 35 or rule 36 or rule 37 shall be in such form and manner as may be specified by the Narcotics Commissioner.

(2) A fee of rupees five thousand shall be payable to the Central Government for each licence issued under rule 37 or for renewal thereof.

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1. Subs. by G.S.R. 359(E), dated 5th May, 2015, for rule 37 (w.e.f. 5-5-2015). Earlier rule 37 was amended by G.S.R. 95(E), dated 4th February, 2004 (w.e.f. 4-2-2004); by S.O. 166(E), dated 13th July, 2010 (w.e.f. 13-7-2010) and by G.S.R. 426(E), dated 1st July, 2014, (w.e.f. 1-7-2014). Rule 37, before substitution by G.S.R. 359(E) dated 5th May, 2015, stood as under:

   "*37. Manufacture of synthetic manufactured drugs.*—(1) Subject to the provisions of rule 36, the manufacture of manufactured drugs notified under sub-clause (b) of clause (xi) of section 2 of the Act (hereafter referred to as the drug) but not including preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess is prohibited save under and in accordance with the conditions of a licence granted by the Narcotics Commissioner or such other officer as may be authorised by the Central Government in this behalf, in Form No. 3 appended to these rules.

   (2) A fee of rupees five thousand shall be payable in advance to the Central Government for each licence issued under this rule for renewal thereof.".

2. Subs. by G.S.R. 359(E), dated 5th May, 2015, for rule 38 (w.e.f. 5-5-2015). Earlier rule 38 was amended by G.S.R. 350(E), dated 25th June, 1997 (w.e.f. 27-6-1997) and by G.S.R. 95(E), dated 4th February, 2004 (w.e.f. 4-2-2004). Rule 38, before substitution by G.S.R. 359(E) dated 5th May, 2015, stood as under:

   "*38. Application for licence.*—Every application for a licence or for renewal thereof under rule 36 or rule 37 or under the proviso to rule 35 shall be in such form as may be specified by the Narcotics Commissioner.".

(3) On receipt of an application for issue or renewal of a licence under rule 37, the Narcotics Commissioner shall issue or renew the licence in Form No. 3 within thirty working days from the date of receipt of such application.

(4) In case the licence is not issued or renewed within the period specified in sub-rule (3), the Narcotics Commissioner or any other officer authorised by him in this regard shall inform the applicant the reasons thereof.]

[1][**39. Commencement of manufacture.**—(1) A person who has been issued a licence under rule 36 or rule 36A or rule 37 shall not commence manufacture without obtaining the licences required under the Drugs and Cosmetics Act, 1940 (23 of 1940) for the manufacture of the drug, and the rules framed under section 10 of the Act by State Government of the State in which he has his place of business, for the possession, sale and distribution of the drug.

(2) The licencee shall send copy of the licences specified in sub-rule (1) to the Narcotics Commissioner before commencement of manufacture of the drug.

(3) In the event of revocation of licence issued under the Drugs and Cosmetics Act, 1940 (23 of 1940) for the manufacture of the drug or the rules framed under section 10 of the Act by State Government of the State in which he has his place of business, for the possession, sale and distribution of the drug, the licence issued under rule 36 or rule 36A or rule 37, as the case may be, shall be deemed to be revoked.]

40. Manufacture only from materials lawfully possessed.—[2][(1)] The licensee shall not manufacture the drug save from materials which he is lawfully entitled to possess.

[3][(2) The licencee shall not manufactrure the drug without allotment of quota for that drug under sub-rule (2) of rule 67E].

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1. Subs. by G.S.R. 359(E), dated 5th May, 2015, for rule 39 (w.e.f. 5-5-2015). Earlier rule 39 was amended by S.O. 166(E), dated 12th July, 2010 (w.e.f. 13-7-2010). Rule 39, before substitution, stood as under:

   "*39. Conditions for issue of licences.*—(1) No licence shall be issued under rule 37 for under the proviso to rule 35 unless the applicant therefore has—

   (i) produced to the issuing authority licences granted to him under (a) the Drugs and Cosmetics Act, 1940 (23 of 1940) for the manufacture of the drug, and (b) the rules framed under section 10 of the Act by State Government of the State in which he has his place of business, for the possession, sale and distribution of the drugs; and

   (ii) made a deposit of Rs. 5,000.00 as security in the manner specified by the issuing authority for the due observance of the conditions of the licence and has furnished proof to the satisfaction of the issuing authority that he is equipped as to the land, building and other paraphernalia to properly carry on the business described in the application and is of good financial standing.

   (2) Licence referred to in sub-rule (2A) of rule 36 and rule 36A shall be issued subject to the condition that before commencing of the manufacture, the licensee shall obtain the licences required as per the Drugs and Cosmetics Act, 1940 (23 of 1940) from the authority in-charge of drug control in the State and the licence issued by the State Government under section 10 of the Act, or any other licence required under any other law for the time being in force.".

2. Rule 40 re-numbered as sub-rule (1) thereof by G.S.R. 359(E), dated 5th May, 2015 (w.e.f. 5-5-2015).

3. Ins. by G.S.R. 359(E), dated 5th May, 2015 (w.e.f. 5-5-2015).

41. Limits of manufacture.—The issuing authority, while issuing the licence, shall take into account all relevant factors for permitting the quantity of the drug to be manufactured by a licensee including the following:—

(a) quantity allotted by the State Government for processing into any preparation in licensee's own manufacture;

(b) quantity required for supply to other firms within or outside the country;

(c) quantity required for reasonable inventory:

Provided that the total quantity of the drug manufactured during any one year does not exceed the estimated requirements of this country for the relevant year as furnished to the International Narcotics Control Board.

42. Security arrangements.—The licensee shall ensure all necessary security arrangements in the manufacturing premises as may be specified by the issuing authority.

[1][**43. Advance notice for cessation and recommencement of manufacture.**—(1) The licencee shall give at least one month's notice in writing to the issuing authority before he ceases to manufacture the drug for any reasons whatsoever:

[2][Provided that the notice referred to in this sub-rule shall not apply in case the cessation of manufacture is on account of unforeseen circumstances beyond the control of the licencee.]

(2) The licencee shall give at least fifteen days notice in writing to the issuing authority prior to the date of recommencement of manufacture of the drug after cessation of manufacture of the drug as mentioned at sub-rule (1).]

45. Possession, sale and distribution.—The licensee shall not possess or sell or distribute the drug otherwise than in accordance with the rules made by the State Government under the Act.

[3][**45A. Destruction of drugs.**—(1) A licencee seeking to destroy the drug shall apply to the Narcotics Commissioner in such form and manner as may be specified by the Narcotics Commissioner.

(2) The Narcotics Commissioner shall, within a period of thirty days from the date of receipt of an application under sub-rule (1), appoint a committee comprising a Gazetted Officer in the office of the Narcotics Commissioner, or

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1. Subs. by G.S.R. 359(E), dated 5th May, 2015, for rule 43 and rule 44 (w.e.f. 5-5-2015). Rule 43 and rule 44, before substitution, stood as under:

"*43. Advance notice for commencement and cessation of manufacture.*—The licensee shall give at least 15 days' notice in writing to the issuing authority of the date on which he proposes to commence manufacture of the drug and at least one month's notice before he ceases to manufacture the same.

44. Cessation of manufacture.—Where the licensee ceases manufacturing operations for any reasons whatsoever, he shall forthwith inform the issuing authority in this behalf indicating the date on which he proposes to recommence manufacture:

Provided that the issuing authority may prohibit all further manufacture in case the period of cessation of manufacture exceeds 30 days.".

2. Ins. by G.S.R. 500(E), dated 17th June, 2015 (w.e.f. 17-6-2015).

3. Ins. by G.S.R. 359(E), dated 5th May, 2015 (w.e.f. 5-5-2015).

Narcotics Control Bureau constituted *vide* notification number S.O. 96(E), dated the 17th March, 1986, Superintendent of Central Excise of the concerned range and an authorised representative of the applicant for supervising the destruction of the drug and such destruction shall be carried out within a period of thirty days from the appointment of the committee.

(3) The destruction of the drug shall be carried out in accordance with the provision of the relevant laws for the time being in force.]

46. Maintenance of accounts and submission of returns.—The licensee shall maintain true accounts of all transactions including the accounts of materials used for the manufacture of the drug, the quantities manufactured, sold or otherwise disposed of and furnish returns in such forms and in such manner as may be specified by the Narcotics Commissioner.

47. Inspection of stocks, etc.—(1) The stocks of the drug and the materials used for its manufacture and all accounts and records of transactions relating thereto, shall be open to inspection by any officer authorised by the issuing authority.

(2) A serially numbered Inspection Book shall be maintained by the licensee in good condition for the use of such officer.

48. Suspension and revocation of licence.—(1) Without prejudice to any action that may be taken under the provisions of the Act, the issuing authority may suspend or cancel a licence—

(i) if the licence is transferred or sublet without the prior approval of the issuing authority; or

(ii) in the event of any breach of any conditions of the licence; or

(iii) if the licensee is convicted for any offence under the Act or under any other law relating to the narcotic drugs for the time being in force in any State.

(2) No order shall be passed under sub-rule (1) unless the licensee has been given a reasonable opportunity showing cause against the said order or is heard in person, if he so desires.

49. Appeal.—(1) The licensee may file an appeal against the decision or order made or passed under rule 48 to—

(i) the Narcotics Commissioner where such decision or order was made or passed by any officer subordinate to him; and

(ii) the [1][Secretary, Government of India, Ministry of Finance, Department of Revenue or any other officer, not below the rank of Additional Secretary to the Government of India, authorised by him in this behalf], in any other case,

within 30 days from the date of communication to him to such decision or order.

(2) Every memorandum of appeal shall be accompanied by a copy of the decision or order appealed against.

(3) Every appeal under this rule shall be filed in such form and in such manner as may be specified by the [1][Central Government].

1. Subs. by S.O. 739(E), dated 11th April, 2011, for "Board" (w.e.f. 11-4-2011).

50. Procedure for appeal.—(1) The Appellate Authority shall give an opportunity to the appellant to be heard in person, if he so desires.

(2) The Appellate Authority may, at the hearing of an appeal allow the appellant to go into any ground of appeal not specified in the grounds of appeal, if the Appellate Authority is satisfied that omission of that ground from the grounds of appeal was not wilful or unreasonable.

(3) The Appellate Authority may, after making such further inquiry as may be necessary, pass such orders as it thinks fit, confirming, modifying or annulling the decision or order appealed against.

(4) The order of the Appellate Authority disposing of the appeal under this rule shall be in writing and shall state the points for determination, the decision thereon and the reasons for the decision.

51. Surrender of licence.—A licensee may, if he so desires, surrender his licence, by giving not less than 15 days' notice in writing to the issuing authority.

52. Disposal of stocks of drugs on cancellation of licence, etc.—Such stocks or drugs as may be in the possession of a licensee, on the expiry or cancellation or surrender of his licence, shall be disposed of in such manner as may be specified by the Narcotics Commissioner in this behalf.

[1][*CHAPTER VA*

POSSESSION, TRANSPORT, IMPORT INTER-STATE, EXPORT INTER-STATE, SALE, PURCHASE, CONSUMPTION AND USE OF ESSENTIAL NARCOTIC DRUGS

52A. Possession of essential narcotic drug.—(1) No person shall possess any essential narcotic drug otherwise than in accordance with the provisions of these rules.

(2) Any person may possess an essential narcotic drug in such quantity as has been at one time sold or dispensed for his use in accordance with the provisions of these rules.

(3) A registered medical practitioner may possess essential narcotic drug, for use in his practice but not for sale or distribution, not more than the quantity mentioned in the Table below, namely:—

1. Chapter VA (containing rule 52A to rule 52M) inserted by G.S.R. 359(E), dated 5th May, 2015 (w.e.f. 5-5-2015).

TABLE

Sl. No.	Name of the essential Narcotic Drug	Quantity
(1)	(2)	(3)
1.	Morphine and its salts and all preparations containing more than 0.2 per cent. of Morphine	500 Milligrammes
2.	Methyl morphine (commonly known as 'Codeine') and Ethyl morphine and their salts (including Dionine), all dilutions and preparations except those which are compounded with one or more other ingredients and containing not more than 100 milligrammes of the drug per dosage unit and with a concentration of not more than 2.5% in undivided preparations and which have been established in therapeutic practice	2000 Milligrammes
3.	Dihydroxy Codeinone (commonly known as Oxy-codone and Dihydroxycodeinone), its salts (such as Eucodal Boncodal Dinarcon Hydrolaudin, Nucodan, Percodan, Scophedal, Tebodol and the like), its esters and the salts of its ester and preparation, admixture, extracts or other substances containing any of these drugs	250 Milligrammes
4.	Dihydrocodeinone (commonly known as Hydrocodone), its salts (such as Dicodide, Codinovo, Diconone, Hycodan, Multacodin, Nyodide, Ydroced and the like) and its esters and salts of its ester, and preparation, admixture, extracts or other substances containing any of these drugs	320 Milligrammes
5	1-phenethyl-4-N - propionylanilino-piperidine (the international-non-proprietary name of which is Fentanyl) and its salts and preparations, admixture, extracts or other substances containing any of these drugs	Two transdermal patches one each of 12.5 microgram per hour and 25 microgram per hour:

Provided that the Controller of Drugs or any other officer authorised in this behalf by him may by special order authorise, in Form 3B, any such practitioner to possess the aforesaid drugs in quantity larger than as specified in the above Table:

Provided further that such authorisation may be granted or renewed, for a period not exceeding three years at a time.

Explanation.—The expression "for use in his practice" covers only the actual direct administration of the drugs to a patient under the care of the registered medical practitioner in accordance with established medical standards and practices.

(4) For renewal of the authorisation referred to in the second proviso to sub-rule (3), application shall be made to the Controller of Drugs atleast thirty days before the expiry of the previous authorisation.

(5) (a) The Controller of Drugs may, by order, prohibit any registered medical practitioner from possessing for use in his practice under sub-rule (3) any essential narcotic drug, where such practitioner—