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

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—

(i) has violated any provision of these rules; or

(ii) has been convicted of any offence under the Act; or

(iii) has, in the opinion of the Controller of Drugs, abused such possession or otherwise been rendered unfit to possess such drug.

(b) When any order is passed under clause (a) of this sub-rule, the registered medical practitioner concerned shall forthwith deliver to the Controller of Drugs the essential narcotic drug then in his possession and the Controller of Drugs shall issue orders for the disposal of such drugs.

(6) The Controller of Drugs may, by a general or special order, authorise any person to possess essential narcotic drug as may be specified in that order.

(7) A recognised medical institution may possess essential narcotic drug in such quantity and in such manner as specified in these rules.

[1][(8) A manufacturer may possess essential narcotic drug in such quantity as may be specified in the licence issued under rule 36, rule 36A, or rule 37 of these rules or the licence issued for manufacturing the preparations of essential narcotic drugs under the rules made by the State Government under section 10 of the Act:

Provided that there shall be no limit to the possession of essential narcotic drug by the Government Opium Factories.]

(9) A licenced dealer or a licenced chemist may possess essential narcotic drug in such quantity, and in such manner as may be specified in the licence issued under these rules.

52B. Provisions regarding licenced dealer and licenced chemist.—(1) A licenced dealer or a licenced chemist shall apply for a licence to possess, sell, exhibit or offer for sale or distribution by retail or wholesale, essential narcotic drug, to the authority competent to issue licence to possess, sell, exhibit or offer for sale or distribution by retail or wholesale, manufactured drugs under the rules framed under section 10 of the Act by State Government of the State in which he has his place of business.

(2) Every application for issue of licence referred to in sub-rule (1) shall be in such form and manner as may be specified by the authority referred to in the said sub-rule.

(3) The licence to possess, sell, exhibit or offer for sale or distribution by retail or wholesale, essential narcotic drugs shall have the same conditions as are applicable to a licence to possess, sell, exhibit or offer for sale or distribution by retail or wholesale, manufactured drugs under the rules framed under section 10 of the Act by the State Government.

(4) The licence under this rule shall be obtained within a period of one hundred and eighty days from the date of commencement of these rules.

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1. Subs. by G.S.R. 500(E), dated 17th June, 2015, for sub-rule (8) (w.e.f. 17-6-2015). Sub-rule (8), before substitution stood as under:

"(8) A manufacturer may possess essential narcotic durg in such quantity as may be specified in the licence issued under rule 37 of these rules.".

52C. Import Inter-State and Export Inter-State of essential narcotic drugs.—Any person who is permitted to possess essential narcotic drug under rule 52A may import inter-State or export inter-State such drug upto the quantity he is permitted to possess.

52D. Transport of essential narcotic drugs.—(1) Subject to the provisions of rule 52C, no consignment of essential narcotic drugs shall be transported, imported inter-State or exported inter-State unless such consignment is accompanied by a consignment note in Form No. 3C and in the manner as provided in sub-rules (2) and (3).

(2) The consignment note referred to in sub-rule (1) shall be prepared in triplicate, and the original and duplicate copies of the said note shall be sent along with the consignment of essential narcotic drugs to the consignee who shall return the duplicate copy of the note to the consignor for his use after endorsing on the original and duplicate copies, the particulars of the receipt of the quantity consigned.

(3) The consignor and consignee shall preserve such consignment note referred to in sub-rule (1) for a period of two years:

Provided that the said consignment note shall not apply in cases where the sale of the essential narcotic drug is accompanied by a sale bill or invoice or cash memo or any other document duly signed by the consignor or his authorised signatory, which shall include the following information about the consignment:—

(a) name, address and licence number of the consignor and the consignee;

(b) description, batch number and quantity;

(c) mode and particulars of transport:

Provided further that such documents shall be preserved by the consignor and consignee for a period of two years.

Explanation.—Where the consignee is a person to whom the essential narcotic drug has been sold or dispensed for his personal use, research institution, registered medical practitioner, recognised medical institution, or hospital, the requirement of incorporating licence number of the consignee shall not be applicable.

52E. Transmission of essential narcotic drugs by post, courier, rail or road.—The transmission of essential narcotic drugs by inland post or courier or by rail or by road by a manufacturer, licensed dealer or licensed chemist is permitted, subject to the following conditions, namely:—

(i) the parcel of the essential narcotic drugs when sent by post shall be sent by registered post;

(ii) the parcel of essential narcotic drugs shall be accompanied by a declaration showing the names of consignor and consignee, the contents of the parcel in detail, the number of licence or authorisation or recognition held by the consignee;

(iii) the consignee shall show distinctly in his account books, if he is a licencee, the name of the consignee and the consignor respectively, and the quantity of the essential narcotic drug imported inter-State, exported inter-State or transported by and to him, as the case may be, from time to time, by post or by courier or by road or by rail.

52F. Sale.—[1][(1) A manufacturer or licenced dealer shall sell essential narcotic drugs otherwise than on prescription to—

(a) a manufacturer who has been issued a licence under rule 37 of these rules or a manufacture of preparations of essential narcotic drugs who has been issued a licence under the rules made by the State Government under section 10 of the Act;

(b) a licenced dealer;

(c) a licenced chemist;

(d) a registered medical practitioner;

(e) a person who has been authorised by the Controller of Drugs under these rules; or

(f) a recognized medical institution.]

(2) A licenced chemist shall sell essential narcotic drug only on prescription and subject to the provisions of the Drug and Cosmetics Rules, 1945.

(3) A recognised medical institution shall dispense or sell essential narcotic drugs in such manner as specified in these rules.

52G. Registered medical practitioner and conditions relating to their prescriptions.—No prescription for the supply of essential narcotic drugs shall be given by a registered medical practitioner otherwise than in accordance with the following conditions, namely:—

(i) the prescription shall be in writing, dated and signed by the practitioner with his full name, address and registration number and shall specify the name and address of the person to whom the prescription is given and the total quantity of the essential narcotic drug to be supplied alongwith daily dose and period of consumption:

Provided that where such drug to be supplied on the prescription is a patent or proprietary medicine, it shall be sufficient to state the quantity and strength of the medicine to be supplied;

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1. Subs. by G.S.R. 500(E), dated 17th June, 2015, for sub-rule (1) (w.e.f. 17-6-2015). Sub-rule (1), before substitution stood as under:

"*52F. Sale.*—(1) A manufacturer or licenced dealer shall sell essential narcotic drugs otherwise than on prescription to—

(a) a licenced dealer;

(b) a licenced chemist;

(c) a registered medical practitioner;

(d) a person who has been authorised by the Controller of Drugs under these rules; or

(e) a recognized medical institution.".

(ii) the prescription shall not be given for the use of the prescriber himself.

52H. Authorisation and accounts.—(1) The Controller of Drugs may by a general or special order authorise:

(a) any person in-charge of an educational institution or engaged in scientific research to possess and use, for educational or scientific purposes only, essential narcotic drug, in such quantity and in such manner as may be specified in the said order;

(b) a pilot of an aircraft or captain of a ship to possess and use, on the aircraft or ship, as the case may be, in any emergency, essential narcotic drug, in such quantity and in such manner as may be specified in the said order;

(c) a person in-charge of an ambulance or a first-aid station or a first-aid box to possess and use, in an emergency, essential narcotic drug, in such quantity and in such manner as may be specified in the said order.

(2) Every registered medical practitioner, and a person authorised by general or special order under this rule shall maintain day to day accounts in respect of all transactions of essential narcotic drug in Form No. 3D and the records of the daily accounts shall be preserved for a minimum period of two years from the date of last entry.

(3) Every registered medical practitioner shall also maintain a separate record in Form No. 3E for each patient and such record shall be preserved for a minimum period of two years from the date of last entry.

52-I. Suspension and cancellation of authorisation.—(1) Without prejudice to any action that may be taken under the provisions of the Act, the Controller of Drugs may, for the reasons to be recorded in writing, cancel or suspend the authorisation under rules 52A or 52H,—

(a) if the purpose for which the authorisation was granted ceases to exist; or

(b) in the event of any breach, by the holder of such authorisation or by his servant or by any one acting with his express or implied permission on his behalf, of any of the terms and conditions of such authorisation or of any authorisation previously held by him.

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

52J. Appeal.—(1) Appeal against a decision or order made or passed under rule 52-I may be filed by the person against whom such decision or order has been made or passed, to the Secretary to the State Government responsible for implementation of the Drugs and Cosmetic Rules, 1945 in the State within a period of sixty days from the date of communication of such decision or order to him.

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

52K. Procedure for appeal.—(1) The Appellate Authority referred to in sub-rule (1) of rule 52J shall give an opportunity to the appellant to be heard in person, if he so desires.

(2) The said Appellate Authority may, at the hearing of an appeal allow the appellant to raise any other ground not specified in the appeal, if the Appellate Authority is satisfied that omission of that ground was not willful or unreasonable.

(3) The aforesaid Appellate Authority may, after making such further inquiry as may be necessary, pass such order 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 of determination, the decision thereon and the reasons for the decision.

52L. Surrender of authorisation, etc.—An authorised person, if he so desires, surrender his authorisation by giving not less than fifteen days notice in writing to the issuing authority.

52M. Disposal of stocks of essential narcotic drugs on expiry, surrender, cancellation of authorisation, etc.—(1) Such stocks of essential narcotic drugs as may be in the possession of an authorised person, on the expiry or cancellation or surrender of his authorisation, shall be disposed of in such manner as may be specified by the Controller of Drugs in this behalf.

(2) The expired stock of essential narcotic drugs as may be in the possession of an authorised person or a registered medical practitioner shall be destroyed in such manner as may be specified by the Controller of Drugs.]

[1][*CHAPTER VB*

SPECIAL PROVISIONS RELATING TO RECOGNISED MEDICAL INSTITUTION

52N. Government, etc. hospital, dispensary to be deemed recognised medical institution.—Government or Municipal Corporation or Municipal Council or Zilla Parishad hospital, dispensary or medical institution, with at least one registered medical practitioner possessing a minimum qualification of a degree in medicine or dentistry and who 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, who shall prescribe and dispense essential narcotic drugs, shall be deemed to be a recognised medical institution under these rules for possessing, dispensing or selling of essential narcotic drugs for medical purpose.

Explanation.—For the removal of doubts it is hereby clarified that Government or Municipal Corporation or Municipal Council or Zilla Parishad hospital, dispensary and medical institution, shall be exempt only from making application to the Controller of Drugs for recognition as recognised medical

1. Chapter VB (containing rule 52N to rule 52Z and rule 52ZA) inserted by G.S.R. 359(E), dated 5th May, 2015 (w.e.f. 5-5-2015).

institution, but all other provisions of this Chapter shall be equally applicable to such deemed recognised medical institution as are applicable to other recognised medical institution.

52-O. Recognition of medical institutions.—(1) A medical institution seeking, to be a recognised medical institution or renewal of such recognition, under these rules for possessing, dispensing or selling essential narcotic drugs for medical purposes shall apply in Form No. 3F to the Controller of Drugs.

(2) The Controller of Drugs, on receipt of application referred to in sub-rule (1) may, subject to any inquiry which may be necessary, issue a Certificate of Recognition in Form No. 3G and such certificate shall be issued within sixty days from the date of receipt of such application.

(3) In case the Certificate of Recognition is not issued within the period mentioned in sub-rule (2), the Controller of Drugs or any other officer authorised by him in this regard shall inform the applicant the reasons thereof.

(4) The Certificate of Recognition shall be issued for a period not exceeding three years at a time.

(5) For renewal of the recognition referred to in sub-rule (1), application shall be made to the Controller of Drugs at least sixty days before the expiry of previous recognition.

(6) The Certificate of Recognition shall be obtained within a period of one hundred and eighty days from the date of commencement of these rules.

(7) In the event of a change in the constitution of a recognised medical institution, the current recognition shall be deemed to be valid for a maximum period of ninety days from the date on which the change takes place.

52P. Suspension and Cancellation of recognition.—(1) Without prejudice to any action that may be taken under the provisions of the Act, for the reasons to be recorded in writing, the Controller of Drugs may suspend or cancel the recognition referred to in rule 52-O,—

(i) if the essential narcotic drugs obtained by a recognised medical institution were supplied for non-medical use; or

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

(iii) in the event of violation of any of the provisions of the Act or rules and orders made thereunder.

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

52Q. Designated medical practitioner.—(1) Every recognised medical institution shall designate one or more registered medical practitioner who 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, who shall prescribe and dispense essential narcotic drugs.

(2) When more than one registered medical practitioner is designated, one of them shall be designated as over-all in charge.

(3) The name of the designated medicaf practitioner or the over-all in charge, as the case may be, shall be endorsed on the Certificate of Recognition issued under rule 52-O by the Controller of Drugs.

(4) Whenever there is a change in the designated medical practitioner or the over-all in charge, as the case may be, the recognised medical institution shall inform the Controller of Drugs within seven days from date of such change for appropriate endorsement on the Certificate of Recognition.

52R. Duties of designated medical practitioner.—(1) The designated medical practitioner or the over-all in charge, as the case may be, shall,—

(a) register the patients to whom essential narcotic drugs shall be dispensed or sold for medical use only;

(b) maintain separate record in Form No. 3E for each patient, which shall be preserved for a minimum period of two years from the date of last entry;

(c) maintain record of all receipts and disbursements of essential narcotic drugs in Form No. 3H, which shall be preserved for a minimum period of two years from the date of last entry; and

(d) file return for a calendar year on or before the 31st of March of the subsequent year in Form No. 3-I to the Controller of Drugs.

(2) In the event of any change in the constitution of the recognised medical institution, the designated medical practitioner or the over-all in charge, as the case may be, shall inform the Controller of Drugs in writing within thirty days from the date of such change for issue of fresh Certificate of Recognition.

52S. Surrender of recognition.—(1) A recognised medical institution may surrender its recognition by giving not less than thirty days' notice in writing to the Controller of Drugs.

(2) On surrender of the recognition, the essential narcotic drugs as may be in the possession of the recognised medical institution shall be disposed of in such manner, including transfer to another recognised medical institution, as may be specified by the Controller of Drugs.

52T. Estimates of requirement.—(1) Every recognised medical institution shall submit an estimate of its annual requirement of essential narcotic drugs in Form No. 3J by the 30th November of the preceding calendar year to the Controller of Drugs.

(2) If the requirement of a recognised medical institution exceeds the annual estimate submitted to the Controller of Drugs, it shall submit a revised estimate by the 31st August of the calendar year to which the said annual estimate pertains, to the Controller of Drugs.

Explanation.—For the removal of doubts it is hereby clarified that a recognised medical institution may sell and disburse essential narcotic drugs over and above the quantity indicated in the estimate submitted to the Controller of Drugs as specified in this rule, but the designated medical practitioner or the over-all in charge, as the case may be, shall record a brief justification for such increase while filing return in Form No. 3-I.

52U. Possession of essential narcotic drug by recognised medical institution.—A recognised medical institution shall possess essential narcotic drugs in quantities not exceeding the quantities mentioned in the estimate or revised estimate, as the case may be, of the annual requirement of such drug submitted to the Controller of Drugs under rule 52T.

52V. Miscellaneous.—(1) The expired stock of essential narcotic drugs shall be destroyed by the recognised medical institution in the presence of an officer nominated by the Controller of Drugs.

(2) The unused essential narcotic drugs returned by the patients shall be considered as receipts by the recognised medical institution.

(3) Essential narcotic drugs shall not be transferred, loaned or sold by the recognised medical institution to other institutions without the prior approval of the Controller of Drugs.

52W. Home care treatment.—(1) Notwithstanding anything contained in these rules, where home care treatment is provided to a patient registered with a recognised medical institution by deputing qualified personnel of such recognised medical institution to the home or residence or place of stay, either permanent or temporary, of such patient, the designated medical practitioner or the over-all in charge, as the case may be, shall, authorise such personnel to carry such quantity of essential narcotic drugs as may be required for treatment of such patient:

Provided that home care treatment shall not be provided for treatment of opioid dependence.

(2) The designated medical practitioner or the over-all in charge shall maintain proper record of such issue and also of the unused essential narcotic drugs received from such personnel after completion of visit to the patient.

52X. Maintenance of records.—All records generated under this Chapter shall be kept for a period of two years from the date of last entry.

52Y. Inspection of stocks.—The stocks of essential narcotic drugs under the custody of a recognised medical institution shall be open for inspection by the Controller of Drugs or any other officer authorised by him in this regard.

52Z. Appeal.—(1) A recognised medical institution aggrieved by any decision or order passed by the Controller of Drugs under this Chapter may appeal to the Secretary to the State Government responsible for implementation of Drugs and Cosmetic Rules, 1945 within a period of sixty days from the date of communication to him of such decision or order.

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

52ZA. Procedure for appeal.—(1) The Appellate Authority referred to in sub-rule (1) of rule 52Z shall give an opportunity to the appellant to be heard in person, if he so desires.

(2) The Appellate Authority referred to in sub-rule (1) of rule 52Z may, at the hearing of an appeal allow the appellant to raise any other ground not specified in the appeal, if the Appellate Authority is satisfied that omission of that ground from the appeal was not willful or unreasonable.

(3) The Appellate Authority referred to in sub-rule (1) of rule 52Z may, after making such further inquiry as may be necessary, pass such order 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.]

CHAPTER VI

IMPORT, EXPORT AND TRANSHIPMENT OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

[1][**53. General prohibition.**—Import into and export out of India of the narcotic drugs and psychotropic substances is prohibited except with an import certificate or export authorization issued under the provision of this Chapter:

Provided that import into India or export out of India of the narcotic drugs and psychotropic substances specified in Schedule I of these rules shall be for the purpose mentioned in Chapter VIIA.]

[2][***]

54. Import of opium, etc.—The import of—

(i) opium, concentrate of poppy straw, and

(ii) morphine, codeine, thebaine, and their salts is prohibited save by the Government Opium Factory:

[3][Provided that nothing in this rule shall apply to import of morphine, codeine, thebaine and their salts by manufacturers notified by the Government,

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1. Subs. by G.S.R. 224(E), dated 25th March, 2015, for rule 53 (w.e.f. 25-3-2015). Earlier rule 53 was amended by G.S.R. 350(E), dated 25th June, 1997 (w.e.f. 27-6-1997). Rule 53, before substitution, stood as under:

   "*53. General prohibition.*—Subject to the other provisions of this Chapter, the import into and export out of India of the narcotic drugs and psychotropic substances specified in Schedule I is prohibited:

   Provided that nothing in this rule shall apply in case the drug substance is imported into or exported out of India subject to an import certificate or export authorisation issued under the provision of this Chapter and for the purpose mentioned in Chapter VIIA."

2. Rule 53A omitted by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015). Earlier rule 53A was inserted by S.O. 599(E), dated 10th August, 1993 (w.e.f. 10-8-1993) and amended by G.S.R. 556(E), dated 14th July, 1995 (w.e.f. 20-7-1995). Rule 53A, before omission, stood as under:

   "*53A.* (1) Subject to the provisions of sub-rule (2), no person shall export any of the narcotic drug or psychotropic substance or preparation containing any of such narcotic drug or psychotropic substance specified in [Schedule II] to the countries or to the region of such country specified therein.

   (2) Notwithstanding anything contained in sub-rule (1) above, the Narcotics Commissioner may authorise export of specified quantities of such narcotic drug or psychotropic substance or preparation containing such narcotic drug or psychotropic substance on the basis of special import licence issued by the Competent Authority of the country mentioned in Schedule II which intends such import by way of issuance of special import licence. The shipment of the consignment so allowed shall be accompanied by a copy of such special import licence duly endorsed by the Narcotics Commissioner."

3. Ins. by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010).

for use in manufacture of products to be exported or to imports of small quantities of morphine, codeine and thebaine and their salts not exceeding a total of 1 kilogram [1][during a calendar year for analytical purposes by an importer], after following the procedure under rule 55 and subject to such conditions as may be specified in the import certificate issued in Form No. 4A.]

55. Application for import certificate.—[2][(1) Subject to rule 53, no narcotic drug, or psychotropic substance [3][***] shall be imported into India without an import certificate in respect of the consignment issued by the issuing authority, in Form No. 4 [4][or Form No. 4A, as the case may be] appended to these rules.]

(2) The importer applying for an import certificate under sub-rule (1) in relation to narcotic drug shall submit along with his application the original or certified copy of the excise permit issued by the concerned State Government.

[5][(3) Every application for an import certificate shall be in such form and manner and provide such details as may be specified by the Narcotic Commissioner.]

[6][(4) A fee of rupees one thousand shall be paid to the Central Government alongwith the application under sub-rule (1) for issue of each import certificate under this rule.]

56. Issue of import certificate.—[7][(1) The Narcotics Commissioner shall issue or deny the import certificate referred to in sub-rule (1) of rule 55 within a period of twenty one working days from the date of receipt of an application completed in all respects and in case the import certificate is not issued within the stipulated time period or denied, the Narcotics Commissioner or any other officer authorised by him in this regard shall inform the applicant the reasons thereof.]

[8][(1A)] The issuing authority shall prepare seven copies of the import certificate [9][***] and deal with them in the manner hereunder provided, namely:—

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1. Subs. by G.S.R. 470(E), dated 21st June, 2011, for "during a financial year for analytical purposes by any importer notified by the Government" (w.e.f. 21-6-2011).
2. Subs. by G.S.R. 556(E), dated 14th July, 1995 (w.e.f. 20-7-1995).
3. The words "specified in the Schedule of the Act" omitted by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015).
4. Ins. by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010).
5. Subs. by G.S.R. 224(E), dated 25th March, 2015, for sub-rule (3) (w.e.f. 25-3-2015). Sub-rule (3), before substitution stood as under:

   "(3) The application for the import certificate shall state such details as may be specified by the Narcotics Commissioner."
6. Subs. by G.S.R. 224(E), dated 25th March, 2015, for sub-rule (4) (w.e.f. 25-3-2015). Earlier sub-rule (4) was inserted by S.O. 1661(E), dated 13th July, 2010 (w..e.f. 13-7-2010). Sub-rule (4), before substitution stood as under:

   "(4) No import certificate shall be issued unless a fee of rupees one thousand has been paid."
7. Ins. by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015).
8. Sub-rule (1) re-numbered as sub-rule (1A) therof by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015).
9. The words "referred to in sub-rule (1) of rule 55" omitted by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015).

(a) (i) original and duplicate copies should be supplied to the importer who should transmit the original copy to the exporting country and shall produce the duplicate copy at the Customs House, Land Customs Station or Airport where the consignment arrives or, in the case of imports by parcel post, at the post office of delivery, in order to obtain delivery of the consignment of narcotic drugs or psychotropic substances;

(ii) the [1][Commissioner of Customs] or Post Master shall state on the copy presented by the importer that the narcotic drugs or the psychotropic substances have actually been imported and return the document to the importer who shall indicate on it that he has received the goods;

(iii) the importer shall return the duplicate copy of the import certificate incorporating the endorsement from the [1][Commissioner of Customs] or Post Master and his own endorsement to the issuing authority—(1) where the import certificate relates to narcotic drug, through the excise authorities of the State from which excise permit for purposes of sub-rule (2) of rule 55 was produced; (2) where the import certificate relates to psychotropic substance, through the Drugs Controller of the concerned State;

(b) triplicate copy should be supplied to the [1][Commissioner of Customs] concerned who shall return it to the issuing authority along with the copy of the export authorisation to be received at the time of receipt of the consignment from the Government of the exporting country, with an endorsement as to actual quantity of narcotic drugs or psychotropic substances cleared;

(c) quadruplicate copy of the import certificate in relation to narcotic drug should be supplied to the excise authorities of the State into which the narcotic drug is to be imported, and the said copy of the certificate in relation to psychotropic substance should be supplied to the Drugs Controller of the concerned State for comparison with the copy produced before them, by the importer under sub-clause (a) of this sub-rule.

(d) qunituplicate copy should be supplied to the Government of the exporting country for comparison with the copy furnished to them by importer under sub-clause (a) or this sub-rule;

(e) sextuplicate copy should be retained to the Drugs Controller, Government of India;

(f) septuplicate copy should be retained by the issuing authority in his office.

(2) An import certificate issued under sub-rule (1) of rule 55 may allow the importation of the quantity of the concerned drug or the substance in more than one consignment.

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1. Subs. by G.S.R. 224(E), dated 25th March, 2015, for "Collector of Customs" (w.e.f. 25-3-2015).

57. Transit.—Subject to the provisions of section 79 of the Act and rule 53, no consignment of any narcotic drug, or psychotropic substances [1][***] shall be allowed to be transited through India unless such consignment is accompanied by a valid export authorisation in this behalf, issued by the Government of the exporting country:

Provided that the provisions of this rule shall not apply to the carriage by any ship or aircraft, of small quantities of such narcotic drugs and psychotropic substances which are essential for treatment of, or medical aid to, any person on board the ship or aircraft.

58. Application for export authorisation.—[2][(1) No narcotic drug or psychotropic substance shall be exported out of India without an export authorization issued by the issuing authority in respect of the consignment, in Form No. 5 appended to these rules.]

(2) The exporter applying for an export authorisation under sub-rule (1) shall submit,—

(a) where the export authorisation relates to narcotic drug, along with his application the original or an authenticated copy of the excise permit issued by the concerned State Government; and

(b) the import certificate in original, issued by the Government of the importing country certifying the official approval of the concerned Government.

[3][(3) Every application for an export authorization shall be in such form and manner and provide such details as may be specified by the Narcotic Commissioner.]

[3][(4) A fee of rupees one thousand shall be paid to the Central Government along with the application under sub-rule (1) for issue of each export authorization under this rule.]

59. Issue of export authorisation.—[4][(1) The Narcotics Commissioner shall issue or deny the export authorization referred to in sub-rule (1) of rule 58 within

1. The words "specified in Schedule of the Act" omitted by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015). Earlier these words were amended by G.S.R. 556(E), dated 14th July, 1995 (w.e.f. 20-7-1995).

2. Subs. by G.S.R. 224(E), dated 25th March, 2015, for sub-rule (1) (w.e.f. 25-3-2015). Earlier sub-rule (1), was substituted by G.S.R. 556(E), dated 14th July, 1995 (w.e.f. 20-7-1995). Sub-rule (1), before substitution by G.S.R. 224(E), dated 25th March, 2015 stood as under:
"(1) Subject to rules 53 and 53A, no narcotic drugs, or psychotropic substances specified in the Schedule of the Act, shall be exported out of India without an export authorisation in respect of the consignment issued by the issuing authority in Form No. 5 appended to these rules."

3. Subs. by G.S.R. 224(E), dated 25th March, 2015, for sub-rule (3) and (4) (w.e.f. 25-3-2015). Earlier Sub-rule (3) was omitted and sub-rule (4) renumbered as sub-rule (3) thereof by S.O. 556(E), dated 14th July, 1995 (w.e.f. 20-7-1995) and sub-rule (4) was inserted by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010). Sub-rule (3) and (4), before substitution by G.S.R. 224(E), dated 25th March, 2015 stood as under:

"(3) The application for the export authorisation shall state such details as may be specified by the Narcotics Commissioner.

(4) No export authorisation shall be issued unless a fee of rupees one thousand has been paid."

4. Ins. by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015).

a period of twenty one working days from the date of receipt of an application completed in all respects and in case the export authorization is not issued within the stipulated time period or denied, the Narcotics Commissioner or any other officer authorised by him in this regard shall inform the applicant the reasons thereof.]

[1][(1A)] The issuing authority shall prepare five copies of the export authorisation [2][***] and deal with them in the manner hereunder provided, namely:—

(a) the original should be supplied to the consignor which shall accompany the consignment;

(b) the duplicate copy should be forwarded to the [3][Commissioner of Customs] of the port who will return it to the issuing authority indicating on it the date of export and the quantity exported;

(c) the triplicate copy should be forwarded to the Government of the importing country;

(d) the quadruplicate copy should be forwarded to the excise authority of the State in which the exporter has his place of business;

(e) quintuplicate copy should be retained by the issuing authority in his office;

(2) Where the consignment of narcotic drug or psychotropic substance is to be transhipped or transited through one or more countries, such additional number of copies of export authorisation as may be required shall be prepared and sent to the concerned country or, as the case may be, countries.

60. Transhipment.—Subject to the provisions of section 79 of the Act and rule 53, no consignment of narcotic drug, or psychotropic substance [4][***] shall be allowed to be transhipped at any port in India save with the permission of the [5][Commissioner of Customs].

61. Procedure for transhipment.—The [5][Commissioner of Customs] while allowing any consignment of narcotic drug, or psychotropic substances, [4][***] to be transhipped shall, *inter alia*, satisfy himself that the consignment is accompanied by a valid export authorisation issued by the exporting country.

62. Diversion of consignment.—(1) The [5][Commissioner of Customs] shall take all due measures to prevent the diversion of such consignment to a destination other than that named in the aforesaid export authorisation.

(2)(a) The [5][Commissioner of Customs] may permit diversion of such a consignment to a country other than that named in the accompanying copy of

1. Subs-rule (1) re-numbered as sub-rule (1A) thereof, by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015).
2. The words "referred to in sub-rule (1) of rule 58" omitted by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015).
3. Subs. by G.S.R. 224(E), dated 25th March, 2015, for "Collector of Customs" (w.e.f. 25-3-2015).
4. The words "specified in Schedule of the Act" omitted by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015). Earlier these words were amended by G.S.R. 556(E), dated 14th July, 1995 (w.e.f. 20-7-1995).
5. Subs. by G.S.R. 224(E), dated 25th March, 2015, for "Collector of Customs" (w.e.f. 25-3-2015).

the export authorisation subject to the production of export authorisation issued by the issuing authority as provided under rule 58, as if the diversion were an export from India to the country, or territory of new destination.

(b) The [1][Commissioner of Customs] shall inform the issuing authority regarding the actual quantity of the narcotic drug or psychotropic substance, the diversion of the consignment of which was allowed under clause (a), whereupon the issuing authority shall, inform the country from which the export of the consignment originated.

63. Prohibition of import and export of consignments through a post office box, etc.—The import or export of consignments of any narcotic drug or psychotropic substance through a post office box or through a bank is prohibited.

CHAPTER VII

PSYCHOTROPIC SUBSTANCES

[2][**64. Manufacture of psychotropic substances.**—(1) No person shall manufacture any of the psychotropic substances except in accordance with the conditions of a licence granted under the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the 1945 rules) framed under the Drugs and Cosmetics Act, 1940 (23 of 1940), by an authority in-charge of Drugs Control in a State appointed by the State Government in this behalf:

Provided that a licence to manufacture a psychotropic substance specified in Schedule I shall be issued only for the purposes mentioned in Chapter VIIA:

Provided further that the authority in charge of the drug control in a State shall consult the Narcotics Commissioner before issuing a licence to manufacture a psychotropic substance specified in Schedule I.

(2) The authority in charge of drugs control in a State (hereinafter referred to as the Licensing Authority) shall consult the Narcotics Commissioner with regard to the assessed annual requirements of each of the psychotropic substances in bulk form referred to in sub- rule (1) in the country and taking into account the requirement of such psychotropic substances in the State, the quantity of such substance required for supply to other manufacturers outside the State and the quantity of such substance required for reasonable inventory to be held by a manufacturer, shall specify, by order, the limit of the quantity of such substance which may be manufactured by the manufacturer in the State.

(3) The quantity of the said psychotropic substance which may be manufactured by a licensee in a year shall be intimated by the Licencing Authority to the licensee at the time of issuing the licence.]

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1. Subs. by G.S.R. 224(E), dated 25th March, 2015, for "Collector of Customs" (w.e.f. 25-3-2015).
2. Subs. by G.S.R. 224(E), dated 23rd March, 2015, for rule 64 (w.e.f. 23-3-2015). Rule 64, before suhbstitution, stood as under:

   "*64. General prohibition.*—No person shall manufacture, possess, transport, import inter-State, export inter-State, sell, purchase, consume or use any of the psychotropic substances specified in Schedule I."

[1][**65. Registration and submission of returns.**—(1) A person who has been issued licence to manufacture one or more psychotropic substances shall register with the Narcotics Commissioner for each of the substances in the form and manner as may be specified by the Narcotics Commissioner:

Provided that the requirement of registration under this sub-rule shall be complied within a period of one hundred and eighty days from the date of coming into force of these rules.

(2) A person who has registered with the Narcotics Commissioner under sub-rule (1) shall file quarterly return with the Narcotics Commissioner in such form and manner as may be specified by the Narcotics Commissioner.

(3) The return for a quarter shall be filed before the last day of the month following that quarter.

(4) If the return for a quarter is not filed before the due date by a person registered under sub-rule (1), the Narcotics Commissioner may issue notice to explain the reasons therefor and after considering the reasons submitted, if any, may pass orders for revoking the registration.

(5) The registration under sub-rule (1) shall be deemed to be revoked, if the quarterly return for three successive quarters is not filed.

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1. Subs. by G.S.R. 224(E), dated 25th March, 2015, for rule 65 (w.e.f. 25-3-2015). Earlier rule 65 was amended by G.S.R. 350(E), 25th June, 1997 (w.e.f. 27-6-1997) and by G.S.R. 214(E), dated 19th March, 2002 (w.e.f. 19-3-2002). Rule 65, before substitution, stood as under:

"*65. Manufacture of psychotropic substances.*—(1) Subject to the provisions of sub-rule (2), the manufacture of any of the psychotropic substances other than those specified in Schedule I shall be in accordance with the conditions of a licence granted under the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the 1945 Rules) framed under the Drugs and Cosmetics Act, 1940 (23 of 1940), by an authority in charge of Drugs Control in a State appointed by the State Government in this behalf:

Provided that the authority in charge of drug control in a State referred to above may issue a licence to manufacture a psychotropic substance specified in Schedule III for the purpose of export only;

(2) The authority in charge of drugs control in a State (hereinafter referred to as the Licensing Authority) shall consult the Drugs Controller (India) in regard to the assessed annual requirements of each of the psychotropic substances in bulk form referred to in sub-rule (1) in the country and taking into account the requirement of such psychotropic substances in the State, the quantity of such substance required for supply to other manufacturers outside the State and the quantity of such substance required for reasonable inventory to be held by a manufacturer, shall specify, by order, the limit of the quantity of such substance which may be manufactured by the manufacturer in the State.

(3) The quantity of the said psychotropic substance which may be manufactured by a licensee in an year shall be intimated by the Licencing Authority to the licensee at the time of issuing the licence:

Provided that nothing contained in this rule shall apply in case the psychotropic substances specified in Schedule I are manufactured, possessed, transported, imported inter-State, exported inter-State, sold, purchased, consumed or used subject to other provisions of this Chapter which applies to psychotropic substances which are not included in Schedule I and for the purposes mentioned in Chapter VIIA:

Provided further that the authority in charge of the drug control in a State referred to in sub-rule (2) of rule 65 shall consult the Narcotics Commissioner before issuing a licence under rule 65 in respect of psychotropic substances included in Schedule I and Schedule III.".

(6) An appeal against an order passed under sub-rule (4) may be made to the 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, authorized by him in this behalf, within thirty days from the date of communication of such order.

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

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

Explanation.—For the purposes of this rule, the expression "quarter" shall be January to March, April to June, July to September and October to December of every year.]

[1][**65A. Sale, purchase, consumption or use of psychotropic substances.**—No person shall sell, purchase, consume or use any psychotropic substance except in accordance with the Drugs and Cosmetics Rules, 1945:]

[2][Provided that sale, purchase, consumption or use of a psychotropic substance specified in Schedule I shall be only for the purposes mentioned in Chapter VIIA.]

66. Possession, etc., of psychotropic substances.—[3][(1) No person shall possess any psychotropic substance for any of the purposes covered under 1945 rules, unless he is lawfully authorized to possess such substance for any of the said purposes under these rules:

Provided that possession of a psychotropic substance specified in Schedule I shall be only for the purposes mentioned in chapter VIIA.]

(2) Notwithstanding anything contained in sub-rule (1), any research institution or a hospital or dispensary maintained or supported by Government or local body or by charity or voluntary subscription, which is not authorised to possess any psychotropic substance under the 1945 Rules, or any person who is not so authorised under the 1945 Rules, may possess a reasonable quantity of such substance as may be necessary for their genuine scientific requirements or genuine medical requirements, or both for such period as is deemed necessary by the said research institution or, as the case may be, the said hospital or dispensary or person:

Provided that where such psychotropic substance is in possession of an individual for his personal medical use the quantity thereof shall not exceed one hundred dosage units at a time:

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1. Ins. by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010).
2. Ins. by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015).
3. Subs. by G.S.R. 224(E), dated 25th March, 2015, for sub-rule (1) (w.e.f. 25-3-2015). Sub-rule (1), before substitution, stood as under:

   "(1) No person shall possess any psychotropic substance for any of the purposes covered by the 1945 Rules, unless he is lawfully authorised to possess such substance for any of the said purposes under these rules."

[1][Provided further that an individual may possess the quantity of exceeding one hundred dosage units at a time [2][but not exceeding three hundred dosage units at a time] for his personal long term medical use if specifically prescribed by a Registered Medical Practitioner.]

(3) The research institution, hospital and dispensary referred to in sub-rule (2) shall maintain proper accounts and records in relation to the purchase and consumption of the psychotropic substance in their possession.

67. Transport of psychotropic substance.—[3][(1) No consignment of psychotropic substance shall be transported, imported inter-State or exported inter-State unless such consignment is accompanied by a consignment note in Form 6 appended to these rules and in the manner as provided hereinafter:

Provided that a psychotropic substance specified in Schedule I shall be transported, imported inter-State or exported inter-State only for the purposes mentioned in Chapter VIIA:

Provided further that a psychotropic substance specified in Schedule I shall be transported for export out of India only after an export authorization is issued by the Narcotics Commissioner under rule 59.]

(2) The consignment note referred in sub-rule (1) shall be prepared in triplicate, and the original and duplicate copies of the said note shall be sent along with the consignment of psychotropic substances to the consignee who shall return the duplicate copy of the note to the consignor for his use after endorsing on the original and duplicate copies the particulars of the receipt of the quantity consigned.

[4][***]

(4) The consignor and consignee shall keep such consignment note for a period of two years and the said note may be inspected at any time by an officer authorised in this behalf by the Central Government.

[5][Provided that consignment note in Form 6 shall not apply in cases where the sale of the psychotropics substance is accompanied by a sale bill or invoice or cash memo or any other document duly signed by the consignor or his authorised signatory, which shall include the following information about the consignment:—

1. Ins. by G.S.R. 639(E), dated 13th October, 2006 (w.e.f. 13-10-2006).
2. Ins. by G.S.R. 2(E), dated 1st January, 2008 (w.e.f. 1-1-2008).
3. Subs. by G.S.R. 224(E), dated 25th March, 2015, for sub-rule (1) (w.e.f. 25-3-2015). Earlier sub-rule (1), was amended by G.S.R. 104(E), dated 25th February, 2005 (w.e.f. 25-2-2005). Sub-rule (1), before substutution stood as under:

   "(1) Subject to the provisions of rule 64, no consignment of psychotropic substance shall be transported, imported inter-State or exported inter-State unless such consignment is accompanied by a consignment note in [Form 6] appended to these Rules and in the manner as provided hereinafter."
4. Sub-rule (3) omitted by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015). Sub-rule (3), before omission, stood as under:

   "(3) The consignor shall make necessary entries on the triplicate copy of the said note with reference to the receipt of quantity of the psychotropic substances indicated on that duplicate copy of the note."
5. Ins. by G.S.R. 104(E), dated 25th February, 2005 (w.e.f. 25-2-2005).

(a) name, address and licence number of the consignor and the consignee;

(b) description, batch number and quantity;

(c) mode and particulars of transport:

Provided further that such document shall be preserved by consignor and consignee for a period of two years for inspection by the officers referred to in sub-rule (4) above.

Explanation.—Where the consignee is a research institution, registered medical practitioner, hospital or dispensary, the requirement of incorporating licence number of consignee shall not be applicable.]

[1][*CHAPTER VIIA*

SPECIAL PROVISIONS REGARDING MANUFACTURE, POSSESSION, TRANSPORT, IMPORT-EXPORT, PURCHASE AND CONSUMPTION OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES FOR [2][MEDICAL, SCIENTIFIC AND TRAINING PURPOSES]

67A. Notwithstanding anything contained in the foregoing provisions of these rules—

(a) a narcotic drug and psychotropic substance may be used for—

(i) scientific requirement including analytical requirements of any Government laboratory or any research institution in India or abroad;

(ii) very limited medical requirements of a foreigner by a duly authorised person of a hospital or any other establishment of the Government especially approved by that Government;

(iii) the purpose of de-addiction of drug addicts by Government or local body or by an approved charity or voluntary organisation or by such other institution as may be approved by the Central Government.

[3][or the authority exercising the powers under sub-clause (iv) of clause (a)]

[3][(iv) the purpose of restraining or immobilising wild animals by or under the authority of the Government and approved by that Government.]

(b) persons performing medical or scientific functions [3][or the authority exercising the powers under sub-clause (iv) of clause (a)] shall keep records concerning the acquisition of the substance and the details of

---

1. Chapter VIIA (containing section 67A) ins. by G.S.R. 350(E), dated 25th June, 1997 (w.e.f. 27-6-1997).

2. Subs. by G.S.R. 639(E), dated 13th October, 2006, for "**MEDICAL AND SCIENTIFIC PURPOSES**" (w.e.f. 13-10-2006).

3. Ins. by G.S.R. 905(E), dated 28th December, 2011 (w.e.f. 28-12-2011).

their use in Form 7 of these rules and such records are to be preserved for at least two years after their (*sic*);

(c) a narcotic drug and psychotropic substance may be supplied or dispensed for use to a foreigner pursuant to medical prescription only from the authorised licensed pharmacists or other authorised retail distributors designated by authorities responsible for public health.]

[1][**67B.** (1) Notwithstanding anything contained in these rules, the government Opium and Alkaloid works may procure, manufacture or import and supply narcotic drugs and psychotropic substances as may be required as samples by various drug law enforcement agencies, testing laboratories and training institutions of the Central and State Governments.

(2) The Government Opium and Alkaloid Works may also supply samples to organisations other than those covered by sub-rule (1) with the prior approval of the Central Government.

(3) Any enforcement agency, laboratory, training institution or organisation requiring the samples shall apply to the Chief Controller of Factories in Form No. 8.

(4) The quantities of various narcotic drugs and psychotropic substances to he supplied as samples shall be determined by the Central Government from time to time. The organisation obtaining the samples shall designate an officer, at the time of sending the request for samples, in whose custody the samples shall be kept.

(5) The organisation requisitioning the samples shall maintain records and submit an annual report to the Chief Controller of Factories in Form No. 9.

(6) When a sample is used for training, the organisation shall maintain a record of the quantity of drug taken out for training and the quantities actually used.]

[1][**67C.** Notwithstanding anything contained in these rules, the Narcotics Commissioner may permit import or export of narcotic drugs and psychotropic substances for the purpose of controlled deliveries, investigations, intelligence collection scientific analysis.]

[2][*CHAPTER VIIB*

REPORTS, RETURNS AND ESTIMATES UNDER INTERNATIONAL CONVENTIONS

67D. Submission of reports and returns under international conventions.— (1) All reports and returns which are required to be submitted under any international convention, shall be submitted to an international agency by such officer the Central Government may, by notification in the Official Gazette, appoint in this behalf from time-to-time.

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1. Ins. by G.S.R. 639(E), dated 13th October, 2006 (w.e.f. 13-10-2006).
2. Chapter VIIB (containing sections 67D and 67E) ins. by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010).

(2) The officer appointed under sub-rule (1) may call for such inputs as may be necessary to submit the returns under sub-rule (1), from the Narcotics Commissioner, the Chief Controller of Factories or any other officer of the Central Government or any State Government indicating the format in which the information is required and the time by which it is required.

(3) The officer from whom inputs have been called for under sub-rule (2), shall provide all inputs which are sought and which are available with him in the format in which it has been called for and within the time indicated in sub-rule (2) and shall also indicate the information not maintained by him or not available.

67E. Estimates and quotas.—(1) If, estimates of requirement of any narcotic drug have to be submitted under any international convention, resolution or commitment, the same shall be submitted to an international agency by such officer the Central Government may, by notification in the Official Gazette, appoint in this behalf from time-to-time.

(2) The estimates for use and consumption of narcotic drugs approved by international agencies for India shall be allotted as quotas to users within the country by such officer as may be notified by the Central Government by notification in the Official Gazette from time-to-time.

(3) The users to whom such quota is allotted shall not exceed the quota allotted to him and shall submit to the officer appointed under sub-rule (2), such statistics of consumption and use of the narcotic drugs and within such time as may be indicated by the officer.]

CHAPTER VIII

MISCELLANEOUS

68. Repeal and savings.—(1) The Central Opium Rules, 1934, the Dangerous Drugs (Import, Export and Transhipment) Rules, 1957, and the Central Manufactured Drugs Rules, 1962 are hereby repealed.

(2) Notwithstanding such repeal, anything done or any action taken or purported to have been done or taken under any of the rules repealed by sub-rule (1) shall, in so far as it is not inconsistent with the provisions of these rules, be deemed to have been done or taken under the corresponding provisions of these rules.

[1][*SCHEDULE I*

(*See* rules 53 and 64)

I. Narcotic drugs

1. Coca Leaf
2. Cannabis (Hemp)
3. (a) Acetorphine
   (b) Diacetylmorphine (Heroin)
   (c) Dihydrodesoxymorphine (Desmorphine)

1. Subs. by G.S.R. 639(E), dated 13th October, 2006, for Schedule I (w.e.f. 13-10-2006).

(d) Etorphine

(e) Ketobemidone

and their salts, preparations, admixtures, extracts and other substances containing any of these drugs.

II. Psychotropic substances

Sl. No.	International non-proprietary names	Other non-proprietary names	Chemical names
(1)	(2)	(3)	(4)
1.	Etryptamine		3-(2-aminobutyl) indole
2.	Methaqualone		2-methyl-3-o-tolyl-4(3H)-quinazolinone
3.		Methcathinone	2-(methylamino)-1 phenylpropan-1-one
[1][4.	Mephedrone	4-methylmethcathinone (4-MMC) 4-methylephedrone	(RS)-2-methylamino-1-(4-methylphenyl) propan-1-one
5.	Salts and preparations of above]		]

[2][***]

[3][***]

IndiaCode

1. Subs. by G.S.R. 74(E), dated 5th February, 2015, for item 4 and entries relating thereto.
2. Schedule II omitted by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015). Earlier Schedule II was substituted by G.S.R. 639(E), dated 13th October, 2006 (w.e.f. 13-10-2006). Earlier to that Schedule II was omitted by G.S.R. 559(E), dated 10th August, 1993 (w.e.f. 10-8-1993) and Schedule IV which was inserted by G.S.R. 559(E), dated 10th August, 1993 (w.e.f. 10-8-1993) was renumbered as Schedule II by G.S.R. 556(E), dated 14th July, 1995 (w.e.f. 20-7-1995).
3. Schedule III omitted by G.S.R. 224(E), dated 25th March, 2015 (w.e.f. 25-3-2015). Earlier Schedule III was substituted by G.S.R. 639(E), dated 13th October, 2006, (w.e.f. 13-10-2006). Earlier to that Schedule III was omitted by G.S.R. 559(E), dated 10th August, 1993 (w.e.f. 10-8-1993) and was inserted by G.S.R. 214(E), dated 19th March, 2002 (w.e.f. 19-3-2002).

FORM NO. 1

(See rule 7)

GOVERNMENT OF INDIA CENTRAL BUREAU OF NARCOTICS

LICENCE TO GROW OPIUM POPPY FOR PRODUCTION OF OPIUM OR POPPY STRAW

Name and Parentage of the licensee	Village	Pargana/District Tehsil	Licence Number	Area Licensed	Plot No.(s) as per revenue records

	Hectares	Area	Signature
Area measured	.....	.....	..... (S.I.)
Area test-measured	.....	.....	..... (Inspector/D.O.O.)
Area harvested	.....	.....	..... (S.I.)

Signature and Seal
District Opium Officer

(Entries to be made at the time of weighments)						(Entries to be made at the time of final payment.			
Class of opium as assigned by D.O.O.	Weight of opium (Kg.)	Assumed weight at 70°C(Kg.)	Price payable on the basis of assumed weight 70°C	Amount withheld pending final examination of opium at factory	Amount paid at weighments	Total weight of opium at 70°C on the basis of factory's report	Average yield of the cultivator	Total amount payable on the basis of factory report	Amount already paid at the time of weighments	Amount paid/ received at the time of final payments
1	2	3	4	5	6	7	8	9	10	11

Signature and Seal
District Opium Officer

IndiaCode

FORM NO. 2

(*See* rule 8)

APPLICATION FOR GRANT OF LICENCE FOR OPIUM POPPY CULTIVATION FOR PRODUCTION OF OPIUM OF POPPY STRAW

Crop year.....

1. Name of the Cultivator.....
2. Father's Name:.....
3. Village.....Tehsil.....District.....
4. Khasra No. of the plot of land in which poppy is to be cultivated.....
5. Whether the plot is in the name of the applicant as per revenue records. If not, in whose name?.....
6. Whether the plot specified in column 4 has irrigation facilities (kind of irrigation facilities available, *i.e.*, well, tubewell, etc., ...
7. Area required for opium poppy cultivation.....
8. Whether the applicant cultivated the poppy in ..... the past, if so, the latest year in which he..... cultivated poppy.
9. Whether the applicant was ever proscribed from poppy cultivation or was de-licensed for tendering adulterated opium, excess cultivation, violations of Departmental instructions. If so, the year and the reasons for proscription.....

I hereby certify that the particulars shown above are correct and the land in which opium poppy is to be cultivated is free from litigation.

.....

Attestation
(to be made by Lambardar)

Signature/Thumb-impression
of cultivator

(To be completed by the Sub-Inspector Incharge)

A. Performance of the cultivator during the preceding crop year.
Crop year.....Area licensed.....
Area measured.....Area harvested.....
Average yield at 70°C.....

B. Whether the cultivator has ever been proscribed on account of excess cultivation and violation of Departmental instructions, etc., if so the particulars thereof.

Signature.....
(Sub-Inspector Incharge)

The particulars above recorded by the Sub-Inspector have been verified by me. The cultivator is eligible/ineligible for grant of a licence.

Signature(Sub-Inspector Incharge)

Area allotted by the District Opium Officer.

.....
Signature of District Opium Officer

IndiaCode

Conditions of licence

1. The licensee shall not transfer this licence and cultivate poppy only for production of opium or poppy straw over the area of land and the plot(s) specified in the licence.

2. The land in which poppy will be cultivated by the cultivator shall be free from litigation.

3. The licensee shall get his daily collections of opium obtained from the crop weighed by the Lambardar and affix his signature/thumb-impressions against each entry made by the Lambardar in token of correctness of such entry made by the Lambardar and shall submit to preliminary weighments carried out by the staff of the Narcotics Department in the village during which he shall produce the entire quantity collected by him.

4. The licensee shall bring to, and deliver at the place fixed and notified for weighments all opium collected by him from the crop and shall accept for opium so brought by him the price fixed by the Central Government for that crop year.

5. The licensee shall deliver the opium either himself or through any person authorised by him at the time of its weighment and his opium shall be weighed under the supervision of the District Opium Officer or any other officer authorised in this behalf by the Narcotics Commissioner in accordance with rule 14 of the Narcotic Drugs and Psychotropic Substances Rules, 1985.

6. If the licensee does not surrender his entire produce of opium to Government or retains, embezzles or otherwise illegally disposes of any part of the same he shall be liable to be prosecuted as per the provisions of the Narcotics Drugs and Psychotropic Substances Act, 1985.

7. The licensee shall extract as much opium as is reasonably possible from all implements, pots and cloth used by him in collecting opium and impregnated with opium in consequence of such use.

8. The final payment for opium delivered by the licensee shall be made to him at appropriate time fixed by the District Opium Officer or any other officer authorised in this behalf.

9. If on the final adjustment of accounts any sum is found due from the licensee, he shall pay it to the District Opium Officer or any other officer authorised in this behalf in the manner specified. If the licensee fails to pay the sum due from him it may be recovered from him in the manner prescribed by section 72 of the Narcotic Drugs and Psychotropic Substances Act, 1985.

10. The licence may be withheld or cancelled at any time if any fact is revealed against the licensee which makes him ineligible for grant of the licence.

11. The licensee shall comply with the provisions of Narcotic Drugs and Psychotropic Substances Act, 1985, the Rules framed thereunder and any order issued by the competent authorities of the Narcotics Department from time to time.

12. The licensee shall be punishable under the relevant provisions of the Narcotic Drugs and Psychotropic Substances Act, 1985 for any breach of the conditions of the licence.

FORM NO. 3

[1][*See* rules 36 and 37]

LICENCE FOR MANUFACTURE OF MANUFACTURED DRUGS

Licence No.....Date of issue.....

.....is hereby licensed to manufacture the following manufactured drugs on the premises situated at.....

1. Subs. by G.S.R. 95(E), dated 4th February, 2004, for "(*See* rule 37)" (w.e.f. 4-2-2004).

Name of drug Quantity

(1)

(2)

2. The licence shall be in force from.....to.....

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985).

Signature.....

Date..... Designation.....

Conditions of licence

1. This licence is not transferable.

2. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an officer detailed for the purpose by the Licensing Authority.

3. The licensee shall not manufacture or keep the drug or the materials used for the manufacture of the drug at any other place except his place of business.

4. The licensee shall ensure manufacture of the drug to the standard and specifications laid down by or under the Drugs and Cosmetics Act, 1940 (23 of 1940).

5. The licensee, if he desires the renewal of his licence, shall apply to the Licensing Authority in the form specified for such renewal, at least thirty days before the expiry of his licence.

6. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the [1][the person or the entity] operating under the licence. Where any change in the constitution of the [1][the person or the entity] takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place or the normal expiry of the licence whichever is earlier unless in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the [1][the person or the entity] with the changed constitution.

[2][FORM NO. 3A

(*See* rule 36A)

Licence No. ..... Date of issue.....

M/s. .....is hereby licensed to manufacture concentrate of poppy straw and the following manufactured drugs on the premises situated at.....

Name of the drug Quantity

(i)

(ii)

(iii)

2. The licence shall be in force from.....to.....

The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985).

Date..... Signature.....

Designation.....

1. Subs. by G.S.R. 95(E), dated 4th February, 2004, for "firm" (w.e.f. 4-2-2004).

2. Ins. by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010).

Conditions of Licence

(a) This licence shall not be transferable;

(b) The licensee shall manufacture concentrate of poppy straw from the poppy straw produced in the fields licensed for the purpose,

(c) This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an officer detailed for the purpose by the Licencing Authority;

(d) The licensee shall ensure that the drugs that he manufactures are as per the specifications laid down by or under the Drugs and Cosmetics Act, 1940;

(e) The licensee shall, if he desires, submit applications for renewal of his licence at least thirty days before the expiry of his licence.

(f) The licensee shall inform the Licencing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place or normal expiry of the licence whichever is earlier unless in the meantime, a fresh licence has been taken from the Licencing Authority in the name of the firm with the changed constitution;

(g) The licensee shall be fully responsible to ensure the security of the factory premises and ensure that no diversion takes place in them;

(h) The licensee should provide security equipment such as surveillance cameras and other facilities as may be specified by the Narcotics Commissioner to ensure security on the fields;

(i) The licensee should report to the Narcotics Commissioner if he finds any farmer lancing or diverting;

(j) The licensee shall keep the Central Bureau of Narcotics informed of all matters relating to cultivation, production, transport, etc., of poppy straw and changes in agricultural practices;

(k) The licensee shall defray the cost of the Central Bureau of Narcotics staff posted to supervise the cultivation of opium for production of poppy straw and production of concentrate of poppy straw at such rates as may be decided by the Government from time-to-time;

(l) The licensee shall notify well before the sowing season, the price which they are willing to pay for the pods;

(m) The licensee should identify and enter into agreements with the farmers who are willing to cultivate opium poppy for production of poppy straw for sale to the licencee;

(n) The farmers with whom the licensee has entered into agreements will be licensed to grow opium poppy subject to such verifications as may be felt necessary by the Narcotics Commissioner,

(o) Such other conditions as may be specified by the Narcotics Commissioner from time-to-time.]

[1][FORM NO. 3B

[*See* rule 52A(3)]

SPECIAL AUTHORISATION FOR POSSESSION OF ESSENTIAL NARCOTIC DRUGS BY REGISTERED MEDICAL PRACTITIONER

Authorisation No.....Date of issue.....

.....is hereby authorised to possess the following essential narcotic drugs on the premises situated at.....for use in his practice.

Name of essential narcotic drug Quantity

(1)

(2)

2. The authorisation shall be in force from.....to.....

3. The authorisation is subject to the conditions stated below and to such other conditions as may be specified under the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and the rules made thereunder.

Signature.....

Designation.....

Conditions of authorisation

1. This authorisation is not transferable.
2. This authorisation and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an officer detailed for the purpose by the issuing authority.]

[1][FORM NO. 3C

(*See* rule 52D)

CONSIGNMENT NOTE

Date and time of dispatch of the consignment:.....

1.	Name and complete postal address of the consignor	:	
2.	Whether Manufacturer or Licenced Dealer	.	
	(Quote Licence Number and the Issuing Authority)		
3.	Name and complete postal address of the consignee	:	
4.	Description and quantity of the consignment	:	

Particulars of the essential narcotic drugs showing Trade Marks, Proprietary Names, Batch number, etc.	Number of packages	Quantity	
		Gross	Net

5.	Mode of transport (particulars of the transporter, Registration number of the vehicle or Railway Receipt./Lorry Receipt, if the transport is by railways good transports)	:	

Full Name/Designation (if any)	Signature of the Consignor with date

To be filled by the consignee

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

6.	Date and time of receipt by the consignee and his remarks	:	
7.	Whether the consignment received in full as per description and quantity mentioned at serial number 4 above	:	Yes / No (If 'no', details to be mentioned below.)

Full Name/Designation (if any) Signature of the Consignee with date

Note:

(1) This consignment note shall be serially numbered on annual basis.

(2) The consignor shall record a certificate on the cover page of each book containing consignment note indicating the number of pages contained in the consignment note-book.

(3) The consignor shall maintain a Register showing the details of the books of consignment note brought in use during a particular year.

(4) This consignment note shall be retained for a period of two years from the date of transaction.

(5) The records referred to in this note shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/ investigation.]

[1][FORM NO. 3D

[*See* **rule** 52H(2)]

DAILY ACCOUNTS OF ESSENTIAL NARCOTIC DRUGS TO BE MAINTAINED BY REGISTERED MEDICAL PRACTITIONER AND AUTHORISED PERSONS

Name of the Essential Narcotic Drug		:	.....	Authorised limit	:	.....
Date		:	.....			
1.	Opening stock				:	
2.	Quantity received				:	
2(i)	Received from (give details)				:	
2(ii)	Consignment Note/Bill/Invoice/Cash Memo, Number etc.				:	
3.	Quantity dispensed				:	
4.	Name and address of the person to whom dispensed (include patient registration number maintained in Form No. 3E, where applicable)				:	
5.	Closing stock				:	

Full Name/Designation (if any) Signature

Note:

(1) This record shall be maintained on day to day basis and entries shall be made for each day.

(2) Entries shall be completed for each day before the close of the day.

(3) The pages of the register shall be serially numbered.

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

(4) Separate record shall be maintained for each essential narcotic drug.

(5) This record shall be retained for two years from the date of last entry.

(6) This record shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/investigation.]

[1][FORM NO. 3E

[*See* rule 52H(3)]

DETAILS OF THE PATIENT

TO WHOM ESSENTIAL NARCOTIC DRUGS DISPENSED

(TO BE MAINTAINED BY REGISTERED MEDICAL PRACTITIONER/ RECOGNISED MEDICAL INSTITUTION)

Registration Number : ..... Date : .....

1.	Name	:	
2.	Complete postal address (with contact number, if any)	:	
3.	Brief description of the illness	:	
4.	Whether registered with any other registered medical practitioner/recognised medical institution (If yes, details to be recoded)	:	
5.	Details of the essential narcotic drugs dispensed	:	

Date	Name of the essential narcotic drugs	Quantity	Signature/Thumb impression of the patient	Remarks, if any

Note:

(1) This record shall be retained for two years from the date of last entry.

(2) This record shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/investigation.]

[1][FORM NO. 3F

[*See* rule 52-O(l)]

APPLICATION FOR ISSUE/RENEWAL OF CERTIFICATE OF RECOGNITION AS RECOGNISED MEDICAL INSTITUTION

1.	Name and complete postal address of the institution with telephone number, facsimile number and e-mail ID (relevant supporting documents to be submitted)	:	
2.	Name of the Head/In-charge of the Institution	:	
3.	Number of persons employed	:	
	(i) Doctors (ii) Nursing staff (iii) Others		

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

4.	Number of patients treated during the previous calendar year (i) in patients (ii) out patients (iii) home care	:	
5.	Name(s) of the qualified medical practitioner(s) who would prescribe essential narcotic drugs (give details of their training in pain relief and palliative care or opioid dependence treatment)	:	
6.	If there is more than one qualified medical practitioner who would prescribe essential narcotic drugs, indicate the name of the medical practitioner who shall be overall in charge	:	
7.	Number and date of the certificate of recognition issued earlier (attach copy)	:	
8.	Whether the recognition of the institution was withdrawn earlier (if the recognition was withdrawn earlier, the details are to be given)	:	

Date..... Signature:.....

Place..... Full name: .....

Seal: Position:.....]

[1][FORM NO. 3G

[*Sec* rule 52-O(2)]

CERTIFICATE OF RECOGNITION

No..... Date of issue.....

This is to certify that.....(Name of the institution)..... situated at.....is a Recognised Medical Institution to possess, dispense and sell essential narcotic drugs.

2. The institution is a Recognised Medical Institution since..... (mention date of the certificate issued for the first time).....

3. This certificate shall be in force from.....to.....

4. The certificate is subject to the conditions stated below and to such other conditions as may be specified under the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and the rules made thereunder.

Signature.....

Designation.....

Seal.....

Conditions of recognition

1. This certificate is non-transferable.
2. This certificate and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an officer authorised for the purpose by the issuing authority.]

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

[1][FORM NO. 3H

[*See* rule 52R(1)(c)]

DAILY ACCOUNTS OF ESSENTIAL NARCOTIC DRUGS TO BE MAINTAINED BY RECOGNISED MEDICAL INSTITUTION

Name of the Essential Narcotic Drug : ..... Date : .....

1.	Opening stock	:	
2.	Quantity received	:	
2(i)	Received from (give details)	:	
2(ii)	Consignment Note/Bill/Invoice/Cash Memo, Number etc.	:	
3.	Quantity dispensed	:	
4.	Specify registration number of the patent(s) maintained in Form No. 3E and quantity dispensed to each)	:	
5.	Closing stock	:	

Full Name/Designation (if any) Signature of the overall in charge

Note:

(1) This record shall be maintained on day to day basis and entries shall be made for each day.

(2) Entries shall be completed for each day before the close of the day.

(3) The pages of the register shall be serially numbered.

(4) Separate record shall be maintained for each essential narcotic drug.

(5) This record shall be retained for two years from the date of last entry.

(6) This record shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/investigation.]

[1][FORM NO. 3-I

[*See* rule 52R(1)(d)]

ANNUAL RETURN OF PROCUREMENT/DISBURSEMENT OF ESSENTIAL NARCOTIC DRUGS (TO BE FILLED BY RECOGNISED MEDICAL INSTITUTION)

Return for the year	:	.....	Date of submitting return	:	.....

1.	Number and date of the current certificate of recognition	:	
2.	Name of the Recognised Medical Institution	:	

Sl. No.	Name of essential narcotic drug	Quantity in original annual estimate	Quantity in revised annual estimate (if any)	Opening stock	Quantity procured during the year	Quality disbursed to patients during the year	Closing stock
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

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

*The designated medical practitioner or the over-all in charge, as the case may be, shall record a brief justification where the actual disbursement is more than ten per cent of the estimate or revised estimate, as the case may be.

Full Name/Designation (if any) Signature of the overall in charge.]

[1][FORM NO. 3J]

[*See* rule 52T(1)]

ESTIMATE OF ANNUAL REQUIREMENT OF ESSENTIAL NARCOTIC DRUGS

Estimate for the year	:	.....	Date of submitting estimate	:	.....

1.	Number and date of the current certificate of recognition	:	
2.	Name of the Recognised Medical Institution	:	
3.	Details of the estimated annual requirement of essential narcotic drugs		

Sl. No.	Name of essential narcotic drug	Quantity disbursed during previous year	Estimated annual requirement	Revised estimated annual requirement*	Reason for revision
(1)	(2)	(3)	(4)	(5)	(6)

*Please attach copy of the original estimate

Full Name/Designation (if any) Signature of the overall in charge.]

FORM NO. 4

(*See* rule 55)

Official Seal of the Issuing Authority

S. No.....

F. No.....

GOVERNMENT OF INDIA

MINISTRY OF FINANCE

(Department of Revenue)

CERTIFICATE OF OFFICIAL APPROVAL OF IMPORT

(The Narcotic Drugs and Psychotropic Substances Rules, 1985)

.....(The Issuing Authority) being the authority empowered to issue Import Certificate under the Narcotic Drugs and Psychotropic Substances Rules, 1985 hereby approves the importation into India of the consignments containing narcotic drugs or psychotropic substances as specified in the Schedule below by—

M/s.....

From M/s.....subject to the condition that the consignment containing such drugs or substances shall be imported before..... by.....to (airport/sea port) in India.

In approving the importation of the consignment containing the said drugs or substances specified..... (Issuing Authority) is satisfied that it is required solely for medical and scientific purposes.

Address of the Issuing Authority Designation of the Issuing Authority

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

Schedule specifying the narcotic drugs or psychotropic substances contained in the consignment to be imported.

1. This document is for.....(The authority to whom and the purpose for which it is being sent to be indicated).

2. The certificate is not valid unless it bears the Official Seal of the Issuing Authority on the top right hand corner.

Official Seal of Issuing Authority
S.No. .....
F.No. .....

[1][FORM NO. 4A

(*See* rules 54 and 55)

(Official seal of the Issuing authority)
S. No. .....
F. No. .....

MINISTRY OF FINANCE
(GOVERNMENT OF INDIA
(DEPARTMENT OF REVENUE)

CERTIFICATE OF OFFICIAL APPROVAL OF IMPORT UNDER THE PROVISO TO RULE 54

(The Narcotic Drugs and Psychotropic Substances Rules, 1985)

....., (The Issuing Authority) being empowered to issue Import Certificate under the Narcotic Drugs and Psychotropic Substances Rules, 1985, hereby, approves the importation into India of the following consignments of narcotic drugs:—

(1) .....;
(2) .....;
(3) .....;

By M/s.....from M/s.....to manufacture formulations for export/for analytical purposes (strike out whichever is not applicable) subject to the following conditions:—

Conditions of import certificate

(i) The consignment containing the drugs shall be imported before..... by.....to (airport/sea-port) in India.

(ii) If the import is for manufacture of formulations for export, the manufacturer shall,—

(a) ensure that no part of the drug imported under this certificate shall be sold or used to manufacture formulations for domestic sale;

(b) ensure that the formulations manufactured out of the drug imported against this certificate shall not be diverted for domestic sale;

(c) furnish to the Narcotics Commissioner and the Drugs Controller General of India details of export of drugs on completion of export along with documentary evidence such as shipping bills, bills of lading and invoices;

(d) obtain transport permit from their State Excise authority/State Food and Drugs Administration permitting transport of their consignment from port of entry to the factory premises;

(e) maintain separate accounts of actual quantity of narcotic drug imported, formulations produced, consignments dispatched and the quantity lying in balance;

1. Ins. by S.O. 1661(E), dated 13th July, 2010 (w.e.f. 13-7-2010).

(f) submit a monthly return of receipt/import, consumption and export of the narcotic drug to the Narcotics Commissioner;

(g) follow the procedures prescribed in rules 42, 45, 46 and 47 for security arrangements, maintenance of accounts and submission of returns, possession, sale and distribution of formulations manufactured from the drugs imported under this certificate.

[1][(iii) If the import is for analytical purposes, the importer shall,—

(a) ensure that no part of the drug imported under this certificate shall be used for any purpose other than for analytical purpose;

(b) inform the Narcotics Commissioner about the complete utilisation of the Narcotic Drug imported; and

(c) follow the procedures specified in rules 42, 45, 46 and 47.]

3. Any quantity of morphine, codeine, thebaine and their salts or finished formulations for export that have not been utilized shall be surrendered to the Government Opium and Alkaloids Works.

4. This document is for..... (The authority to whom and the purpose for which it is being sent to be indicated).

5. The certificate is not valid unless it bears the Official Seal of the Issuing Authority on the top right hand corner.]

FORM NO. 5

(*See* rule 58)

GOVERNMENT OF INDIA

MINISTRY OF FINANCE

(Department of Revenue)

AUTHORISATION FOR OFFICIAL APPROVAL OF EXPORT

(The Narcotic Drugs and Psychotropic Substances Rules, 1985)

.....(The Issuing Authority) being the authority empowered to issue export authorisation under the Narcotic Drugs and Psychotropic Substances Rules, 1985 hereby authorises and permits the following exportation of Narcotic Drugs or Psychotropic Substances from India:—

Exporter.....

Consigned.....

Port of export.....Port of entry.....

Narcotic Drugs or Psychotropic Substances to be exported:

Item No.	Number of packages	Name of the drug substance/preparations	Basic drug substance content

The exportation to be made in one consignment from the designated port of export on or before the.....day of.....(Month), 20

The importation of these drugs into the country of destination has been authorised by official import certificate No..... dated..... issued by..... (Authority of the importing country).

Date of Issue.....

Place of Issue..... Designation of the Issuing Authority

1. Ins. by G.S.R. 470(E), dated 21st June, 2011 (w.e.f. 21-6-2011).

1. This document is for.....(the authority to whom and the purpose for which it is being sent is to be indicated).

2. This authorisation is not valid unless it bears the official seal of the Issuing Authority on the top right hand corner.

[1][FORM NO. 6]

(*See* rule 67)

Date and time of despatch of the consignment.

1. Name and address of consignor (manufacturer/dealer/distributor and his Licence No. etc. (Issued under the Drugs and Cosmetics Rules, 1945).

2. Name and address of the consignee (manufacturer/dealer/distributor) and his Licence No. (Issued under the Drugs and Cosmetics Rules, 1945).

3. Description and quantity of the consignment.

(a)	(b)	(c)	
Particulars of the drugs with reference to the Schedule(s) to the 1945 Rules, Trade Marks; Patent and Proprietary Names, etc.	No. of packages.	Quantity Gross	Net

4. Mode of transport (Particulars of the transporter, Registration Number of the vehicle, R.R. if the Transport is by Railway, etc.,)

5. Date and time of receipt by the consignee and his remarks.

....

Signature of the consignee with date *Signature of the Consignor with date*

....

(Name in capital letters) (Name in capital letters)

Note.—(1) This Consignment Note should be serially numbered on annual basis.

(2) The Consignor should record a Certificate on the cover page of each book containing consignment note indicating the number of pages contained in such consignment note-book.

(3) The Consignor should maintain a Register showing the details of the books of consignment notes brought in use during a particular year.

(4) The books containing consignment not used or currently under use and the register as referred to at item (3) have to shall be produced to the officers whenever called upon during the course of their inspections.

[2][FORM NO. 7

(*See* rules 35, 53, 64 and 67A)

[3][1. Name of the laboratory/research institution/hospital/dispensary/person/authority]

2. Address

3. Name of the Drug

4. From whom the drug was obtained/purchased

1. Form No. 6 deleted and Form No. 7 re-numbered as Form 6 by G.S.R. 556 (E), dated 14th July, 1995 (w.e.f. 20-7-1995).
2. Ins. by G.S.R. 350(E), dated 25th June, 1997 (w.e.f. 27-6-1997).
3. Subs. by G.S.R. 905(E), dated 28th December, 2011, for item 1 (w.e.f. 28-12-2011).

[1][5. Quantity obtained/purchased]

6. Date on which obtained/purchased

Details of Use:

Sl. No.	Date	Quantity consumed	Purpose	Signature of the user

Note.— (1) This form shall be kept for 2 years from the last date of consumption.

(2) This shall be produced for verification by any of the officers empowered under section 41 or 42 of the Narcotic Drugs and Psychotropic Substances Act or any officer-in-charge of a police station.]

[2][FORM NO. 8

(*See* rule 67B)

APPLICATION/REQUISITION FOR STANDARD SAMPLES OF NARCOTIC DRUGS OR PSYCHOTROPIC SUBSTANCES

1. Name of the Organisation or Agency
2. Full postal address of the Organisation or Agency
3. Purpose for which sample of standard Narcotic drug or Psychotropic Substances is required
4. Name and quantity of standard sample required
5. Name and designation of officer under whose custody the samples shall be kept
6. Copy of Stock Register of narcotic samples maintained by the organisation duly verified by the controlling officer
7. Other relevant information (if any)

Signature.....

Designation.....

of Indenting Officer with Rubber Stamp]

[2][FORM NO. 9

[*See* rule 67B(5)]

ANNUAL REPORT TO THE CHIEF CONTROLLER OF FACTORIES ON RECEIPT, CONSUMPTION AND BALANCE OF SAMPLES OF NARCOTIC DRUGS OR PSYCHOTROPIC SUBSTANCES

Sl. No.	Narcotic drug/ Psychotropic substance	Opening Balance	Receipt	Consumption	Closing Balance

Signature.....

Designation.....

of Indenting Officer with Rubber Stamp.]

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1. Subs. by G.S.R. 905(E), dated 28th December, 2011, for item 5 (w.e.f. 28-12-2011).
2. Ins. by G.S.R. 639(E), dated 13th October, 2006 (w.e.f. 13-10-2006).