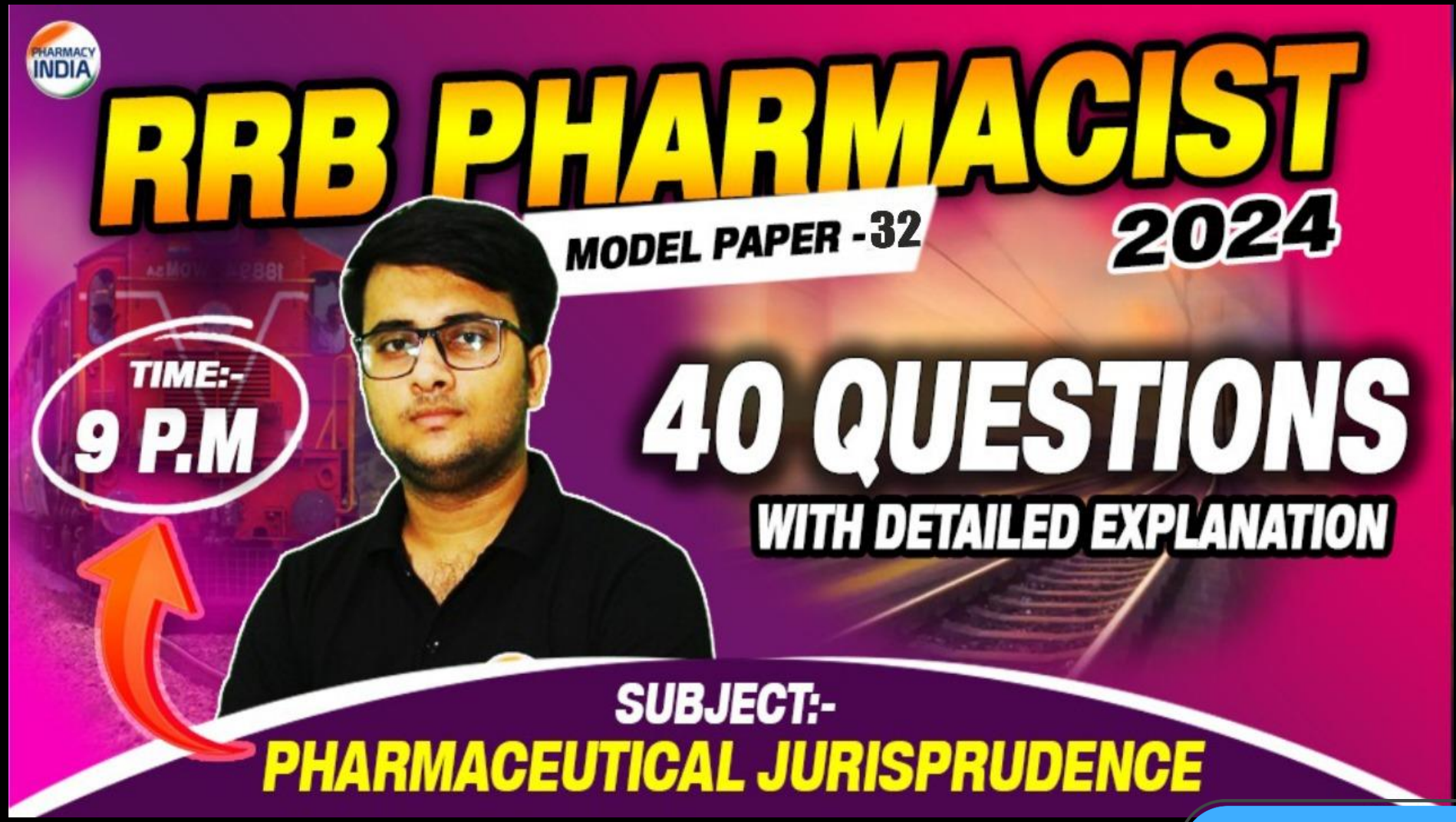

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1. Insulin Injection comes under Schedule of Drugs and Cosmetics Act

(a) S

(b) P

(c) G

(d) A

1. Insulin Injection comes under Schedule of Drugs and Cosmetics Act

(a) S

(b) P

(c) G

(d) A

Insulin Preparations under schedule P

Drug Name	Period in months	Storage Condition
Globuline Zinc Insulin Injection	24	At temp. between 2 to 8°C, must not be allowed to freeze
Insulin Injection	24	At temp. between 2 to 8°C, must not be allowed to freeze
Insulin Zinc Suspension	24	At temp. between 2 to 8°C, must not be allowed to freeze
Insphane Insulin Injection	24	At temp. between 2 to 8°C, must not be allowed to freeze

2. Repacking of drug means

(a) Formulation of drugs in bulk and packing in bulk for packing in small units

(b) Breaking up of any drug from a bulk container into small packs and labelling them for sale

(c) Packing, dispensing or formulation of drugs for retail sale

(d) Compounding of drug in wholesale business

2. Repacking of drug means

(a) Formulation of drugs in bulk and packing in bulk for packing in small units

(b) Breaking up of any drug from a bulk container into small packs and labelling them for sale

(c) Packing, dispensing or formulation of drugs for retail sale

(d) Compounding of drug in wholesale business

Repacking of drug means breaking up of any drug from a bulk container into small packs and labelling them for sale.

3. Repacking license are granted in drugs specified in following schedules EXCEPT

(a) Schedule X

(b) Schedule C & C1

(c) Schedule H

(d) Schedule O

3. Repacking license are granted in drugs specified in following schedules EXCEPT

(a) Schedule X

(b) Schedule C & C1

(c) Schedule H

(d) Schedule O

PURPOSE	DRUG	APPLICATION MADE IN FORM	LICENSE GRANTED IN FORM
REPACKING LICENSE	Drugs other than specified in schedule C and C1	24B	25-B

4. Which agency advices government and DTAB on issues related to uniform operation of D & C Act throughout the Country

(a) Drug Consultative Committee
(b) Central Drugs Laboratory
(c) Drugs Control Department
(d) Central Drugs Research Institute

4. Which agency advices government and DTAB on issues related to uniform operation of D & C Act throughout the Country

(a) Drug Consultative Committee

(b) Central Drugs Laboratory

(c) Drugs Control Department

(d) Central Drugs Research Institute

DRUG CONSULTATIVE COMMITTEE (DCC)

- It is constituted by the Central Government and its function is to advise the Central Government, or State Government and DTAB on any matter tending to secure uniformity throughout India in the administration of this Act.

Constitution

- Two persons are nominated by the Central Government.
- One person from each State is nominated by that concerned State Government.

5. Drugs Inspector is appointed as per the provisions of

(a) Pharmacy Act 1940

(b) Drugs and Cosmetics Act 1945

(c) Drugs Inspector Act 1940

(d) Narcotic and Psychotropic Substances Act 1985

5. Drugs Inspector is appointed as per the provisions of

(a) Pharmacy Act 1940

(b) Drugs and Cosmetics Act 1945

(c) Drugs Inspector Act 1940

(d) Narcotic and Psychotropic Substances Act 1985

DRUG INSPECTOR: SECTION 3 (E)

1. In relation to any drug or cosmetic, Drug Inspector appointed by Central Govern mentor State Government under section 21; or

2. In relation to Ayurvedic, Siddha or Unani systems of Medicine, Drug Inspector appointed by Central Government or State Government under section 33G

6. Restricted licenses in Forms 20 A and 21-B are issued for

(a) Narcotic and psychotropic substances

(b) Pethidine and related drugs

(c) Wholesale dealing of drugs which does not require the supervision of a registered pharmacist

(d) Drugs specified in Schedule X

6. Restricted licenses in Forms 20 A and 21-B are issued for

(a) Narcotic and psychotropic substances

(b) Pethidine and related drugs

(c) Wholesale dealing of drugs which does not require the supervision of a registered pharmacist

(d) Drugs specified in Schedule X

PURPOSE	DRUG	APPLICATION MADE IN FORM	LICENSE GRANTED IN FORM
RESTRICTED LICENSE	(i) Drugs other than those specified in schedule C, C1 and X	---	20A
	(i) Drug specified in C, C1 but not in schedule X	---	21A

7. As per Drugs and Cosmetics Act 1945. the term "Drugstore" refers to

(a)Licenses where the service of registered pharmacist is employed but do not maintain pharmacy

(b) Licenses who employ the service of registered pharmacist and maintain a pharmacy for compounding against prescription

(c) Licenses where drugs are temporarily stored

(d) Licenses where service of a qualified person is not required

7. As per Drugs and Cosmetics Act 1945. the term "Drugstore" refers to

(a)Licenses where the service of registered pharmacist is employed but do not maintain pharmacy

(b) Licenses who employ the service of registered pharmacist and maintain a pharmacy for compounding against prescription

(c) Licenses where drugs are temporarily stored

(d) Licenses where service of a qualified person is not required

As per Drugs and Cosmetics Act 1945. the term "Drugstore" refers to Licenses who employ the service of registered pharmacist and maintain a pharmacy for compounding against prescription.

8. Which form is given by licensing authority for the certificate of GMP. of ASU drugs

(a) Form 26E1
(b) Form 26B
(c) Form 260
(d) Form 24D

8. Which form is given by licensing authority for the certificate of GMP of ASU drugs

(a) Form 26E1

(b) Form 26B

(c) Form 260

(d) Form 24D

ANNEXURE-VI

FORM 26-E-1
[See Rule 155-A]

(Certificate of Good Manufacturing Practices (GMP) to manufacture of Ayurveda / Siddha or Unani drugs)

Certified that manufacturing unit license, namely ……..……...…… situated at ……..……... State …..……. License No…….. comply with the requirements of Good Manufacturing Practices of Ayurveda-Siddha-Unani drugs as laid down in Schedule T of the Drugs and Cosmetics Rules, 1945.

This certificate is valid for a period of one year.

Date ……..

Place ……..

Signature……..

Designation……..
Licensing Authority for Ayurveda/ Siddha/Unani Drugs.

9. What is in the "First Schedule" of Drugs & Cosmetic Act, 1940

(a) List of books

(b)List of Glass-wares

(c) List of Equipments

(d) List of Forms

9. What is in the "First Schedule" of Drugs & Cosmetic Act, 1940

(a) List of books

(b) List of Glass-wares

(c) List of Equipments

(d) List of Forms

SCHEDULE TO THE ACT

1. **First Schedule:** It prescribes the list of books specified in Ayurvedic, Siddha or Unani systems of medicine.
2. **Second Schedule:** It prescribes the standards to be complied with by imported drugs and by the drugs manufactured for sale, sold stocked or exhibited for sale or distributed.

10. What is the duration of renewal license periods for selling drugs

(a) 5 Years
(b) 3 Years
(c) 4 Years
(d) 6 Year

10. What is the duration of renewal license periods for selling drugs

(a) 5 Years

(b) 3 Years

(c) 4 Years

(d) 6 Year

DURATION OF LICENSE

The licenses are valid up to 31st December of the year, following the year it should be renewed. The licences should be renewed within 6 months after its expiry. Even after 6 months the licences can be renewed under specified conditions.

RENEWAL OF LICENCES

The licences in Form 20, Form 21, Form 20B, Form 21B, Form 20F, Form 20G, Form 200 and Form 20D are valid for the period of five years from the date of granting them.

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11. Under which section of Indian Penal Code the Drug Inspectors are appointed

(a) Section 23

(b) Section 17

(c) Section 21

(d) Section 22

11. Under which section of Indian Penal Code the Drug Inspectors are appointed

(a) Section 23

(b) Section 17

(c) Section 21

(d) Section 22

DRUG INSPECTOR: SECTION 3 (E)

1. In relation to any drug or cosmetic, Drug Inspector appointed by Central Govern mentor State Government under section 21; or

2. In relation to Ayurvedic, Siddha or Unani systems of Medicine, Drug Inspector appointed by Central Government or State Government under section 33G

12. Application form 19C used for the following schedule

(a) Schedule C and C1

(b) Schedule C

(c) Homeopathic drugs

(d) Schedule X

12. Application form 19C used for the following schedule

(a) Schedule C and C1

(b) Schedule C

(c) Homeopathic drugs

(d) Schedule X

- **Form 19 - Application for grant or renewal of a licence to sell, stock, exhibit or offer for sale, or distribute drugs other than those specified in Schedule X.**
- **Form 19A - Application for grant or renewal of a restricted licence to sell, stock or exhibit or offer for sale, or distribute drugs by retail by dealers who do not engage the service of a qualified person.**
- **Form 19B - Application for licence to sell, stock or exhibit or offer for sale, or distribute Homoeopathic Medicines.**
- **Form 19C - Application for grant or renewal of a [licence to sell, stock, exhibit or offer for sale, or distribute] drugs specified in Schedule X.**

13. Which form number should be used for the application to import drugs for personal use

(a) Form 24C
(b) Form 8
(c) Form 19
(d) Form 12A

13. Which form number should be used for the application to import drugs for personal use

(a) Form 24C

(b) Form 8

(c) Form 19

(d) Form 12A

To facilitate import of such drugs in small quantities for personal use, it is provided under the Drugs and Cosmetics Rules, 1945, that a permit for import of small quantities of drugs for personal use in Form 12B could be obtained from the office of the Drugs Controller General (India).

14. What does DTAB abbreviate for

(a) Drugs Technology Advisory Board

(b) Directorate of Technological Advisory Board

(c) Directorate of Technical Advisory Board

(d) Drugs Technical Advisory Board

14. What does DTAB abbreviate for

(a) Drugs Technology Advisory Board

(b) Directorate of Technological Advisory Board

(c) Directorate of Technical Advisory Board

(d) Drugs Technical Advisory Board

DRUG TECHNICAL ADVISORY BOARD

- DTAB is constituted by the central govt. to advice the central and state government to advice the central and state government on technical matters arising out of the administration of this act.
- It consist of 18 members, of whom 8 are ex-officio, 5 nominated and 5 elected member.

15. Penalty for non-disclosure of the name of the manufacturer is

(a) 2000

(b) 500

(c) 10000

(d) 20,000

15. Penalty for non-disclosure of the name of the manufacturer is

(a) 2000

(b) 500

(c) 10000

(d) 20,000

Penalty for non-disclosure of the name of the manufacturer, etc. Whoever contravenes the provisions of section 18A [or section 24] shall be punishable with imprisonment for a term which may extend to one year, or [with fine which shall not be less than twenty thousand rupees or with both].

16. As per Schedule A of Drugs and Cosmetics Act 1940 and Rules 1945, Form 19-B is for

(a) Application for licence to sell, stock or exhibitor offer for sale or distribute Homoeopathic medicines

(b) Licence to manufacture for sale or for distribution of Homoeopathic medicines

(c) Licence to manufacture for sale or for distribution of drugs other than those specified in licence to sell, stock or Schedule C, C1 & X

(d) Certificate of renewal of exhibit or offer for sale or distribute Homoeopathic medicines

16. As per Schedule A of Drugs and Cosmetics Act 1940 and Rules 1945, Form 19-B is for

(a) Application for licence to sell, stock or exhibitor offer for sale or distribute Homoeopathic medicines

(b) Licence to manufacture for sale or for distribution of Homoeopathic medicines

(c) Licence to manufacture for sale or for distribution of drugs other than those specified in licence to sell, stock or Schedule C, C1 & X

(d) Certificate of renewal of exhibit or offer for sale or distribute Homoeopathic medicines

- **Form 19 - Application for grant or renewal of a licence to sell, stock, exhibit or offer for sale, or distribute drugs other than those specified in Schedule X.**
- **Form 19A - Application for grant or renewal of a restricted licence to sell, stock or exhibit or offer for sale, or distribute drugs by retail by dealers who do not engage the service of a qualified person.**
- **Form 19B - Application for licence to sell, stock or exhibit or offer for sale, or distribute Homoeopathic Medicines.**
- **Form 19C - Application for grant or renewal of a [licence to sell, stock, exhibit or offer for sale, or distribute] drugs specified in Schedule X.**

17. When ayurvedic drug manufacturer have to submit the register of "Record of market complaints" to licensing authority

(a) Once a year
(b) Once in a six month
(c) Every 3 year
(d) Never

17. When ayurvedic drug manufacturer have to submit the register of "Record of market complaints" to licensing authority

(a) Once a year

(b) Once in a six month

(c) Every 3 year

(d) Never

Once in a period of six months the manufacturer shall submit the record such complaints to the Licensing Authority. The Register shall also be available for inspection during any inspection of the premises.

18. Provisions applicable to homeopathic medicines state that

(a) A license is necessary for the import of a new homeopathic medicine which is not specified in the Pharmacopoeia of India, USA, UK or Germany or not recognised as efficacious

(b) A license is necessary for the import of a homeopathic medicine which is not specified in the Homeopathic Pharmacopoeia of India or not recognised as efficacious

(c) A license is necessary for the import of a new homeopathic medicine which is not specified in the Homeopathic Pharmacopoeia of India, USA, UK. Japan or not recognized as efficacious

(d) A license is necessary for the import of a new homeopathic medicine which is not specified in the Britain or not Homeopathic Pharmacopoeia recognised as efficacious

18. Provisions applicable to homeopathic medicines state that

(a) A license is necessary for the import of a new homeopathic medicine which is not specified in the Pharmacopoeia of India, USA, UK or Germany or not recognised as efficacious

(b) A license is necessary for the import of a homeopathic medicine which is not specified in the Homeopathic Pharmacopoeia of India or not recognised as efficacious

(c) A license is necessary for the import of a new homeopathic medicine which is not specified in the Homeopathic Pharmacopoeia of India, USA, UK. Japan or not recognized as efficacious

(d) A license is necessary for the import of a new homeopathic medicine which is not specified in the Britain or not Homeopathic Pharmacopoeia recognised as efficacious

IMPORT OF HOMEOPATHIC MEDICINES

Homeopathic medicines can be imported into India without any licence. However a licence is necessary for the import of a 'New Homeopathic Medicine' meaning a homeopathic medicine or a combination of homeopathic medicine which is not specified in the Homeopathic Pharmacopeia of India, USA, UK or Germany or not recognised in authoritative.

19. Which of the following serves as one of the laboratories for producing oral polio vaccine

(a) Central Research Institute, Kasauli

(b) Central India Pharmacopoeia Laboratory, Ghaziabad

(c) Department of Biochemical Engineering, IIT, New Delhi

(d) Pasteur Institute of India, Coonoor

19. Which of the following serves as one of the laboratories for producing oral polio vaccine

(a) Central Research Institute, Kasauli

(b) Central India Pharmacopoeia Laboratory, Ghaziabad

(c) Department of Biochemical Engineering, IIT, New Delhi

(d) Pasteur Institute of India, Coonoor

Institute/ Laboratory	Function
Central Research Institute, Kasauli	Testing of sera, solutions of serum proteins for injection, vaccines, toxins, antigens, antitoxins, sterilised surgical ligature and sutures and bacteriophages are carried out.
Veterinary Research Institute, Izatnagar or Mukteshwar	Testing of antisera, vaccines, toxoids, and diagnostic antigens, all for veterinary use, are carried out.
Central Drugs Testing Laboratory, Chennai	Testing of condoms shall be carried out.
Pasteur Institute of India, Conoor and Enterovirus Research Centre, Haffkine Institute Com- pound, Mumbai	Testing for samples of oral poliomyelitis vaccines.
Laboratory of Serologist and Chemical Examiner to the Government of India, Kolkata	Testing for samples of VDRL antigen
Central Drugs Testing Laboratory, Thane	Testing for Intra-uterine Devices and Falope Rings shall be carried out

20. Schedule 'H' and schedule 'S' as per the Drugs and Cosmetics Act deal with the following

(P) Prescription drugs which are required to be sold by retail only on prescription of R.M.P

(Q) Standards for cosmetics

(R) Biological and special products

(S) List of coal tar colours permitted to be used in cosmetics and soaps

(a) P, Q

(b) (b) P, R

(c) (c) Q, S

(d) (d) R, S

20. Schedule 'H' and schedule 'S' as per the Drugs and Cosmetics Act deal with the following

(P) Prescription drugs which are required to be sold by retail only on prescription of R.M.P

(Q) Standards for cosmetics

(R) Biological and special products

(S) List of coal tar colours permitted to be used in cosmetics and soaps

(a) P, Q

(b) (b) P, R

(c) (c) Q, S

(d) (d) R, S

Schedule

H - List of prescription drugs.

S - Standard for cosmetics.

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21. Which of the following is NOT a 'drug' as per the law

(a) Empty gelatin capsule
(b) Mosquito repellent cream
(c) Substances for diagnosis of disease
(d) None of these

21. Which of the following is NOT a 'drug' as per the law

(a) Empty gelatin capsule

(b) Mosquito repellent cream

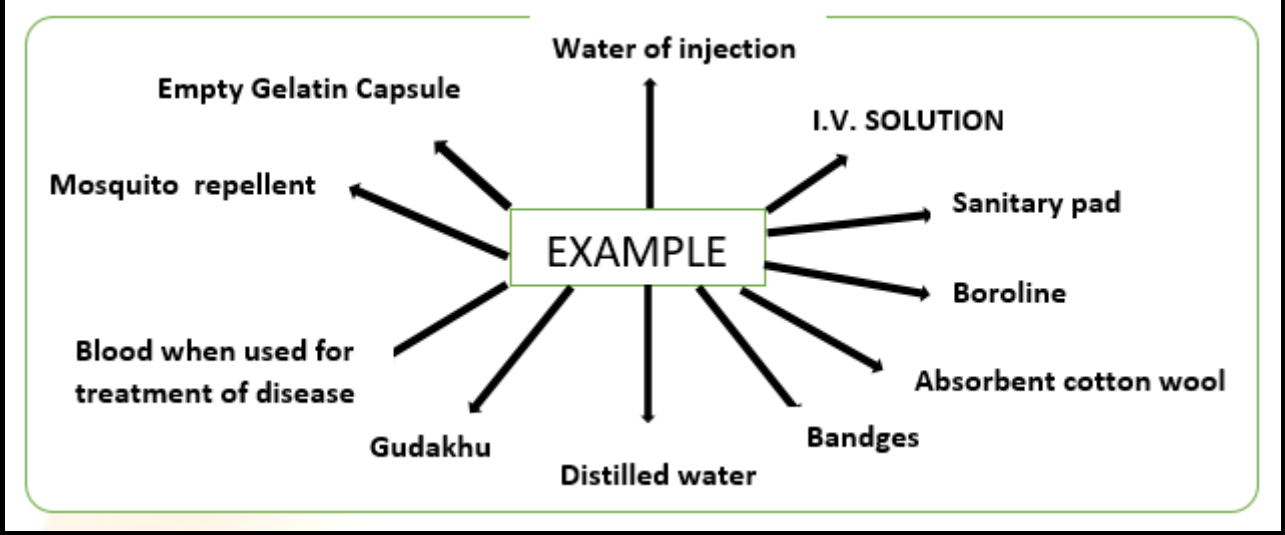
(c) Substances for diagnosis of disease

(d) None of these

DEFINITION OF IMPORTANT TERMS

DRUG [SECTION 3 (B)]

All medicine for internal or external use of human beings or animals and all substance intended to be used for diagnosis, treatment, mitigation, or prevention of any disease or disorder in human being or animal including preparation applied on human body for the purpose of repelling insect like Mosquito.



22. What is minimum space requirement for Manufacturing ASU drugs

(a) 1200 sq. ft.
(b) 1600 sq. ft.
(c) 1800 sq. ft.
(d) 1300 Sq. ft.

22. What is minimum space requirement for Manufacturing ASU drugs

(a) 1200 sq. ft.

(b) 1600 sq. ft.

(c) 1800 sq. ft.

(d) 1300 Sq. ft.

The minimum covered area required for manufacturing Ayurvedic Siddha Unani (ASU) drugs is 1,200 square feet. The space should have separate cabins or partitions for each activity. If the same premises are also used to manufacture Ayurveda or Siddha medicines, an additional 400 square feet is required.

23. What is minimum space requirement for Manufacturing Asava/ Arishta

(a) 150 sq. ft.
(b) 250 sq. ft.
(c) 200 sq. ft.
(d) 100 sq. ft.

23. What is minimum space requirement for Manufacturing Asava/ Arishta

(a) 150 sq. ft.

(b) 250 sq. ft.

(c) 200 sq. ft.

(d) 100 sq. ft.

23. What is minimum space requirement for Manufacturing Asava/ Arishta

(a) 150 sq. ft.

(b) 250 sq. ft.

(c) 200 sq. ft.

(d) 100 sq. ft.

The minimum manufacturing space required for Asava or Arishta is 200 sq ft. Part II of Schedule T of the Department of AYUSH, Government of India, also lists the minimum manufacturing premises required for different categories of ASU medicines, including Asava and Arishta.

24. Which of the following is a poisonous substance that should be avoided in the Ayurvedic preparation

(a) Vishamushti
(b) Jatiphalam
(c) Shigdhajiraka
(d) Satapushpi

24. Which of the following is a poisonous substance that should be avoided in the Ayurvedic preparation

(a) Vishamushti

(b) Jatiphalam

(c) Shigdhajiraka

(d) Satapushpi

[See rule 161 (2)]

List of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine

A. AYURVEDIC SYSTEM		
I. *Drugs of vegetable origin*		
1	Ahipena (Except seeds)	*Papaver somniferum* Linn.
2	Arka	*Calotropis procera* (Ait.) R.Br. ex.
3	Bhallataka	*Semecarpus anacardium* Linn. F.
4	Bhanga (Except seeds)	*Cannabis sativa* Linn. (Except seeds)
5	Danti	*Baliospermum montanum* Mull. Arg.
6	Dhattura	*Datura metal Linn..*
7	Gunja (seed)	*Abrus precatorium* Linn. (seed)
8	Jaipala (seed)	*Croton tiglium* Linn.
9	Karaveera	*Rerium indicum* Mill.
10	Langali	*Gloriosa superba* Linn.
11	Parasika Yavani	*Hyoscyamus niger* Linn.
12	Vatsanabha Vishamushti	*Acontium chasmanthum* Stapf ex Holm. *Strychnox nuxvomica* Linn.
13	Shringivisha	*Acontium chasmanthum* Stapf ex Holm.
II. *Drugs of Animal Origin*		
14	Sarpa Visha	Snake poison.

25. Two ex-officio members of the Drugs Technical Advisory Board under Drugs and Cosmetics Act are

(a) The Drugs Controller General of India and The President, Medical Council of India

(b) Drugs Controller General of India and The Secretary, Pharmacy Council of India

(c) The Secretary, Pharmacy Council of India and The Director, NIPER, India

(d) The Drugs Controller General of India and The Director, NIPER, India

25. Two ex-officio members of the Drugs Technical Advisory Board under Drugs and Cosmetics Act are

(a) The Drugs Controller General of India and The President, Medical Council of India

(b) Drugs Controller General of India and The Secretary, Pharmacy Council of India

(c) The Secretary, Pharmacy Council of India and The Director, NIPER, India

(d) The Drugs Controller General of India and The Director, NIPER, India

DRUG TECHNICAL ADVISORY BOARD

Elected member:

1. Director General of Health services Chairman
2. Drug controller of India
3. Director of Central Drug Laboratory, Kolkata
4. Director of Central research institute, Kasauli
5. Director Indian Veterinary research institute, Izatnagar
6. Director of Central Drug Research Institute, Lucknow
7. President - Medical Council of India (MCI)
8. President Pharmacy Council of India (PCI

Total = 8

Nominated member:

1. Two Person nominated by the central govt. amongst person who are incharge of drug control in India
2. One person from pharmaceutical industry nominated by central govt.
3. Two govt. analyst nominated by central govt.

Total = 5

Ex-officio member:

1. A teacher in pharmacy or pharmaceutical chemistry or pharmacognosy elected by executive committee of PCI
2. A teacher in medicine or therapeutics elected by executive committee of PCI
3. One pharmacologist elected by governing body of Indian council of medical research.
4. One person elected by the council of central medical association.
5. One person to be elected by the council of the Indian pharmaceutical association.

Total = 5

26. One of the following is needed for the cosmetics manufacture

(a) Form 36

(b) Form 32

(c) Form 20

(d) Form 22

26. One of the following is needed for the cosmetics manufacture

(a) Form 36

(b) Form 32

(c) Form 20

(d) Form 22

FORMS FOR MANUFACTURE LICENSE

1. Homoeopathic drugs	**24C**	**25C**
2. (i) Cosmetic	31	32
(ii) Loan manufacture of Cosmetic	31A	32A
3. (i) Ayurvedic and Unani Drugs	24D	25D
(ii) Loan manufacturing of Ayurvedic and Unani drugs	24E	25E
4.Drugs specified in schedule C,C1, and X	27B	28B
(ii) Drugs specified in schedule C and C1 excluding those specified in Schedule X	27	28
(iii) Drugs other than those specified in schedule C, C1 and X	24	25
(iv) Drugs specified in schedule X	24F	25F
5 Manufacture for examination test or analysis	---	29

27. Which pharmaceutical products is NOT included in schedule C

(a) Toxins
(b) Sera
(c) Antigen
(d) Capsule

27. Which pharmaceutical products is NOT included in schedule C

(a) Toxins

(b) Sera

(c) Antigen

(d) Capsule

SCHEDULE C

(See rules 23, 61 and 76 and Part X)

Biological and Special Products

1. Sera.
2. Solution of serum proteins intended for injection.
3. Vaccines for parenteral injections.
4. Toxins.
5. Antigen.
6. Antitoxins.
7. Neo-arsphenamine and analogous substances used for the specific treatment of infective diseases.
8. Insulin.
9. Pituitary (Posterior Lobe) Extract.
10. Adrenaline and Solutions of Salts of Adrenaline.
11. Antibiotics and preparations thereof in a form to be administered parenterally.]
12. Any other preparation which is meant for parenteral administration as such or after being made up with a solvent or medium or any other sterile product and which-

    (a) requires to be stored in a refrigerator; or

    (b) does not require to be stored in a refrigerator.]

13. Sterilized surgical ligature and sterilized surgical suture.
14. Bacteriophages.
15. Ophthalmic preparations.]
16. Sterile Disposable Devices for single use only.]

28. Blood bank comes under the schedule

(a) B

(b) D

(c) F

(d) G

28. Blood bank comes under the schedule

(a) B

(b) D

(c) F

(d) G

Schedule F_1 -

Part I - Provisions applicable to the production of all bacterial and viral vaccine.

Part II - Provisions applicable to the production of all sera from living animal of blood components.

Part III - Provisions applicable to the manufacture and standardization of diagnostic agent (Bacterial origin).

F_2 - Standards for surgical dressings.

F_3 -Standards for sterilized umbilical tapes.

FF- Standards of ophthalmic preparations.

29. Grant a licence to manufacture a drug requires

(a) Form 24
(b) Form 25
(c) Form 26
(d) Form 27

29. Grant a licence to manufacture a drug requires

(a) Form 24

(b) Form 25

(c) Form 26

(d) Form 27

FORMS FOR MANUFACTURE LICENSE

PURPOSE	APPLICATION MADE IN FORM	LICENSE GRANTED IN FORM
1. Homoeopathic drugs	24C	25C
2. (i) Cosmetic	31	32
(ii) Loan manufacture of Cosmetic	31A	32A
3. (i) Ayurvedic and Unani Drugs	24D	25D
(ii) Loan manufacturing of Ayurvedic and Unani drugs	24E	25E
4.Drugs specified in schedule C,C1, and X	27B	28B
(ii) Drugs specified in schedule C and C1 excluding those specified in Schedule X	27	28
(iii) Drugs other than those specified in schedule C, C1 and X	24	25
(iv) Drugs specified in schedule X	24F	25F
5 Manufacture for examination test or analysis	---	29

30. Ampicillin capsule should be used within 24 months, this statement comes under

(a) Schedule C

(b) Schedule R

(c) Schedule M

(d) Schedule P

30. Ampicillin capsule should be used within 24 months, this statement comes under

(a) Schedule C

(b) Schedule R

(c) Schedule M

(d) Schedule P

Life Period of Drugs

Antibiotics

1. Adramycin - 30 months
2. Ampicillin - 36 months
3. Ampicillin Capsules - 24 months
4. Ampicillin Dry Syrup - 24 months
5. Ampicillin Injection - 24 months
6. Ampicillin Sodium - 36 months
7. Ampicillin Trihydrate - 30 months
8. Amoxycilline Trihydrate - 36 months
9. Amoxycilline Trihydrate Capsules - 24 months
10. Amoxycilline Trihydrate Dry Syrup - 18 months

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31. Chemist, druggist and drug stores comes under

(a) Rule 61

(b) Rule 69

(c) Rule 65

(d) Rule 2

31. Chemist, druggist and drug stores comes under

(a) Rule 61

(b) Rule 69

(c) Rule 65

(d) Rule 2

GOVERNMENT ANALYST : SECTION 3 (C)

It means

1. In relation to any drug or cosmetic, Government Analyst appointed by Central Government or State Government under section 20; or

2. In relation to Ayurvedic, Siddha or Unani system of Medicine, Government Analyst appointed by Central Government or State Government under section 33 F.

DRUG INSPECTOR: SECTION 3 (E)

1. In relation to any drug or cosmetic, Drug Inspector appointed by Central Govern mentor State Government under section 21; or

2. In relation to Ayurvedic, Siddha or Unani systems of Medicine, Drug Inspector appointed by Central Government or State Government under section 33G

DRUG STORE: [RULE 65 (15(A)]

It is a licensed premise for the sale of drug which do not require the services

of Qualified Person and where drugs are not compounded against prescription.

CHEMIST AND DRUGGIST: [RULE65 (15(B)]

It is a licensed premise for the sale of drug which requires services of Qualified Person but where drugs are not compounded against prescription.

PHARMACY: [RULE 65 (15(C)]

It is a licensed premis for the sale of drug which requires the services of "Qualified Person" and where drugs are compounded against prescription.

LOAN LICENCE [RULE 69A]

It means a licence granted to a person who do not have his own arrangements of manufacture but who intends to avail himself of the manufacturing facilities owned by another manufacturer.

32. Crocin is sold under the schedule

(a) H

(b) G

(c) W

(d) Y

32. Crocin is sold under the schedule

(a) H

(b) G

(c) W

(d) Y

Schedule-W

- Contains the drugs which shall be marketed under generic names only & the label contains the names and quantities of active ingredients.
- This includes only five drugs marketed under generic names only Analgin, Aspirin and its salt, Chlorpromazine and its salt, Ferrous sulphate, Piperazine and its salts.

33. Dettol comes under

(a) Schedule N
(b) Schedule O
(c) Schedule P
(d) Schedule Q

33. Dettol comes under

(a) Schedule N

(b) Schedule O

(c) Schedule P

(d) Schedule Q

Products comes under Schedule O

- Dettol
- Harppic
- Lysol
- Windex
- Savlon etc.

34. For schedule X drug use of human beings, special labelling requirement is

(a) Symbol X given in red

(b) Symbol N in red displayed on left top corner of the label

(c) Symbol N displayed on the left top corner of the label

(d) Symbol H displayed on right top corner of the label

34. For schedule X drug use of human beings, special labelling requirement is

(a) Symbol X given in red

(b) Symbol N in red displayed on left top corner of the label

(c) Symbol N displayed on the left top corner of the label

(d) Symbol H displayed on right top corner of the label

For schedule X drug use of human beings, special labelling requirement is

1. Symbol N in red, conspicuously displayed on left top corner of the label.
2. Schedule X Drugs – Warning: To be sold by retail on the prescription of the RMP only.

35. If "Analgin" is imported under the name of "Aspirin", it will be called

(a) Adulterated drug

(b) Spurious drug

(c) Misbranded drug

(d) Substitute drug

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(a) Adulterated drug

(b) Spurious drug

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(d) Substitute drug

SPURIOUS DRUG

- If it is imported (manufactured in relation to manufacture, sale and distribution of drugs) under a name which belong to another drugs.
- If it has been substituted wholly or in part by another drugs or substance.
- If it purports to be the product of a manufacture of whom it is not truly a product.

36. Expiry period of drug preparations included in Schedule "P" of the Drug of Drugs & Cosmetics Rules 1945, cannot exceed

(a)12 months from date of manufacture

(b) 24 months from date of manufacture

(c) 120 months from date of manufacture

(d) 60 months from date of manufacture

36. Expiry period of drug preparations included in Schedule "P" of the Drug of Drugs & Cosmetics Rules 1945, cannot exceed

(a)12 months from date of manufacture

(b) 24 months from date of manufacture

(c) 120 months from date of manufacture

(d) 60 months from date of manufacture

Date of expiry:

Expiry date shall not exceed the period specified in Schedule P of the Drug Rules.

Drugs not included in the Schedule P shall bear on their label date of expiry not exceeding 60 months from the date of manufacture.

37. Standards of Patent and Proprietary medicines are contained in

(a) Schedule "O" of Drugs & Cosmetics Rules
(b) Schedule "P" of Drugs & Cosmetics Rules
(c) Schedule "U" of Drugs & Cosmetics Rules
(d) Schedule "V" of Drugs & Cosmetics Rules

37. Standards of Patent and Proprietary medicines are contained in

(a) Schedule "O" of Drugs & Cosmetics Rules

(b) Schedule "P" of Drugs & Cosmetics Rules

(c) Schedule "U" of Drugs & Cosmetics Rules

(d) Schedule "V" of Drugs & Cosmetics Rules

Q - List of coals tar colors permitted to be used in cosmetics.

R - Standard for condoms made of rubber latex and other mechanical contraceptives.

R_1 - Standard for mechanical contraceptive.

S-Standard for cosmetics.

T- Good manufacturing practice for Ayurvedic Siddha, Unani medicines.

U- Particulars to be shown in manufacturing records.

U_1 - Particulars to be shown in manufacturing, raw material and analytical records of cosmetic

V - Standard for patent or proprietary medicines.

W - List of drug which is to be marketed under generic names only.

X - List of drugs whose import, manufacture and sale, labeling and packaging are governed by special provision.

Y-Requirement and guideline for permission to import and manufacture of new drugs for sale or to undertake clinical trial

38. As per Drugs & Cosmetics Rules 1945 'Cool place' means a place having temperature

(a) Between 8°C to 25°C

(b) Between 4°C to 8°C

(c) Not exceeding 80°C

(d) Not exceeding 8°C

38. As per Drugs & Cosmetics Rules 1945 'Cool place' means a place having temperature

(a) Between 8°C to 25°C

(b) Between 4°C to 8°C

(c) Not exceeding 80°C

(d) Not exceeding 8°C

Cool Place

- A cool place is an environment where the temperature is between 8° C and 25° C.
- An article for which storage in a cool place is indicated may, alternatively, be stored in a refrigerator, unless otherwise specified in the individual monograph.
- Drugs like antibiotics, hormone preparations, vitamins, liver preparations, etc. are required to be stored in a cool place.

39. Which of the following drugs can be marketed under generic name

(a) Aspirin

(b) Paracetamol

(c) Ibuprofen

(d) Diazepam

39. Which of the following drugs can be marketed under generic name

(a) Aspirin

(b) Paracetamol

(c) Ibuprofen

(d) Diazepam

This includes only five drugs that shall be marketed under generic names only :

1. Analgin
2. Aspirin and its salt
3. Chlorpromazine and its salt
4. Ferrous sulfate
5. Piperazine and its salt

40 Which of the following can be treated as "Competent Person" for manufacture of drugs under the Drugs & Cosmetics Rule

(a) B. Sc. with 18 months of experience in manufacture of drugs

(b) B. Pharm from PCI approved institution with 18 months of experience in a manufacture of drugs

(c) B. Pharm from PCI any university with 18 months of experience in manufacture of drugs

(d) M.B.B.S. with 18 months experience in manufacture of drugs

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(d) M.B.B.S. with 18 months experience in manufacture of drugs

In the charge of a competent person, who;

(a) is a Registered Pharmacist, or;

(b) has passed the Matriculation Examination or its equivalent examination from a recognized Board with four years experience in dealing with sale of drugs or;

(c) holds a degree of a recognized University with one year's experience in dealing with drugs.

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