# DR. B. C. ROY COLLEGE OF PHARMACY AND ALLIED HEALTH SCIENCES

M. Pharm / B. Pharm. 3rd Year 6th Semester, 20 23

Sessional Test No. CA3 Date 29.03.23

Name Sushovan Maity

Sl. No. / University Roll No. 18901920054

Paper Pharmaceutical Biotechnology Code PT-619

Sl. No. I/23/02/ 10874

29/03/23
Signature of Invigilator

FOR EVALUATION ONLY

( Marks Obtained ) [ Full Marks ..... ]

| Question Number | | | | | | | | | | | | Total Marks | Examiner's Signature |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Marks Obtained | | | | | | | | | | | | | |

[ START ANSWERING FROM THE SPACE BELOW ]

1. 50 and 50.

2. One restriction endonuclease can recognized 4 b.p sequence. If a 10000 bp long randomly sequenced linear DNA molecule is treated with that enzyme the expected number of fragment will be 256.

3. BamHI can recognize a 6 b.p palindrome sequence. If first 3 nucleotides from 5' end of one stand are 5' GGAA then next 3 nucleotides of the same strand will be CCT 3',

5. Vitamin B12 is produced by _____ organism.

4 Bacteria protect their DNA from cutting by their own restriction enzymes through gene sequence / genome sequence

6. The pH for the citric acid production is set at 6.5 orange peel media

7. ~~Agar Agar~~ is the name of the media for vit B12 production

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1. Antibiotics : These are those drug prevent and protect the any microbes and bacteria growth and kill him that is antibiotics

Ex. - Peniciline, Amoxiciline

3. Design a fermentor

(i) Arreation system
(ii) temparatur controling system
(iii) Air presure controling system
(iv) Fermentor base
(v) UV light controling system
(vi) Water suplier controling system

2 - Citric acid :- citric acid many type of fruit present as ora lemon etc. But larg of amount citric acid produce orga growing at fermentor as formation proces.

citric acid highly required the juice factory.

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# DR. B. C. ROY COLLEGE OF PHARMACY AND ALLIED HEALTH SCIENCES

M. Pharm / B. Pharm. / D. Pharm. 4th Year 7 Semester / Part, 20

CA / IA No. - 3 Date - 12.10.2022

Name - Ishika Dey. Exam. Cell Sl. No. - 18901919021

Paper Industrial Pharmacy - II Code RT- 716A

Sl. No. IE 01590

12/10/22
Signature of Invigilator

## FOR EVALUATION ONLY

( Marks Obtained ) [ Full Marks ..... ]

| Question Number | | | | | | | | | | | | | | Total Marks | Examiner's Signature |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Marks Obtained | | | | | | | | | | | | | | 14 | |

[ START ANSWERING FROM THE SPACE BELOW ]

2.) D. diethylene glycol.

3.) C. Vaccine.

5.) a.) 1940

~~6)~~ ~~(d)~~ ~~xxxxx~~

1) B.) ~~Regional~~ National

6) c) Is a Pharmacovigilance program in India.

Short note —

(1)

Roles of Regulatory professional -

(1) Regulatory affairs is a med. profession which is developed from the desire of government to protect the Public health by ensuring the safety, efficacy, toxicity of the pharmaceuticals, agrochemical, medical device, etc.

→ To regulate the development of the drug product by ensuring the safety, efficacy of the drug.

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2) Also help to interference between the regulatory authority and pharmaceutical industry.

3) Regulatory profesional also be give advice and strategig of the pharmaceutical industry to fro the beginning of the development of the drug

4) It also help to ensure the prodedure also be produce the drug and product quality.

5) Regulatory profesional also be responsible for the marketing of the drug.

6) It also be responsible for the review and submitting the document about the ADR, pharmacokinetics.

7) It also be responsible the collecting the scientific data.

8) The important role play about the new dru development to marketing this product.

9) Also be introduced the guidelines and rules about the safety, efficacy of the drug Produc

10) Also be helpful of the drug quality of the drug.

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Indian

4) History of drug regulatory framework -

In this, 1950 ; that time no regulation and guidelines about the drug use.

Sulfanilamide Elixir tragedy - In 1937; that Pharmaceutical company also be prepare the Sulfanilamide drug, In this preparation di ethylen glycol solvent is used, It also be poisonous to human body, but in that time pharmacist or Chemist not aware about it. This drug is marketed.

In 1938; American medical association al be received report about the death cases of the people by using this drug.

In that time US-FDA also be remove this drug form the market.

New Rules and regulation also be come in India.

Dalkon Shield :- Dalkon company also be produced Dalkon Shield as a intrauterine device. This marketed heavily. This company also be deen that it is a safer than the birth control p But, it is not a US-FDA approved. Af that it also be problem created the placenta and uterus.

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and bacterial injection. So this intra-uterine device is banned from the market.

1976, Medical device also be approved by the FDA and trial also be conduct.

Thalidomide Tragedy:- Thalidomide also be used as a morning sickness, anxiety.

It is widely use of the pregnant woman. This drug is marketed and report medico association received report about the birth defect of the new born baby. This drug also be cese and cause the birth defect. and new born child also be death. Those who survive they are defect the limb, etc.

In 1962 new amendent is introduced

European union that led to stringent clinical trial guidelines-

Ans) Clinical trial is a performing the test to new drug development and marketing.

Preclinical Trial:- This trial conduct the animal testing.

1) In vitro 2) In vivo

① In vitro - This test is performed, the inside the body.

② In vivo - This test is performed the outside the body.

4) Clinical trial :- This trial also be performed to human volunteer and human beings.

- Phase-0 - This trial also be performed 10-100 of the people. The is done because the how to drug is effect to the body.

Phase-1 - This trial also be performed 20-100 of the people. This is done because to know the drug toxicity, side effect etc.

Phase-2 - This trial also be performed 100-200 of the people.

Phase-3 - This is the post marketing.

Phase-4 - This is the trial to market the drug

5) Global - This regulatory bodies is the Global
- Ex- US

Regional - This regulatory bodies in the regional

National - This regulatory bodies in the national

- ① EU
- ② GCC.
- ③ APEC.



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Significance :-

1) This regulatory bodies also be important role about the safety, efficacy of the drug product.

2) To protect the public health.

3) To establish the rules and guidness of the development of the drug in the pharmaceutical company.

4) Pharmaceutical company also be preapare the document about the ~~drug~~ procedure of the drug.

5) Regulatory bodies also be implement the various deparment —

(1) Production
(2) Packing.
(3) Quality assurance.
(4) Quality control.
(5) Raw material
(6) Drug Development

6) It also be responsible to the submit and review of the scientific data.

7) Regulatory bodies also be ensure the quality of the product ~~under~~ the gaverment.

8) Also be responsible for the marketing of the drug.

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