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Courses » Current regulatory requirements for conducting clinical trials in India

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## Unit 3 - Week 1

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### Course outline

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## Assignment 1

The due date for submitting this assignment has passed.

As per our records you have not submitted this assignment. **Due on 2019-03-13, 23:59 IST.**

1) Clinical trials for new drugs in India are regulated under the provisions of Drugs and Cosmetics Act \_\_\_\_\_ as amended from time to time.

No, the answer is incorrect.

Score: 0

Accepted Answers:  
(Type: Numeric) 1940

0.5 points

2) Clinical trials for new drugs in India are regulated under the provisions of Drugs and Rules \_\_\_\_\_, as amended from time to time.

No, the answer is incorrect.

Score: 0

Accepted Answers:  
(Type: Numeric) 1945

0.5 points

3) State whether you agree or disagree to the following statement Academic trial and regulatory trial are not same.

- Agree  
 Disagree

No, the answer is incorrect.

Score: 0

Accepted Answers:

1 point

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No, the answer is incorrect.

Score: 0

Accepted Answers:

True

5) As per Section (eb) of D & C Rules, phytopharmaceutical drugs should have how many bio-active or phytochemical compounds (qualitatively and quantitatively assessed)?



No, the answer is incorrect.

Score: 0

Accepted Answers:

(Type: String) 4

(Type: String) Four

(Type: String) four



1 point



6) Indian Pharmacopoeia Commission is located at \_\_\_\_\_

No, the answer is incorrect.

Score: 0

Accepted Answers:

(Type: String) Ghaziabad

(Type: String) ghaziabad

1 point

7) There are more than \_\_\_\_\_ Rules, followed by Schedule A to Y.

No, the answer is incorrect.

Score: 0

Accepted Answers:

(Type: Numeric) 170

1 point

8) A fixed dose combination of four or more drugs, individually approved earlier for certain claims, which now proposed to be combined for the first time in a fixed ratio, or if the ratio of the ingredients in an already marketed combination is proposed to be changed with certain claims, viz; indications, dosage, dosage form (including sustain release form) and route of administration.

1 point

True

False

No, the answer is incorrect.

Score: 0

Accepted Answers:

False

9) All vaccines and Recombinant DNA derived drugs are new drugs unless \_\_\_\_\_ 1 point

Certified otherwise by the Licensing Authority under Rule 22

Certified otherwise by the Licensing Authority under Rule 21

Not certified otherwise by any Licensing Authority under Rule 21

Not certified otherwise by the Licensing Authority under Rule 22

**No, the answer is incorrect.**

**Score: 0**

**Accepted Answers:**

*Certified otherwise by the Licensing Authority under Rule 21*

10) A new drug shall continue to be considered as new drug for a period of \_\_\_\_\_ years from the date of its first approval

**No, the answer is incorrect.**

**Score: 0**

**Accepted Answers:**

*(Type: String) 4*

*(Type: String) Four*

*(Type: String) four*

**1 point**

11) Cosmetics requires prescription.

**1 point**

True

False

**No, the answer is incorrect.**

**Score: 0**

**Accepted Answers:**

*False*

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