

Q1: Before a new drug can be widely used. What process must occur?

A= Accept any 1 of the following:

Testing • **Clinical Trials** • (1 mark) Q2: Why are clinical trials vital to drug development? A= Accept 1 of the following: • Works well • Safe as possible (1 mark) Q3: Explain what a new drug needs to be considered a good medicine. A= 1 mark for each of the following: • Effective – must achieve purpose Safe- Limited side effects • Stable – must be able to store Successful uptake and removal from the body. •

Q4: Circle how long it can take to make a new drug available for general use.



5 years

20 years

2 years

10 years

(1 mark)

(4 marks)

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Q5: What term is used when describing if a drug does its job?
A= Efficiency (1 mark)
Q6: Once a drug has been chemically tested, what is required before a drug can be tested on humans?
A= Animal testing (1 mark)
Q7: Discuss the stages of preclinical testing.
A= Accept either Cell/ Tissues (1) - Live animals (1) (2 marks)
Q8: Explain how clinical trials of new drugs are carried out.
 A= Accept any 5 of the following: Use healthy volunteers/ Patients 1st give low dose – side effects Given to small numbers of patients – check it treats disease Test on larger numbers – determine dose Legal tests – licence for use Monitor long term effects – safety (5 marks)
Q9: Define what a placebo is.
A= A substance that has no physical effect and used to check physiological effect of a drug.
(1 mark)
Q10: Clinical Trials rely on double blind study's to see how effective their new drugs are. Explain how a double blind study is carried out.
 A= Accept any 4 of the following: Use target disease patients Some get placebo/ some new medicine Patients allocated randomly

- Doctor and patients don't know which group
- Monitor groups carefully.

(4 marks)

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Q11: Explain why results clinical trials are published and why.

A= 1 mark for each of the following:

- Peer review
- Prevent false results/ claims

(2 marks)