

Item

18. Companies seeking new drug approval are required to conduct clinical trials involving human volunteers. During these trials, people with the disease are separated into different groups. One group receives a placebo (an inert or harmless substance used in controlled experiments). Each of the remaining groups receives a different dose of the drug (i.e., Group A receives a 30 mg dose once a day, Group B receives a 50 mg dose once a day, etc.).

Describe two reasons for testing new drugs at varying doses. Respond in the space provided in your **Answer Document**. (2 points)

Sample Response for Item 18 (Short Answer):

Sample Response:

- To assess any differences in side-effects at various dose levels.
- To determine the minimum effective dose in individuals.
- To determine the maximum effective dose in individuals.
- To determine if there are adverse reactions to higher doses.
- To compare effectiveness and side-effects of the potential new drug to effectiveness and known side-effects of established drugs in similar doses.

Other acceptable responses.

Scoring Guidelines for Item 18

Score Point	Description
2 points	The student response demonstrates a complete understanding of the task by providing two acceptable reasons for assessing new drugs in varying doses.
1 point	The student response demonstrates a partial understanding of the task by providing one acceptable reason for assessing new drugs in varying doses.
0 points	The student response demonstrates no understanding of the task. The response may provide incorrect information or be irrelevant to the task. The student may only repeat information from the passage or prompt without any supporting information responsive to the task. The student may have written "I don't know."

One reason for testing new drugs is because it could be a healer for diseases. Another reason would be testing the drug might be turned into a medicine.

Score Point: 0

The response does not meet the criteria required to earn one point. The response describes two benefits of testing new drugs but does not address reasons for testing the drugs in varying doses.

1st reason

- The drug could be used as a protectant against the disease

2nd reason:

- The drug could possibly cure the disease

Score Point: 0

The response does not meet the criteria required to earn one point. The response describes two benefits of testing new drugs but does not address reasons for testing the drugs in varying doses.

1. if different people with the same disease get different amounts of the drug then they can find out which actually works better.
2. to see which one to put on the market.

Score Point: 1

The response provides one acceptable reason for assessing new drugs in varying doses. ("they can find out which actually works better.")

They use various doses to see wch dose they react to better.

Score Point: 1

The response provides one acceptable reason for assessing new drugs in varying doses. ("to see wch dose they react to better.")

They want to see have
the people react at different
levels of that dose. This
way they know how much to
give to a person.

Score Point: 1

The response provides one acceptable reason for assessing new drugs in varying doses. ("to see have the people react at different levels of that dose. This way they know how much to give to a person.")

One reason for testing at various doses
is that you can find out if that much would
or wouldn't be strong enough for that disease.
Another reason would be that you can see
how long it would need to be taken for an
positive affect, if any.

Score Point: 1

The response provides one acceptable reason for assessing new drugs in varying doses. ("find out if that much would or wouldn't be strong enough for that disease.")

companies use varying doses when testing drugs to see what dosage a person with the disease will need. Another reason why the test with varying doses is because of safety. They want to make sure what dosage is safer.

Score Point: 2

The response provides two acceptable reasons for assessing new drugs in varying doses. ("to see what dosage a person with the disease will need. ... They want to make sure what dosage is safer.")

Testing new drugs at varying doses is very important because the results show how different people act to different doses. It is also important because the results will show an appropriate and safe dose that the drug should be taken. Also, the results will show what kind of side effects the drug might cause.

Score Point: 2

The response provides two acceptable reasons for assessing new drugs in varying doses. ("results will show an appropriate and safe dose ... results will show what kind of side effects the drug might cause.")

They have to test drug in doses on people before they can start using it on a regular bases. If they just started dosing a lot of people with too much of a drug the people could get really sick, or even die. or people could get too small of a dose and it not even help them. Thats why doctors have to test how much doses of a drug people need to take.

Score Point: 2

The response provides two acceptable reasons for assessing new drugs in varying doses. ("too much of a drug the people could get really sick, or even die. ... or people could get too small of a dose and it not even help them.")

1. By varying the amount in each dose you can tell at what level the drug will be most effective at.

2. By varying the amount in each dose you can tell if too much of the drug is taken at one time may pose a threat to the patients health.

Score Point: 2

The response provides two acceptable reasons for assessing new drugs in varying doses. ("you can tell at what level the drug will be most effective at. ... you can tell if too much of the drug is taken at one time may pose a threat to the patients health.")

One reason for testing new drugs at varying doses is so they know what amount they can prescribe to people. Another reason would be so they can see what side effects can come with different doses.

Score Point: 2

The response provides two acceptable reasons for assessing new drugs in varying doses. ("so they know what amount they can prescribe to people. ... so they can see what side effects can come with different doses.")