Write your name here

Surname

Other names

Edexcel GCE

Centre Number

Candidate Number

Biology
Advanced Subsidiary
Unit 3B: Practical Biology and Research Skills

Friday 15 January 2010 – Afternoon
Time: 1 hour 30 minutes

Paper Reference
6BI07/01

You must have:
Ruler, Calculator, HB pencil

Total Marks

Instructions

* Use **black** ink or ball-point pen.
* **Fill in the boxes** at the top of this page with your name, centre number and candidate number.
* Answer **all** questions.
* Answer the questions in the spaces provided
  – *there may be more space than you need*.

Information

* The total mark for this paper is 40.
* The marks for **each** question are shown in brackets
  – *use this as a guide as to how much time to spend on each question.*

Advice

* Read each question carefully before you start to answer it.
* Keep an eye on the time.
* Try to answer every question.
* Check your answers if you have time at the end.

Turn over ▶

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Answer ALL questions

1   Many bacteria are evolving resistance to antibiotics. Some plant extracts have antibacterial properties and, in some cases, these extracts may be useful as antibiotics.

Experiments were carried out to investigate the effect of extracts, from garlic and from nutmeg plants, on the growth of bacteria.

(a) (i)   The two plant extracts were prepared using the following method.

Some plant material was crushed and shaken with ethanol. Suggest **two** improvements that could be made to this method.

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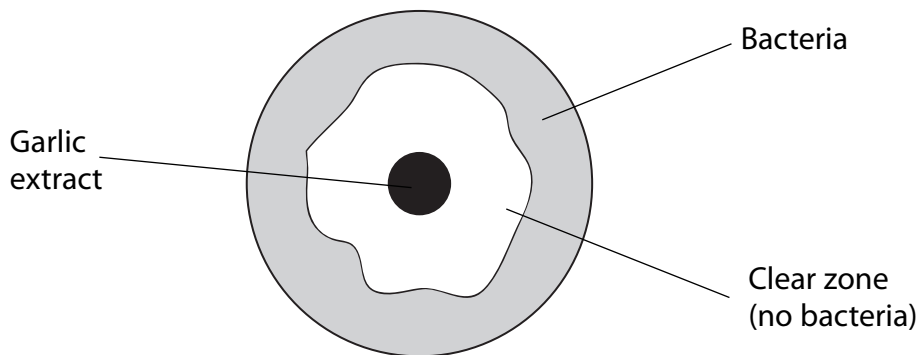
(ii) The diagram below shows the effect of garlic extract on bacteria growing on an agar plate.

Describe how you would prepare an agar plate that would produce this result, using a sterile Petri dish, sterile nutrient agar, a pure culture of a suitable bacterium in a bottle and some garlic extract.

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(iii) The effectiveness of the extract can be estimated by measuring the size of the clear zone. Suggest an accurate method for finding the size of the clear zone in the diagram in (a)(ii).

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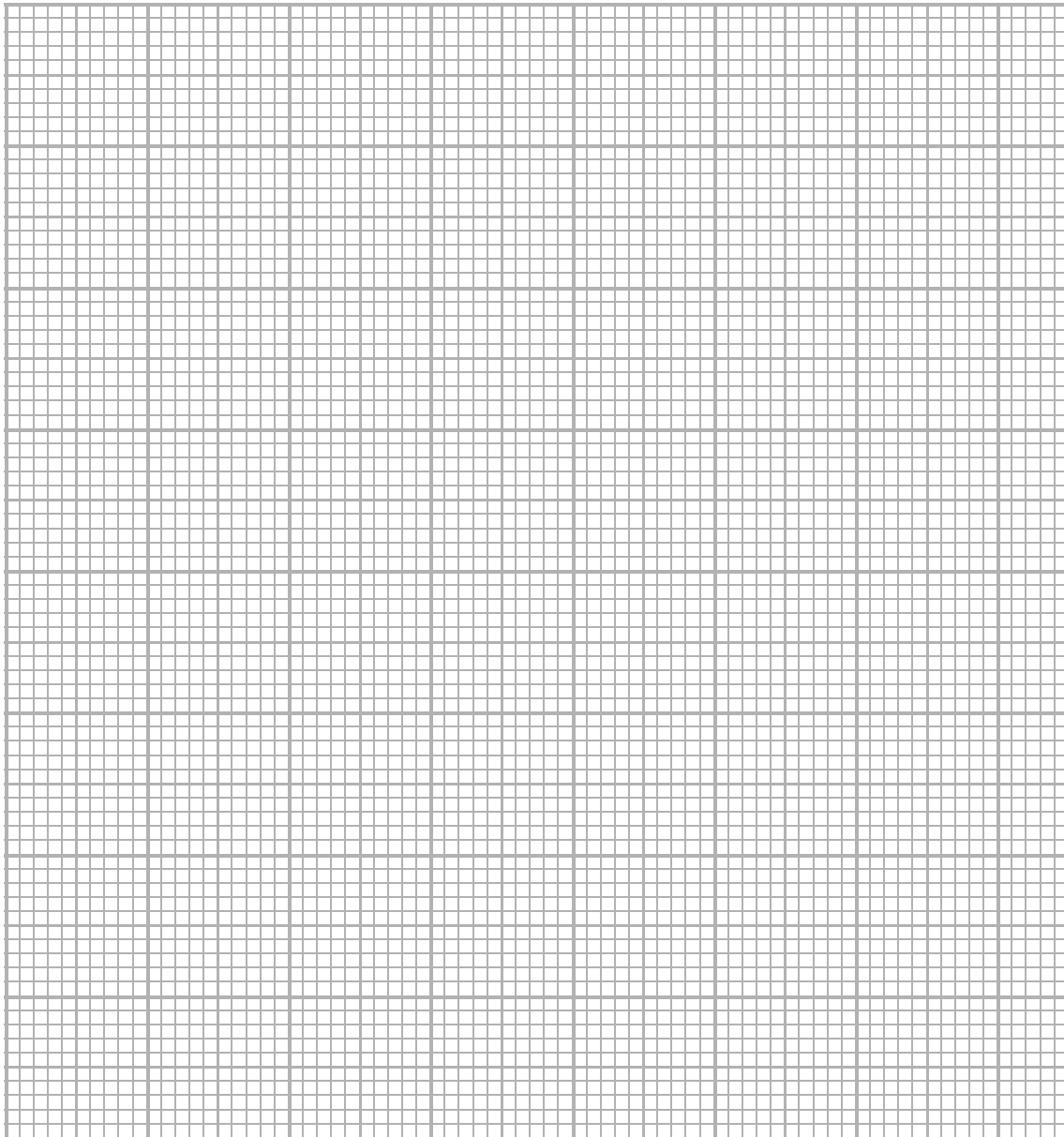
(b) The 100% garlic extract used was then diluted to produce 75%, 50%, 25% and 10% solutions and the experiment repeated.
The diameter of each clear zone was measured. The results are shown in the table below.

Concentration of garlic extract (%)	Diameter of clear zone / mm
0	0
10	0
25	0
50	11
75	15
100	20

(i)   Present the data in the table in a suitable graphical form.

(4)

(ii) What do these results suggest about the relationship between the concentration of garlic extract and its antibacterial effects?

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(c) In a second investigation the antibacterial activity of the 100% garlic extract was compared with that of three antibiotics.
The clear zones on 20 agar plates, for each of the antibiotics and the garlic extract, were measured. The results are shown in the table below.

Sample Number	Diameter of clear zone / mm			
	Antibiotics			Plant extract
	Chloramphenicol	Tetracycline	Streptomycin	Garlic
1	28	16	15	20
2	26	19	13	28
3	29	11	14	18
4	28	21	12	25
5	26	7	14	27
6	29	11	15	26
7	22	8	9	25
8	25	21	14	25
9	29	10	12	29
10	25	16	13	30
11	31	18	18	26
12	28	13	13	25
13	27	20	14	30
14	26	11	13	28
15	26	19	13	25
16	28	17	15	27
17	28	20	13	20
18	26	22	14	28
19	29	22	14	18
20	28	10	13	25
Mean	**26**	**16**	**14**	

(i) Complete the table opposite by calculating the mean diameter of the clear zone for the garlic extract.

(1)

(ii) Compare the antibacterial effect of garlic extract with that of the three antibiotics.

(2)

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(d) To check the validity of the results for the garlic extract in the second investigation, a student searched the scientific literature for similar studies. She found data for the antibacterial effect of onion (*Allium cepa*), which is closely related to garlic (*Allium sativum*). The data for onion extract are shown below.

Complete the table for the garlic extract in the second investigation by writing in the mean you calculated in c(i).

Plant extract	Mean diameter of clear zone / mm
Garlic	
Onion	21

What does this information suggest about the validity of the results for the garlic extract?

(2)

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(Total for Question 1 = 20 marks)

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N35114A0916

2 Read the following carefully:

In 1775, William Withering published *A Treatise on the Foxglove*. In this he reported his research on the use of an extract of foxglove to treat a condition called dropsy. In this condition, the patient's blood pressure is raised, leading to tissue fluid collecting in the feet, legs and other areas, causing swelling. The patient may eventually die as fluid fills the lungs, drowning the patient.

After seeing a woman treat herself successfully with a digitalis soup, William Withering tried the soup on a few people, with some success. However, after a patient nearly died, Withering gave up his research until he moved to Birmingham, where he studied 163 patients with dropsy. He devised a method to find out the correct dose for his patients and finally described very carefully-recorded findings in his *Treatise*.

Withering's researches are seen as the earliest example of a scientific drug trial. A modern drug trial is made up of several stages. In pre-clinical research, the drug is tested on animals to investigate its general safety before being trialled on humans. However, unlike humans, animals cannot say whether they are experiencing side effects such as feeling sick, dizziness or mental problems.

Phase 1 is the first stage of a clinical trial. In this phase, information is gathered about whether a drug is safe to give to humans. People can volunteer to be part of a drug trial. The trial team monitors these people carefully. They observe their behaviour, ask them how they feel and measure their blood pressure and temperature. Blood and urine samples are taken to look for signs that things might be going wrong. The level of the drug in the bloodstream or tissues is measured and these data help to determine the safe dose.

Phase II testing is used to find the experimental conditions that will allow phase III of the trial to give a good result. In particular, the trial team tries to establish the best dose to give. One thing that must be established immediately is the desired end point. For instance, the usual end point sought when screening a new antibacterial drug (such as an antibiotic) is whether a patient is free of infection after treatment.

In Phase II, a control group is used to distinguish between a natural improvement and the effects of the drug. Ideally, neither the trial team nor the patients know whether they are part of the treatment group or the control group – in other words, they are "blind" to the type of treatment being given to them. A placebo may be used. A placebo is made to look exactly like the drug and the patients are treated with this or the drug, in exactly the same way.

Phase III is the final stage in which larger numbers of patients take part. The team running the trial will have identified at least one group of patients who are expected to benefit, how they benefit and the best way to administer treatment. The phase III trial can provide confirmation that a drug works. If the results of phase III testing are not positive, several options remain. By studying the large amount of data collected, the trial team may identify another smaller group, within the larger group, who seem to have benefited. Another full-scale phase III trial is carried out on this type of patient.

It is common for phase III trials to be repeated in order to identify a group of patients for whom the drug is effective.

(a) The timeline for the development of a modern drug is shown in the diagram below.

PRECLINICAL RESEARCH | CLINICAL STUDIES | REVIEW | POSTMARKETING OBSERVATION

* Discovery and early screening of compound
* Large-scale synthesis
* Animal testing

Phase I
1.5 YEARS

Phase II
2 YEARS

Phase III
3.5 YEARS

Approval

* Watch for side effects

AT LEAST 5 YEARS   7 YEARS   1.5 YEARS   ONGOING
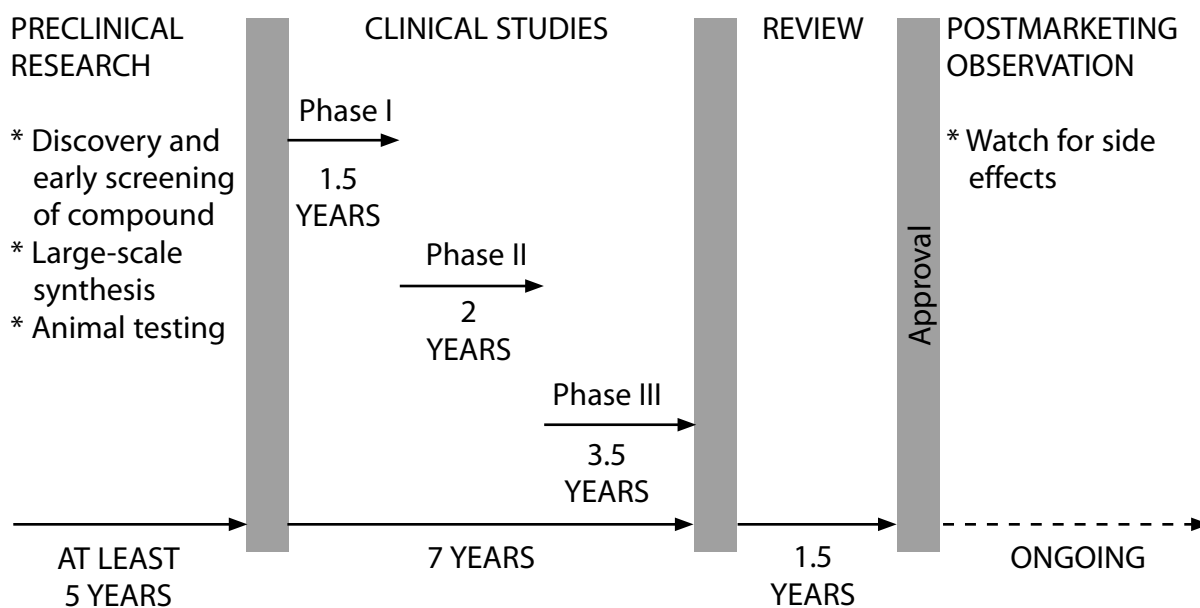
(i) Using the diagram above to help you, draw a similar flow chart summarising Withering's research.

(4)

(ii) Discuss **one** economic implication of modern drug trialling, compared with Withering's methods.

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(iii) Identify **one** similarity and **one** difference, other than economic factors, between Withering's drug trial and a modern drug trial. In each case, give an explanation for your answer.

(4)

Similarity ....

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Explanation ....

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Difference ....

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Explanation ....

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(b) Cholesterol lowering drugs (statins) have been trialled and developed as a treatment for coronary vascular disease (CVD).
The following three figures show data gathered during drug trials for statins.

Figure 1. Percentage of people reporting muscle problems after taking statins.
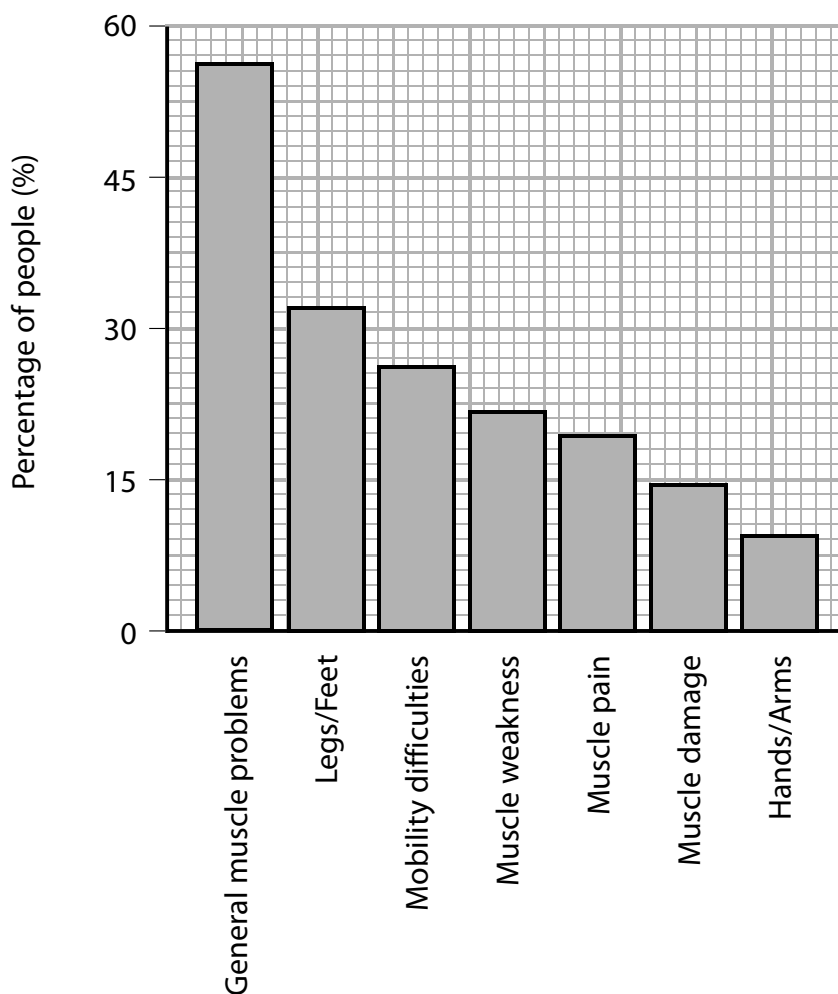
Figure 2. Deaths per 10 000 men from all causes and from coronary vascular disease (CVD) at different levels of blood cholesterol.
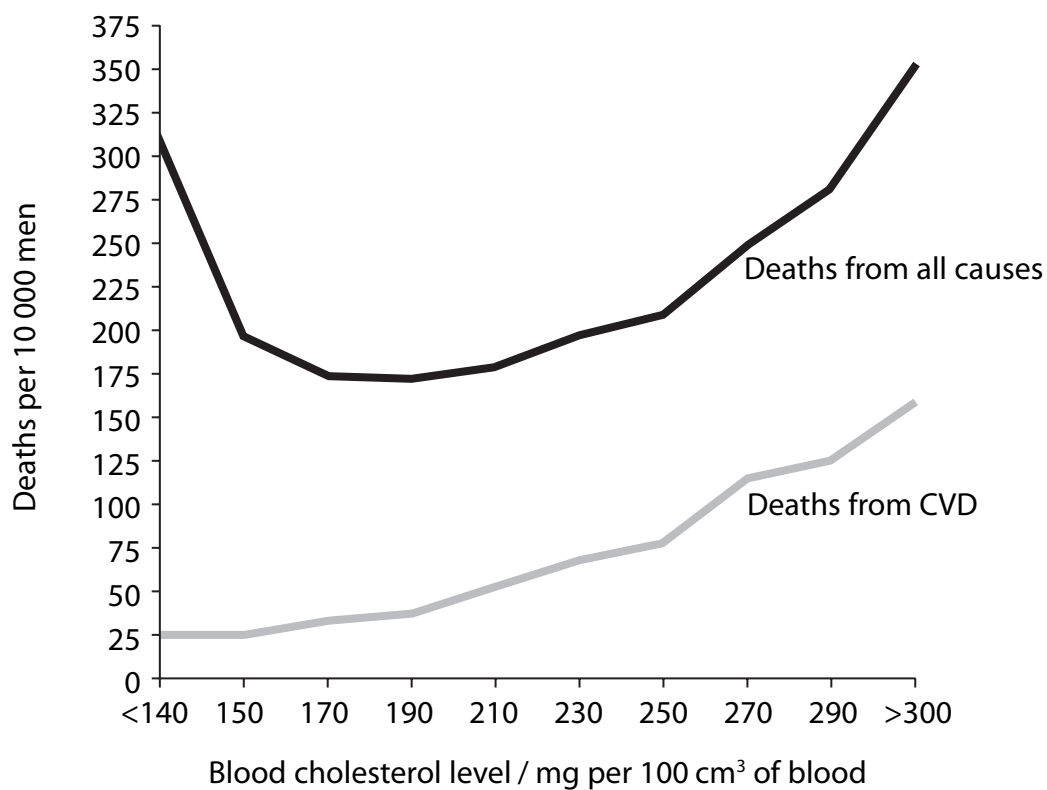
Figure 3. Risk of death from CVD in women at different blood cholesterol levels.

N 3 5 1 1 4 A 0 1 4 1 6

(i) Using all the information in Figures 1, 2 and 3, evaluate the benefits and risks to humans of lowering blood cholesterol with statins.

There will be up to 2 marks awarded for the quality of spelling, punctuation and grammar and the use of technical terms in your answer to this question.

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QUESTION 2 CONTINUES ON THE NEXT PAGE

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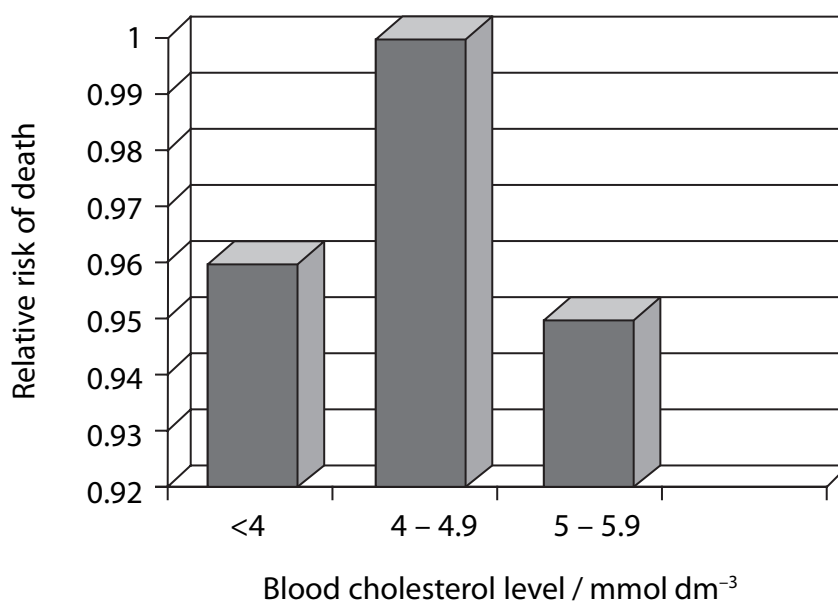
(ii) Suggest how the information that you have been given about statins, cholesterol and CVD might be expanded upon. Consider **what** further questions you might want to ask, and **where** you might look for answers.

(3)

What further questions you might want to ask

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Where you might look for answers

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(iii) Suggest a source of information about the effects of statins on CVD that might be unreliable or biased.

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(Total for Question 2 = 20 marks)

TOTAL FOR PAPER = 40 MARKS