UNIVERSITY OF RUHUNA – FACULTY OF MEDICINE

ALLIED HEALTH SCIENCES DEGREE PROGRAMME

SECOND B.PHARM PART I EXAMINATION - NOVEMBER/DECEMBER 2015

PH 2143 - BIOSTATISTICS II

INDEX NO: .....

THREE (03) HOURS

INSTRUCTIONS

- **No paper should be removed from the examination hall.**
- **Create a folder on the desktop with your index number as the name of the folder and save all your work in that folder**
- **Answer all Questions.**

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1. Two different formulations of a tablet of a new drug were to be compared with regard to rate of dissolution. Ten tablets of each formulation were tested, and the percent dissolution after 15 min in the dissolution apparatus was observed. The results were tabulated in the following table. The object of this experiment was to determine if the dissolution rates of the two formulations differ.

Formulation A	Formulation B
68	74
84	71
81	79
85	63
75	80
69	61
80	69
76	72
79	80
74	65

(a) State the null and alternative hypotheses to determine whether the dissolution rates of the two formulations are differ.

(10 marks)

(b) To test the hypotheses in part (a) with pooled t-test, we must make certain assumptions. What are those assumptions?

(*25 marks*)

(c) Check whether the above assumptions are satisfied or not. Explain using computer outputs.

(*15 marks*)

(d) Complete the pooled t-test and state your conclusion.

(*20 marks*)

(e) Find the 90% and 99% confidence limits on the differences of the mean dissolution rates of the two formulations. Interpret your answer.

(*30 marks*)

2. Dissolution was compared for three experimental batches with the following results (each point is the time in minutes for 50% dissolution for a single tablet).

Batch 1: 15, 18, 19, 21, 23, 26

Batch 2: 17, 18, 24, 20

Batch 3: 13, 10, 16, 11, 9

(a) State the null and alternative hypotheses for a one-way analysis of variance test.

(*10 marks*)

(b) Construct side by side boxplots. Does it appear that there is a difference among the three batches?

(*10 marks*)

(c) Construct normal Q-Q plots for each batch. Does the normality assumption seem to be satisfied?

(*10 marks*)

(d) Obtain descriptive statistics of the data for each batch. Do you think the population standard deviations are homogeneous? Explain.

(*10 marks*)

(e) Do you think that the assumptions for the F test are satisfied? Explain.

(*10 marks*)

(f) Complete an analysis of variance output.

(*10 marks*)

(g) Test the hypothesis that there is no difference among the three batches. Be sure to state your conclusions.

(*20 marks*)

(h) Determine whether a multiple comparison test is necessary. If it is, complete the test and indicate what differences exist among the three batches.

(*20 marks*)

3.

(a) A pilot study was planned to test the efficacy of vitamin E supplementation as a possible preventive agent for a certain disease. Twenty subjects age 65+ were randomized to either a supplement of vitamin E of 400 IU/day (group 1), or placebo (group 2). It is important to compare the total vitamin E intake (from food and supplements) of the two groups at baseline. The baseline intake of each group in IU/day is as follows:

Group 1 : 7.5, 12.6, 3.8, 20.2, 6.8, 403.3, 2.9, 7.2, 10.5, 205.4

Group 2 : 8.2, 13.3, 102.0, 12.7, 6.3, 4.8, 19.5, 8.3, 407.1, 10.2

(i) Construct the normal Q-Q plots of the two samples. Does normality seem reasonable in either distributions?

(*10 marks*)

(ii) Construct side by side boxplots of the two samples. Comment on the shapes of the two distributions.

(*10 marks*)

(iii) Based on your results in parts (i) and (ii), use an appropriate test to compare the baseline vitamin E intake between the two groups.

(*30 marks*)

(b) In a community health survey, individuals were randomly selected for participation in a telephone interview. The study used a cross-sectional design. The respondents' smoking status was classified into three categories (smoker, quitter, never smoker). The following table shows the results for the cross-tabulation of smoking status and health status. Determine whether the relationship is statistically significant at the $\alpha = 0.05$ level.

	Smoking Status			
Self-reported health status	Smoker	Quitter	Never	**Total**
Excellent	40	100	229	369
Very good/good	172	189	485	846
Fair/poor	61	63	153	277
Total	273	352	867	1,492

Answer the question by carrying out the following steps:

(i) State the null and alternative hypotheses of the test.

(***10 marks***)

(ii) Construct a table with the expected and observed cell counts.

(***10 marks***)

(iii) Write down the value of the test statistic and the value of the degrees of freedom.

(***10 marks***)

(iv) Write down the p-value.

(***10 marks***)

(v) Write down your conclusion.

(***10 marks***)

4. Adults show a strong relationship between blood pressure and age. Data were collected from school children to see if this relationship continued to hold in the age group 5-18. The data in the following table were obtained from boys in this age group.

Age, x	5	6	7	8	9	10	11
Mean systolic blood pressure (mm Hg), y	94.4	97.7	101.9	104.5	106.3	109.3	112.6

Age, x	12	13	14	15	16	17	18
Mean systolic blood pressure (mm Hg), y	113.8	117.7	121.6	122.3	123.6	124.9	131.0

(i) Construct a scatter diagram. Dose it appear a linear relationship between blood pressure and age?

(10 marks)

(ii) Obtain the least square estimates of β_0 and β_1 for the model $y = \beta_0 + \beta_1 x + \varepsilon$.

(20 marks)

(iii) Interpret the meaning of β_1 in this problem.

(20 marks)

(iv) Test the hypothesis that $\beta_1 = 0$. Write down the value of test statistic and p-value. Do the results of this test indicate that a linear trend is significant?

(30 marks)

(v) What the expected blood pressure is for an average 13-year old boy as predicted from the regression line?

(20 marks)

5.

(a) Briefly explain the following designs:

(i) Completely randomized design,

(15 marks)

(ii) Matched pairs design,

(15 marks)

(iii)Randomized block design.

(20 marks)

(b) A production manager at ABC Drug company is monitoring the quality of the company's production process. There has been concern relative to the quality of the operation to accurately fill the 16ml of liquid. The product is designed for a fill level of 16.00 ± 0.30. The company collected the following sample data on the production process:

	Observations			
Sample	1	2	3	4
1	16.40	16.11	15.90	15.78
2	15.97	16.10	16.20	15.81
3	15.91	16.00	16.04	15.92
4	16.20	16.21	15.93	15.95
5	15.87	16.21	16.34	16.43
6	15.43	15.49	15.55	15.92
7	16.43	16.21	15.99	16.00
8	15.50	15.92	16.12	16.02
9	16.13	16.21	16.05	16.01
10	15.68	16.43	16.20	15.97

(i) Develop the control charts for the process mean and range. Use the control rules: Above + 3 sigma and Below – 3 sigma.

(15 marks)

(ii) Are the process mean and range in statistical control?

(15 marks)

(iii) Do you think this process is capable of meeting the design standard? Explain.

(20 marks)

6. Answer **all** parts.

6.1. In clinical trials, randomization and manipulation of sample subjects are two important issues.

(30 marks)

6.1.1. What is randomization?

6.1.2. What is manipulation of sample subjects?

6.2. Morbidity and mortality rates are vital statistics in any health care system. Explain each of the terms using an example.

(30 marks)

a). Morbidity and

b). Mortality

6.3. List two advantages and two disadvantages of cohort studies. ***(40 marks)***

a). Advantages :

b). Disadvantages: