BIRLA INSTITUTE OF TECNOLOGY AND SCIENCE – PILANI
PILANI CAMPUS
Second Semester 2022 – 2023
Course No.: **PHA G546**   Course Title: **Pharmaceutical Biostatistics**
__**Comprehensive Exam** (Closed Book)__
Max. Marks: **15**   Duration: **90 min.**   Date: **13/5/2023**

1. A pharmaceutical company is testing the efficacy of two different dosages (low and high) of a new drug on the blood pressure of patients with hypertension. Additionally, the company is interested in investigating whether there is a difference in drug efficacy between male and female patients. Considering blood pressure is normally distributed in the human population. Conduct a hypothesis test to investigate whether there is a significant difference in the mean blood pressure reduction between the two dosages and whether the effect of the dosage varies by gender. Identify if there exists any interaction between dose and gender. Use a significance level of 0.05.
   The data presented in the table below is systolic blood pressure (SBP) of each patient measured at baseline and after 4 weeks of treatment: **[12]**

Dose	Gender	Baseline SBP	Post treatment SBP
Low	Male	158	146
Low	Male	155	144
Low	Male	150	137
Low	Male	153	139
Low	Male	162	150
Low	Female	162	150
Low	Female	159	145
Low	Female	157	142
Low	Female	161	149
Low	Female	167	154
High	Male	168	132
High	Male	174	136
High	Male	172	130

High	Male	169	135
High	Male	170	131
High	Female	174	139
High	Female	172	135
High	Female	170	132
High	Female	170	138
High	Female	176	130

2. Explain how mean of a chi-square distribution is equal to its degree of freedom. [**3**]

Table A.5. F-distribution where α = 0.05

V_1	V_2 1	2	3	4	5	6	7	8	9	10	12	15	20	24	30	40	60	120	∞
1	161.4	199.5	215.7	224.6	230.2	234.0	236.8	238.9	240.5	241.9	243.9	245.9	248.0	249.1	250.1	251.1	252.2	253.3	254.3
2	18.51	19.00	19.16	19.25	19.30	19.33	19.35	19.37	19.38	19.40	19.41	19.43	19.45	19.45	19.46	19.47	19.48	19.49	19.50
3	10.13	9.55	9.28	9.12	9.01	8.94	8.89	8.85	8.81	8.79	8.74	8.70	8.66	8.64	8.62	8.59	8.57	8.55	8.53
4	7.71	6.94	6.59	6.39	6.26	6.16	6.09	6.04	6.00	5.96	5.91	5.86	5.80	5.77	5.75	5.72	5.69	5.66	5.63
5	6.61	5.79	5.41	5.19	5.05	4.95	4.88	4.82	4.77	4.74	4.68	4.62	4.56	4.53	4.50	4.46	4.43	4.40	4.36
6	5.99	5.14	4.76	4.53	4.39	4.28	4.21	4.15	4.10	4.06	4.00	3.94	3.87	3.84	3.81	3.77	3.74	3.70	3.67
7	5.59	4.74	4.35	4.12	3.97	3.87	3.79	3.73	3.68	3.64	3.57	3.51	3.44	3.41	3.38	3.34	3.30	3.27	3.23
8	5.32	4.46	4.07	3.84	3.69	3.58	3.50	3.44	3.39	3.35	3.28	3.22	3.15	3.12	3.08	3.04	3.01	2.97	2.93
9	5.12	4.26	3.86	3.63	3.48	3.37	3.29	3.23	3.18	3.14	3.07	3.01	2.94	2.90	2.86	2.83	2.79	2.75	2.71
10	4.96	4.10	3.71	3.48	3.33	3.22	3.14	3.07	3.02	2.98	2.91	2.85	2.77	2.74	2.70	2.66	2.62	2.58	2.54
11	4.84	3.98	3.59	3.36	3.20	3.09	3.01	2.95	2.90	2.85	2.79	2.72	2.65	2.61	2.57	2.53	2.49	2.45	2.40
12	4.75	3.89	3.49	3.26	3.11	3.00	2.91	2.85	2.80	2.75	2.69	2.62	2.54	2.51	2.47	2.43	2.38	2.34	2.30
13	4.67	3.81	3.41	3.18	3.03	2.92	2.83	2.77	2.71	2.67	2.60	2.53	2.46	2.42	2.38	2.34	2.30	2.25	2.21
14	4.60	3.74	3.34	3.11	2.96	2.85	2.76	2.70	2.65	2.60	2.53	2.46	2.39	2.35	2.31	2.27	2.22	2.18	2.13
15	4.54	3.68	3.29	3.06	2.90	2.79	2.71	2.64	2.59	2.54	2.48	2.40	2.33	2.29	2.25	2.20	2.16	2.11	2.07
16	4.49	3.63	3.24	3.01	2.85	2.74	2.66	2.59	2.54	2.49	2.42	2.35	2.28	2.24	2.19	2.15	2.11	2.06	2.01
17	4.45	3.59	3.20	2.96	2.81	2.70	2.61	2.55	2.49	2.45	2.38	2.31	2.23	2.19	2.15	2.10	2.06	2.01	1.96
18	4.41	3.55	3.16	2.93	2.77	2.66	2.58	2.51	2.46	2.41	2.34	2.27	2.19	2.15	2.11	2.06	2.02	1.97	1.92
19	4.38	3.52	3.13	2.90	2.74	2.63	2.54	2.48	2.42	2.38	2.31	2.23	2.16	2.11	2.07	2.03	1.98	1.93	1.88

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1. A study was conducted to compare the bone density (normally distributed) levels of individuals who followed three different diets - a high protein diet, a low protein diet, and a control diet. At the end of the study, the participants' bone density levels were measured using a bone densitometer and recorded in grams per square centimeter (g/cm²). The data is presented in the table below:

Bone density levels (g/cm²)		
High protein diet	**Low protein diet**	**Control diet**
1.8	1.2	1.5
1.9	1.4	1.4
1.7	1.6	1.6
2.0	1.4	1.8
1.4	1.5	1.5
1.6	1.3	1.4

Using an appropriate parametric test perform a hypothesis test to determine if there is a significant difference in bone density levels among the three diets at a significance level of 0.01. **[12]**

2. You are developing a new formulation for a particular drug and want to determine how the concentration of the active ingredient in the formulation (X) affects the bioavailability of the drug (Y). You administered the new formulation to 8 healthy volunteers at different concentrations and measured the bioavailability of the drug in each individual. **[7]**

X (Concentration of active ingredient in mg/ml)	Y (Bioavailability in %)
10	8
20	13
30	17
40	23
50	28
60	33
70	38
80	44

(i) Determine the correlation coefficient between Concentration of active ingredient and Bioavailability.

(ii) Derive the equation of the regression line for predicting the bioavailability of the drug based on the concentration of the active ingredient in the formulation.

3. Sixteen laboratory C57BL/6 mice were fed a special diet from birth through age 12 weeks. Their weight (in grams) is as follows:

23, 28, 27, 24, 25, 23, 24, 27, 28, 25, 24, 27, 28, 30, 25, 26

Can we conclude from the data that the diet results in a mean weight different from 25 grams? Let $\alpha=0.05$. We do not have information regarding the distribution of weight. (Choose a test that uses most of the available information) **[6]**