

BM5033 Statistical Inference Methods in Bioengineering

Exam 2 Solution

1. A biopharmaceutical company manufactures a therapeutic monoclonal antibody across two separate facilities (Facility X in Hyderabad and Facility Y in Bengaluru). Quality control engineers collect 10 random production batches from Facility X (data stored in variable x) and 10 random production batches from Facility Y (data stored in variable y), measuring protein aggregation levels (% aggregated). Company policy dictates that a penalty is imposed on a facility if its average aggregation level strictly exceeds a safety threshold of 2.5%. You are tasked with checking if a penalty has to be imposed on any of the two facilities.

- (a) State the null and alternative hypotheses you will be testing. (5)

We have to test for the deviation at both facilities separately. Therefore, the statistical hypotheses are

- for facility X, $H_0 : \mu_x = 2.5\%$, $H_a : \mu_x > 2.5\%$
- for facility Y, $H_0 : \mu_y = 2.5\%$, $H_a : \mu_y > 2.5\%$

Note: Only writing hypotheses in terms of μ without specifying what is meant by μ is an incomplete answer. $H_0 : \mu_x \leq 2.5\%$ is also not correct as it does not allow the calculation of p -value.

- (b) Write down the R function you will use to test this. (Note: Documentation of R functions is given at the end.) (5)

```
t.test(x, y = NULL, alternative = "greater", mu = 2.5)
```

```
t.test(x=y, y = NULL, alternative = "greater", mu = 2.5)
```

2. A tissue engineering lab synthesizes collagen scaffolds using two different cross-linking techniques (Method A and Method B) to improve ultimate tensile strength (UTS in MPa). The lab technician takes a batch of 24 raw collagen matrices, splits them randomly into two equal sets of 12, and applies Method A to the first set and Method B to the second set. The research team wants to verify if there is any difference in mean UTS between the two methods. However, their boss expresses concern that with only 12 matrices per group, the study might fail to detect a meaningful engineering difference of 1.5 MPa (assuming a standard deviation of 1.2 MPa and $\alpha = 0.05$).

- (a) Write down the null and alternative hypotheses for this study. (5)

$H_0 : \mu_A = \mu_B$, $H_a : \mu_A \neq \mu_B$ where μ_A and μ_B are the population mean values of UTS with methods A and B, respectively.

- (b) How will you confirm/disprove the suspicion of the boss? Write down the R function, if needed. (5)

We can estimate power for the given values. For the given values, if statistical power is high, we are less likely to fail in detecting the difference. We do this

```
power.t.test(n = 12, delta = 1.5, sd = 1.2, sig.level = 0.05, power = NULL,  
            type = "two.sample",  
            alternative = "two.sided")
```