Pharmaceutical statistics

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Dr. Rola Aqeel

ARKAN
ACADEMY

P-value (two sided):

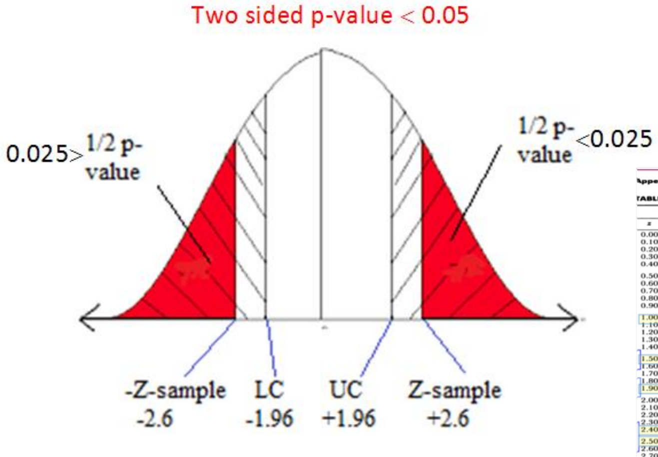
- The p value of the hypothesis testing is the probability of obtaining a value of the test statistic as extreme or more extreme (in the direction of supporting H_A) than the one actually computed.
- In a two-tailed test, we are interested in extreme values on both ends of the distribution (positive and negative Z-values). For a Z-test:
  - ➢ Calculate the probability of getting a value greater than or equal to the observed Z-sample on the positive side: P ($Z \geq$ Z sample).
  - ➢ Add this probability to the corresponding probability on the negative side: P ($Z \leq -$Z sample)
  - ★ Example:

    Tablets of a drug are compressed in a machine at target average weight 300 mg. A batch was made and a random sample of 30 tablets showed an average weight of 307. The company has specified σ to be 15 mg. Does the batch meet target tablet weight at significance level (α) of 0.05.
    - ✓ The p value indicates the probability of observing $Z \geq$ Z-sample or $Z \leq$ -Z-sample.
    - ✓ In our case study:

      $P(Z \geq 2.6) = 0.0047$ (this is the area in the right tail beyond Z=2.6).

      $P(Z \leq -2.6) = 0.0047$ (this is the area in the left tail beyond Z=−2.6).
    - ✓ Since the test is two-tailed: p-value = $P(Z \geq 2.6) + P(Z \leq -2.6) = 0.0047 + 0.0047$

      $= 2 \times 0.0047 = 0.0094$



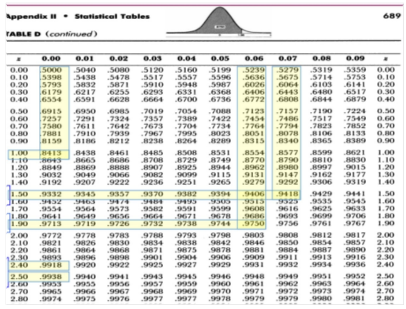


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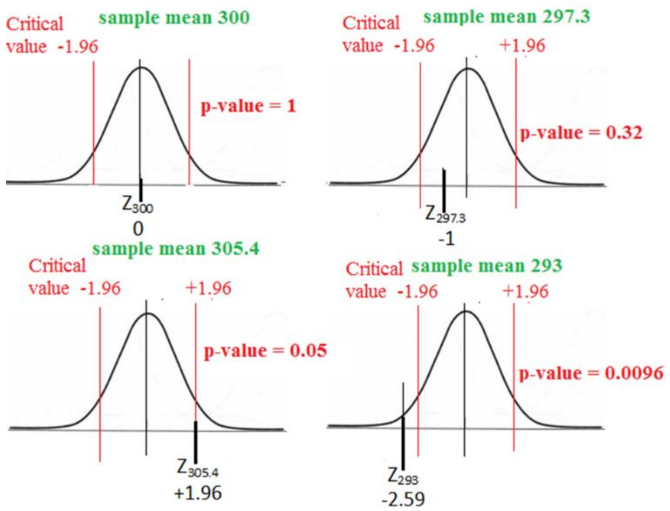
TABLE D (continued)

z	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09	z
0.00	.5000	.5040	.5080	.5120	.5160	.5199	.5239	.5279	.5319	.5359	0.00
0.10	.5398	.5438	.5478	.5517	.5557	.5596	.5636	.5675	.5714	.5753	0.10
0.20	.5793	.5832	.5871	.5910	.5948	.5987	.6026	.6064	.6103	.6141	0.20
0.30	.6179	.6217	.6255	.6293	.6331	.6368	.6406	.6443	.6480	.6517	0.30
0.40	.6554	.6591	.6628	.6664	.6700	.6736	.6772	.6808	.6844	.6879	0.40
0.50	.6915	.6950	.6985	.7019	.7054	.7088	.7123	.7157	.7190	.7224	0.50
0.60	.7257	.7291	.7324	.7357	.7389	.7422	.7454	.7486	.7517	.7549	0.60
0.70	.7580	.7611	.7642	.7673	.7704	.7734	.7764	.7794	.7823	.7852	0.70
0.80	.7881	.7910	.7939	.7967	.7995	.8023	.8051	.8078	.8106	.8133	0.80
0.90	.8159	.8186	.8212	.8238	.8264	.8289	.8315	.8340	.8365	.8389	0.90
1.00	.8413	.8438	.8461	.8485	.8508	.8531	.8554	.8577	.8599	.8621	1.00
1.10	.8643	.8665	.8686	.8708	.8729	.8749	.8770	.8790	.8810	.8830	1.10
1.20	.8849	.8869	.8888	.8907	.8925	.8944	.8962	.8980	.8997	.9015	1.20
1.30	.9032	.9049	.9066	.9082	.9099	.9115	.9131	.9147	.9162	.9177	1.30
1.40	.9192	.9207	.9222	.9236	.9251	.9265	.9279	.9292	.9306	.9319	1.40
1.50	.9332	.9345	.9357	.9370	.9382	.9394	.9406	.9418	.9429	.9441	1.50
1.60	.9452	.9463	.9474	.9484	.9495	.9505	.9515	.9525	.9535	.9545	1.60
1.70	.9554	.9564	.9573	.9582	.9591	.9599	.9608	.9616	.9625	.9633	1.70
1.80	.9641	.9649	.9656	.9664	.9671	.9678	.9686	.9693	.9699	.9706	1.80
1.90	.9713	.9719	.9726	.9732	.9738	.9744	.9750	.9756	.9761	.9767	1.90
2.00	.9772	.9778	.9783	.9788	.9793	.9798	.9803	.9808	.9812	.9817	2.00
2.10	.9821	.9826	.9830	.9834	.9838	.9842	.9846	.9850	.9854	.9857	2.10
2.20	.9861	.9864	.9868	.9871	.9875	.9878	.9881	.9884	.9887	.9890	2.20
2.30	.9893	.9896	.9898	.9901	.9904	.9906	.9909	.9911	.9913	.9916	2.30
2.40	.9918	.9920	.9922	.9925	.9927	.9929	.9931	.9932	.9934	.9936	2.40
2.50	.9938	.9940	.9941	.9943	.9945	.9946	.9948	.9949	.9951	.9952	2.50
2.60	.9953	.9955	.9956	.9957	.9959	.9960	.9961	.9962	.9963	.9964	2.60
2.70	.9965	.9966	.9967	.9968	.9969	.9970	.9971	.9972	.9973	.9974	2.70
2.80	.9974	.9975	.9976	.9977	.9977	.9978	.9979	.9979	.9980	.9981	2.80

- ➢ If in the case study, 3 more batches were made and tested at the same sample size and α (0.05), but they had different sample means of 300, 297.3, 305.4 and 293. Calculate the p-value for each batch.
- ➢ When the Z score of the sample mean is within the critical region (-1.95 to +1.96), p-value is 0.05 or higher (Fail to reject H_0 as test statistic is within the acceptance region). When it is outside the critical region p-value is less than 0.05 (reject the H_0 as test statistic is in the rejection region). At $\alpha = 0.05$, the best case scenario and the worst case scenario for the acceptance of H_0 are having Z scores of sample mean as 0 and ±1.96, respectively.



- ➢ As Z-sample higher deviates positively from the upper critical value or negatively from the lower critical value, p-value becomes smaller than 0.05 and thus the evidence against H_0 becomes stronger.
- ➢

- **Conventions for interpreting *P* values at α = 0.05 (most commonly used)**
  - In statistical hypothesis testing, **p-values** are used to determine the level of significance of results. The levels of significance help us decide whether to reject or fail to reject the null hypothesis (H_0)
  - $P \geq 0.05$ Result is not significant: usually indicated by no asterisk.
  - $P < 0.05$ Result is significant: usually indicated by one asterisk (*)
  - $P < 0.01$ Result is highly significant: usually indicated by two asterisks (**)
  - $P < 0.001$ Result is very highly significant: usually indicated by three asterisks **(***)**

- If for the case study, 3 more batches were made and tested at the same sample size and α (0.05), but they had different sample means (SM) of 294, 292 and 290. The three batches showed different significant differences from the hypothesized population mean as indicated by asterisks for different p-values.
- At the same significance level, z-critical values are the same (±1.96 for α=0.05), but samples of different means have different Z-scores (Z-sample) and as these scores are more different from the critical values toward the tails, lower p-values are obtained.

Batch	SM	SE	Z-sample	P-two sided
1	294	2.7	-2.22	0.0264^{*}
2	292	2.7	-2.96	0.003^{**}
3	290	2.7	-3.7	0.0002^{***}

- **Making a Decision:**
  - Decision Rule Based on *P*-value
  - To use a *P*-value to make a conclusion in a hypothesis test, compare the *P*-value with α.
    - If $P < \alpha$, then reject H_0.
    - If $P > \alpha$, then fail to reject H_0.

	Claim	
Decision	**Claim is H_0**	**Claim is H_a**
Reject H_0	There is enough evidence to reject the claim.	There is enough evidence to support the claim.
Do not reject H_0	There is not enough evidence to reject the claim.	There is not enough evidence to support the claim.

- **Testing H_0 by Means of a Confidence Interval**
  - When testing a null hypothesis by the mean of confidence interval, we reject H_0 at the α level of significance (0.05 in the case study) if the hypothesized mean (suggested by H0) is not contained within the 95% confidence interval of the sample mean.
  - If the hypothesized mean is contained within the interval, H_0 cannot be rejected at α level of significance.

  - **For the case study:** The hypothesized parameter (300) is not contained in the confidence interval of the sample mean. Thus, the null hypothesis is rejected.
  - The hypothesized mean < LL so the sample came from the upper rejection region.
  - $$\overline{X} \pm Z_{1-\alpha/2} * \frac{\sigma}{\sqrt{n}} =$$
    $$307 \pm 1.96 \times 2.7$$
    $$301.7 \; to \; 312.3$$

ARKAN
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Arkan academy
www.arkan-academy.com
Arkanacademy
+962 790408805