

As explained by Dawson and Trapp (44) the one-tailed test is a directional test, while the two-tailed test is a non-directional test.

A one-tailed test should be used where the goal is to determine if the value of a mean of a sample is significantly greater than the value of the mean for the corresponding population. The one-tailed test is also used where the goal is to determine if the value of a mean of a sample is significantly greater than the value of the mean of another sample.

Thus, a one-tailed test is used where the goal is to determine if a new, improved pill dissolves faster in water than an older formulation of the pill. Also, a one-tailed test is used where the goal is to determine if a drug having expected curative properties results in a better cure than an inactive placebo.

To provide another example, a one-tailed test is used where the goal is to determine if vials containing a vaccine are contaminated with ten or more bacteria (45). In this case, the analyst is only interested in whether the vials contain ten or more bacteria, in view of industry-wide specifications requiring that vials must contain less than ten bacteria. Generally, the one-tailed test is used to determine if sample A is significantly greater than sample B, in the situation where it would not be reasonable to expect sample A to be significantly less than sample B.

But a two-tailed test should be used where the goal is to determine the percentage of tablet weights that are greater or lesser (the sum of the percentage of tablets that are greater plus the sum of the percentage of tablets that are lesser) than the required specification, when comparing tablets made by manufacturer 1 with tablets made by manufacturer 2. Two-tailed tests are more widely used in clinical trials than the one-tailed test, in view of the fact that the two-tailed test is more stringent and more conservative (46,47).

VIII. P VALUE

The P value is used in a procedure called *hypothesis testing*. P, which stands for probability, can be any number between 0.0 and 1.0. According to Whitley and Ball (48) “[v]alues close to 0 indicate that the observed difference is unlikely to be due to chance, whereas a P value close to 1 suggests there is no difference between groups other than that due to random variation.” According to Motulsky (49) “P value is simply a

⁴⁴ Dawson B, Trapp R.G. *Basic and Clinical Biostatistics*. 4th ed. New York, NY: Lange Medical Books/McGraw-Hill; 2004;104.

⁴⁵ Example derived from page 108 of Jones D. *Pharmaceutical Statistics*. Chicago, IL: Pharmaceutical Press; 2002.

⁴⁶ Norman GR, Streiner DL. *Biostatistics*. 3rd ed. Hamilton, Ontario: B.C. Decker, Inc.; 2008;56.

⁴⁷ Motulsky H. *Intuitive Biostatistics: A Nonmathematical Guide to Statistical Thinking*. 2nd ed. New York, NY: Oxford Univ. Press; 2010;99.

⁴⁸ Whitley E, Ball J. Statistics review 3: Hypothesis testing and P values. *Crit Care*. 2002;6:222–225.

⁴⁹ Motulsky H. *Intuitive Biostatistics: A Nonmathematical Guide to Statistical Thinking*. 2nd ed. New York, NY: Oxford Univ. Press; 2010;104.