Batch Consistency: Beyond Passing COAs

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Abstract. Assess batch consistency from process behavior as well as individual COA results. This note distinguishes specification limits from control limits and outlines the prerequisites for interpreting capability. Several passing lots do not by themselves establish a stable process.

Keywords: batch consistency; COA; process capability; control limits; variation

1. Check stability before capability

Capability indices compare a process distribution with specification limits and depend on appropriate data and assumptions [1]. A sequence of passing results alone does not establish a stable process or predict the next lot.

Illustrative calculation: assume a stable, approximately normal process with lower limit 8, upper limit 12, mean 10.0 and suitable within-process standard deviation 0.5. Cp = (12 − 8)/(6 × 0.5) = 1.33. Cpk = min[(12 − 10)/(3 × 0.5), (10 − 8)/(3 × 0.5)] = 1.33.

If the mean shifts to 11.0 with the same standard deviation, Cp stays 1.33 but Cpk falls to 0.67. The spread is unchanged; the process has moved closer to one limit. These hypothetical values illustrate position and spread, not recommended acceptance thresholds.

2. Build a useful lot dataset

2.1 Preserve the sampling structure. Record lot, sampling location, preparation and test replicate separately. Multiple readings of one prepared specimen primarily assess measurement repeatability. They do not count as multiple manufacturing lots and should not inflate the apparent evidence for process capability.

2.2 Separate process and method changes. Annotate changes in equipment, raw material, heat treatment and analytical procedure. Plot results in time order. If the measurement method changes, establish comparability before combining the series into one standard deviation or capability estimate.

2.3 Define a response to unusual results. Use an agreed investigation path that includes checking sample identity, preparation and the retained reference. Repeating until a passing result appears obscures the original signal. Retain the first result and explain any scientifically justified exclusion or replacement.

3. Development decision

Set specifications from the material function and measurement capability, then monitor whether the process consistently meets them. Use capability metrics only after stability and the statistical basis have been assessed.

Table 1. Development comparison and interpretation controls.

Signal in the lot series	Question	Action before tightening limits
Mean drifts	Process change or method drift?	Compare retained control and history
Spread increases	Sampling or manufacturing variation?	Separate repeats from independent lots
Different laboratories disagree	Comparable measurement methods?	Run a shared reference sample
All values pass	Enough stable representative data?	Review time sequence and uncertainty

Scope. The example assumes normality and a suitable estimate of variation. It is not evidence for any Kannrybio lot or a universal minimum capability requirement.

References

1. NIST/SEMATECH. e-Handbook of statistical methods [Internet]. 6.1.6. What is process capability? [cited 2026 Sep 28]. Available from: https://www.itl.nist.gov/div898/handbook/pmc/section1/pmc16.htm

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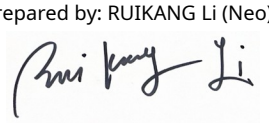

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