

Taking a Material Sample to a Pilot Trial

Kannrybio

Hongkong Kannry Industrial Co., Ltd. | www.kannrybio.com

Abstract. A successful bench sample justifies the next defined trial only when its identity, test conditions and decision criteria are traceable. This proposed workflow helps HA, β -TCP and 45S5 buyers plan a sample evaluation, investigate failures and define evidence for a pilot order. It does not prescribe a universal sample count or qualify a finished device.

Keywords: sample evaluation; pilot trial; HA; β -TCP; 45S5; qualification

1. Agree what the sample must demonstrate

Write the intended process, the required material attributes and the practical endpoint before testing. Examples include redispersibility in a chosen liquid, handling in a defined formulation or phase retention after a defined thermal step. Select endpoints that inform the next purchase decision, rather than collecting tests without a decision attached.

Define acceptance criteria, a comparison material, test conditions and a response to failure. Choose sample quantity and independent lots from the trial needs and risk assessment. Repeated readings of one preparation are not additional production lots. Reserve sufficient material for a justified investigation or repeat.

2. Receive and preserve the evidence

Record grade, form, lot, received mass, packaging condition and document revisions. Photograph any abnormal condition and resolve identity discrepancies before interpreting test data. Store and handle the sample according to the applicable SDS and supplier instructions; log opening and preparation dates.

If particle size or BET area will be compared, retain the method and preparation conditions with the result. ISO 13320 concerns laser-diffraction PSD and ISO 9277 concerns gas-adsorption surface area [1,2]. Neither defines a universal functional acceptance limit for these materials.

3. Trial the material in the intended process

Compare the candidate and reference under the planned conditions. Keep specimen preparation, mixing sequence, conditioning and measurement settings traceable. Record failures and missing data. If a result changes, first check identity, preparation and method comparability before attributing the change to the material.

For HA or β -TCP exposed to heat, decide whether the processed phase composition must be checked. For 45S5 exposed to liquid, record the medium, material dose, time and temperature when interpreting the result. These are trial-design prompts; the actual test plan must fit the application.

4. Define the next decision explicitly

Close the trial as advance, investigate or stop against the agreed criteria. Name the pilot grade, scale, process conditions and remaining questions. Confirm whether the sample and pilot supply share the manufacturing route and specification; document and evaluate relevant differences. Confirm current terms before the pilot order.

Agree how relevant grade, process, site or test-method changes will be communicated before subsequent supply. Where a formal conformity statement is required, agree the decision rule [3]. Keep material screening, pilot feasibility and finished-device qualification as distinct decisions.

Table 1. Evidence to carry from the sample request to the pilot decision.

Stage	Record to retain	Question that permits progress
Plan	Endpoint, criteria, comparator and sample plan	Will this trial answer the buying question?
Receive	Grade, lot, condition and applicable documents	Is the received material identified?
Evaluate	Protocol, raw results, deviations and findings	Were the agreed criteria met?
Pilot decision	Disposition, remaining risks and next order scope	What has been justified at the next scale?

Scope. The sequence is a recommended buyer workflow, not a standard-mandated validation protocol. Pilot success does not establish clinical performance, regulatory approval or long-term supply consistency.

References

- ISO. ISO 13320:2020. Particle size analysis - Laser diffraction methods. Geneva: ISO; 2020.
- ISO. ISO 9277:2022. Determination of the specific surface area of solids by gas adsorption - BET method. Geneva: ISO; 2022.
- ILAC. ILAC-G8:09/2019. Guidelines on decision rules and statements of conformity. Silverwater: ILAC; 2019.

Prepared by: Kannrybio

Technical review pending

Prepared: 30 September 2026

Review date: