DECISION TREE #3: SETTING ACCEPTANCE CRITERIA FOR DRUG SUBSTANCE PARTICLE SIZE DISTRIBUTION

Is the drug product a solid dosage form or liquid containing undissolved drug substance?

NO →

No drug substance particle size acceptance criterion required for solution dosage forms.

YES

1. Is the particle size critical to dissolution, solubility, or bioavailability?
2. Is the particle size critical to drug product processability?
3. Is the particle size critical to drug product stability?
4. Is the particle size critical to drug product content uniformity?
5. Is particle size critical for maintaining product appearance?

If NO to all

No Acceptance Criterion Required

If YES to any

Set Acceptance Criterion