

3.2.S.4.2 Analytical Procedure

Determination of Particle Size of Stelbat by Laser Diffraction (G1112)

Methodology	Particle Size Analyzer Laser Diffraction	
Topic	Item	Description
Equipment	Particle Size Analyzer with Laser Diffraction	Analyzer with disperser and temperature control accessory, or equivalent
Reagents	Dispersant	0.1% Sorbitan monooleate (Span 80) in hexanes (m/v) Shelf-life: Refer to local laboratory expiration date (may be extended with supporting data)

Topic	Parameter	Acceptable Range or Setting
Operating Parameters: Particle size analyzer with laser light diffraction^a ^a Parameters may vary based on instrument model type and manufacturer's recommendation.	Optical properties	Same as for blue light
	Theory	Mie
	Particle refractive index	1.75
	Particle absorption	0.01
	Fluid refractive index	1.38
	Analysis model	General purpose
	Sensitivity	Normal
	Particle Shape	Non-spherical
	Stir speed	2300 rpm
	Sample measurement time	10 seconds (measurement and background)
	Stir time	1 minute
	Obscuration	10-30% (target about 15%)

Topic	Item	Description
Sample Preparation	Concentration	Approximately 10 mg/mL Stelbat in dispersant Vortex approximately 30 seconds. Mix briefly by vortexing immediately before use.
	Number of Preparations	3
Sample Analysis	Number of Analyses	1 replicate for each sample preparation
	Acceptance Criteria	1) Sample obscuration must be within the acceptable range, 10-30 % 2) The %RSD for the $D_{(v, 0.9)}$ must be not more than 15%.

Item	Calculations/Results
Sample Calculation	The particle size result is calculated automatically by the instrument software for each sample.
Reporting	Report the average value as per specification