

MONITORING HOMOGENEIZATION OF PHARMACEUTICAL EMULSIONS USING ADSA™ SEQUIP

Measurements

- Advanced Droplet Size Analyzer (ADSA™) of Sequip is used
- Measurements of a pharmaceutical emulsion:
 - o Only the pharmaceutical emulsion
 - o Powder additive is mixed into the emulsion
- Sample name: *Emulsion + Pharmaceutical crystal in powder form*
- Sample chemical and physical compositions: *confidential*
- Measurement results are presented in Fig. 1. Interpretation can be seen as follow

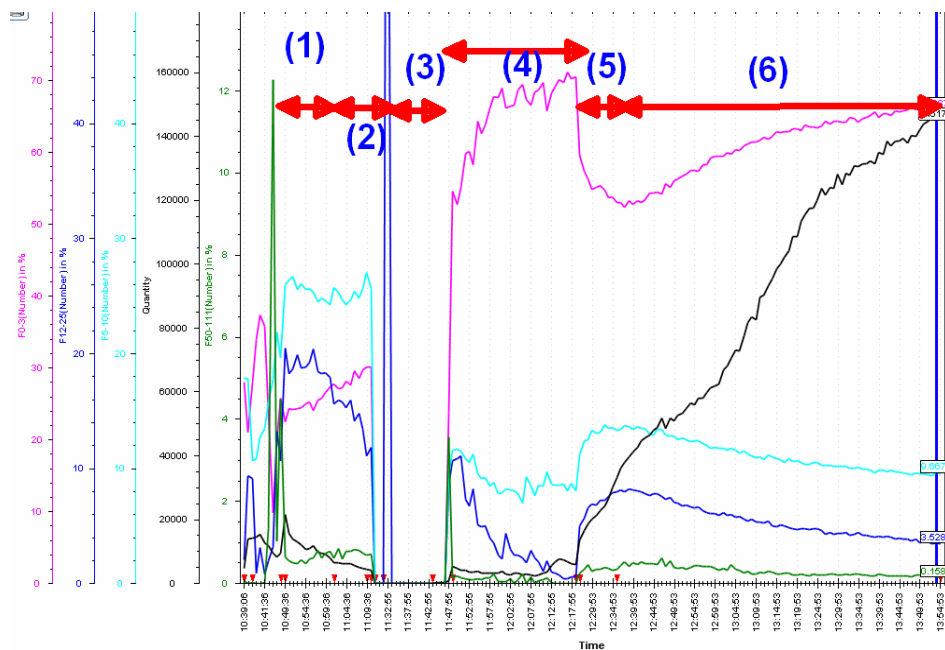
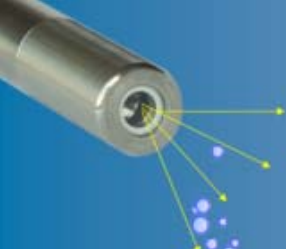


Fig. 1: Measurement results of the emulsion sample for pharmaceutical application

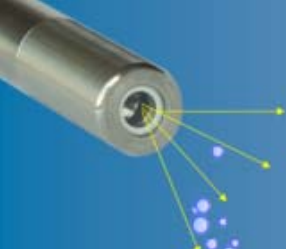


First of all, the emulsion is measured under stirring condition at ambient temperature and pressure (1). Then the sample is cooled down to 10 °C (2). Agitation is stopped (3) to add powders (4) and stirring again. After 15 minutes, temperature is increased gradually to 35 °C (6).

Results are plotted in Fig. 1 and explanation can be considered as 6 events in Table 1.

Table 1: Events and interpretation

<i>No</i>	<i>Event</i>	<i>Interpretation</i>
(1)	Emulsion is quite stable All fractions show small vibration	Relatively good homogeneity
(2)	Cooling	Forming local flocculation, increasing inhomogeneity of the system.
(3)	Stop stirring (still measuring)	Sedimentation has been quickly formed. Particles are out of measurable regime. No measurement signal.
(4)	Powders added	Added powders are quite small. That makes the small fraction (F0-3) increasing significantly. In percentage coordination, other fractions are getting smaller. Surface tensions of powder particles lead to granulation, added powders partly dispersed, partly isolated in granulates.



(5)	Surface tensions interfered	Breaking of granulates of added powders under fluid dynamic conditions
(6)	Heating period	Granulates are thermodynamically unstable at high temperature. They are “broken” to form smaller particles. Thus, the small fraction is progressively increasing but the bigger fractions are getting smaller.

In Fig. 1, at the end of measurement, the tendency of all fractions appears being stable in next few minutes.

Conclusion: *The homogeneity of emulsion and emulsion/additive systems can be fully observed with ADSATM sensor. This application demonstrated how an ADSATM being capable to capture currently events in the process. For process control, ADSATM is an In Situ powerful tool.*

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