

API-Mix

Real-time Multi-point Monitoring for Mixing and Blending





Most pharma and chemical products are obtained by mixing and/or blending of solids and liquids. This can involve complex processes such as sedimentation, emulsification and dissolution. Large volume vessels are often used which can complicate the validation of the process, and lead to out-of-specification product, large volume losses and overestimated processing and mixing times.

The only solution is to perform multi-point analysis into and during the process. API-Mix[®] is the only commercially available solution able to provide the required QC. Processing times will be faster with significant cost and processing benefits.

Single vessel inspection

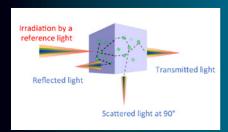


- Immediate analysis of multiple critical points.
- Automatic evaluation of homogeneity.
- Detection of sedimentation
- Mapping of mean particle size vs/depth
- Mapping of chemical concentration vs/depth.
- Ideal in process dev for mixing design (blade shape/speed/vessel) and scale-up phase.

Continuous inspection from mixing to filling



- Full inspection of the vessel, filling, processing & packaging.
- Sedimentation/unmixing identification within the pipe.
- Optimisation of cleaning time for the full line.
- Particularly suited to flexible production lines: switch time and validation of changes from product A to B
- Product identification and flow monitoring in continuous processes



API-Mix at a glance

- SAM-Spec® and SAM-Flex® use a patented NIR-SRS optical technology
- Scattering of photons at different wavelengths provides physical information
- Absorption provides the chemical information on the product
- Comparison of signals between different probes provides homogeneity level within the tank

Typical Performance Levels	
Turbidity range	0->15000 NTU
Concentration accuracy	Typical 1% to 100 %
Mean particle size	Min 200nm to 1000µm

21CFR Part 11 compliance Full IQ/OQ/PQ support GMP compliance

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