

APPLICATION NOTE**3.07 PHARMACEUTICAL & BIOTECH
FORMULATION AND
FILLING OPERATIONS**

- Real time continuous measurement
- Non-conformity control
- Quality control
- Dual-wavelength measurement
- Zero dead volume, no hold up
- Processes Optimization

Formulation and filling include process steps that are necessary to get a purified active component or product into its final dosage form.

APPLICATION

Active Pharmaceutical Ingredients (API:s) are often stored in a concentrated and/or frozen state and first brought in the correct concentration using buffers. After the active component is ready, it is mixed with the inactive components of the drug. Afterwards, the mixture must be transported from the formulation tank to the filling.

The subsequent final filling takes place after transportation to the final sterilization (usually a sterile filtration).

INSTALLATION

Variations in tank levels, pump cycling, pH and temperature can create value deviations in the formulation and filling areas. Kemtrak analyzers provide process operators and quality assurance personnel with a real-time view of process values. Changes can then be made to meet acceptance criteria or stop a non-conforming product batch from going forward.

Depending on the product, Kemtrak analyzers can monitor turbidity, color or concentration to ensure consistency, and provide quality data for QA/QC documentation and process knowledge.

Installing a Kemtrak analyzer inline help monitor consistency, ensure conformity, and evaluate productivity. Kemtrak measurement cells can be installed at tank feeds or outlets and at filler station for verification.

Hygienic [Kemtrak measurement cells](#) are available with FDA and UPS Class VI approved seal materials. The zero dead-volume design assures a fast response without cross contamination. A Kemtrak validation and calibration accessory is available to verify analyzer performance without the need for process interruption.



The [Kemtrak DCP007-UV](#) photometer is the recommended instrument to accurately measure protein concentration. The [Kemtrak TC007](#) turbidimeter is recommended for measuring turbidity and suspended solids, and a [Kemtrak DCP007-VIS](#) is recommended for color measurements.

Turbidity

Many products have a baseline level of turbidity that relates to the product concentration. Such products may need to be diluted to attain the proper target dosage.

Dilutions

Turbid products that are diluted to a certain target concentration can be monitored using the Kemtrak TC007 turbidimeter. Using turbidity as a function of concentration, one can track the dilution and verify

the target turbidity/dosage is met before proceeding to the filling station.

Color

The phenomenon of “opalescence” can affect biologics that are stored in a vessel before filling steps. This usually doesn’t affect potency but can be detrimental in an aesthetic sense, leading to failed batches. Installing a Kemtrak analyzers allow operators to be able to detect value changes in real time, preventing product loss while ensuring quality down the line.



Kemtrak validation and calibration accessory