Case Study

PENDOTECH
Leading Process Analytics

Enhancing Vaccine Filtration Efficiency

With Real-Time In-line Monitoring

Introduction

Filtration is a cornerstone of safe and effective biopharmaceutical manufacturing, demanding precise control to remove contaminants and ensure product integrity. Measuring turbidity and UV absorbance provides critical real-time insights into filtration performance. This case study examines how a leading French vaccine manufacturer leveraged METTLER TOLEDO's PM2 photometer for in-line monitoring. It explores how this technology enabled the company to optimize its extensive vaccine production processes, verifying filter efficiency, and preventing product loss through continuous, accurate data collection.

METTLER TOLEDO

Company profile
The subject of this study is a leading pharmaceutical and healthcare organization based in France. With a global reputation as a top producer of vaccines, the company focuses on the research, development, manufacturing, and marketing of innovative pharmaceutical products. It also ranks among the top three investors in research and development within Canada. The organization is driven by the aim to create transformative medicines using advanced technologies, with a significant focus on improving the production efficiency and quality of vaccines and biologics.

The challenge: Ensuring optimal filtration performance
Filtration plays a crucial role in pharmaceutical manufacturing, ensuring product safety by removing unwanted particles and contaminants. Measuring turbidity, which quantifies the cloudiness caused by suspended solids, serves as a key indicator of filtration efficiency. Maintaining optimal filter performance is essential for meeting stringent product quality standards and regulatory requirements.

Operators need real-time data to continuously assess filter performance, allowing for timely adjustments. Observing the clarity of the fluid downstream of the filter via in-line turbidity measurements provides valuable insights, facilitating the early detection of particle breakthrough and indicating when a filter may be reaching its capacity. This proactive approach is vital for ensuring final products meet clarity and purity standards, enhancing operational efficiency, and reducing the risk of costly reprocessing.

Furthermore, in processes like tangential flow filtration (TFF), monitoring UV absorbance (specifically at 280 nm to detect proteins) on the filtrate line is a critical safety measure. It ensures that product is not inadvertently escaping the TFF loop and going to waste. Detecting unexpected UV absorbance increases allows operators to quickly identify potential losses and take corrective actions, preserving process integrity and maximizing yield. The challenge, therefore, was to implement a reliable monitoring solution capable of providing continuous, real-time data for both turbidity and UV absorbance within the demanding environment of vaccine manufacturing.

The solution: In-line monitoring with METTLER TOLEDO PM2 photometer
To address the need for precise, real-time monitoring of its vaccine manufacturing processes, the company implemented METTLER TOLEDO's PM2 photometer. This versatile tool was chosen for its ability to perform in-line measurement of both UV absorbance and turbidity, providing continuous insights crucial for assessing filter performance and optimizing vaccine production efficiently.

Implementation and validation
To evaluate the PM2 photometer's effectiveness, data were collected through testing to assess the correlation between harvest dilutions and turbidity readings.

Setup: The test utilized a PM2 turbidity sensor equipped with a 6.5 cm optical path length (OPL), mounted within a flow cell stand for in-line measurement.

Calibration: The unit was initially tared using a buffer solution to establish a baseline and ensure measurement accuracy.

Comparison: In-line turbidity measurements obtained from the PM2 photometer (Figure 1) were compared against readings taken concurrently from a calibrated off-line turbidimeter (Figure 2), which served as the control standard.

Results and analysis
The results of the test confirmed the PM2 photometer's suitability for in-line process monitoring:

Turbidity correlation: A nearly perfect linear correlation was observed between the in-line turbidity measurements generated by the PM2 photometer and the data from the off-line turbidimeter. This validated that in-line monitoring accurately reflects true turbidity levels, even across different harvest dilutions, confirming its reliability for real-time process control.

The test also highlighted the PM2's capability to measure UV absorbance at 280 nm (Figure 3). This wavelength is specifically chosen to detect the presence of proteins or other UV-absorbing organic compounds. In TFF applications, monitoring UV 280 nm on the filtrate line is essential for assessing process integrity by quickly identifying any potential product loss. This capability helps maintain product purity and enhances overall efficiency in biopharmaceutical manufacturing.

UV absorbance monitoring:

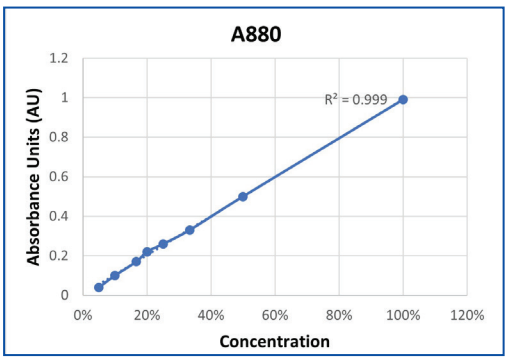


Figure 1: Turbidity of different dilutions (PM2 in-line), UV absorbance at 880 nm for different dilutions

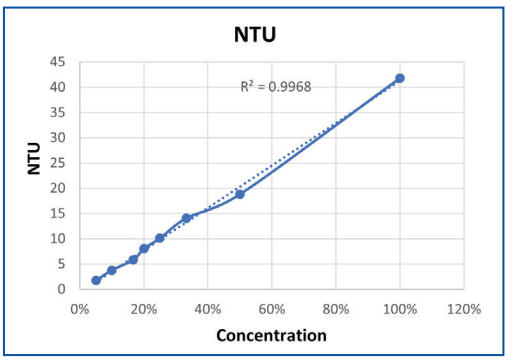


Figure 2: Turbidity of different dilutions (off-line sampling), turbidity measured in NTU at different dilutions

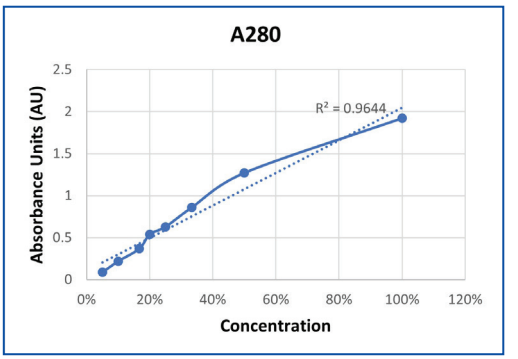


Figure 3: UV Absorbance at 280 nm for different dilutions (PM2 in-line)

Conclusion
Monitoring turbidity and UV absorbance during filtration is crucial for ensuring process efficiency, maintaining stringent quality control, optimizing yields, complying with regulations, and achieving cost savings in biopharmaceutical manufacturing.

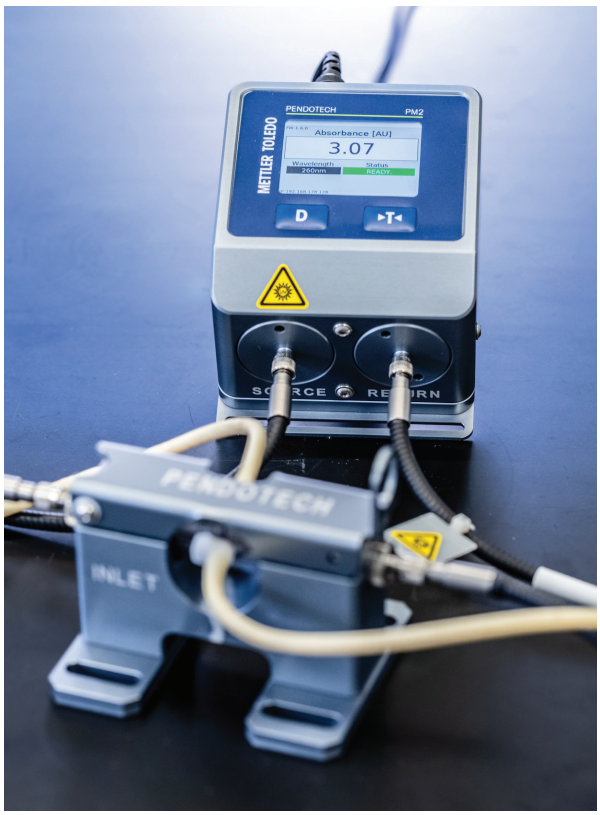
This case study highlights the vital role these metrics play. The implementation of the METTLER TOLEDO PM2 photometer has significantly improved the company's vaccine manufacturing operations by enabling reliable, real-time monitoring of both turbidity and UV absorbance. Its capacity to provide continuous insights into filtration performance allows for prompt adjustments, ensuring adherence to strict clarity and purity requirements.

The strong correlation demonstrated between in-line and off-line turbidity measurements further validates the PM2's effectiveness as a process analytical technology (PAT) tool.

This proactive monitoring strategy enhances operational efficiency, minimizes the risk of expensive reprocessing, and ultimately supports the company's dedication to delivering high-quality pharmaceutical products.

In summary, the positive results from the tests prompted the company to make a significant decision. More than satisfied with the results of the test, the company integrated a PM2 photometer to enhance their harvesting process.

Find out more:
https://pendotech.com/pendotech-products/sensors-and-monitors/on-line-uv-and-turbidity/



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MarCom Plainsboro, USA