



AZZUR LABS

An Azzur Group Company

AZZURLABS.COM



MEETING GLOBAL SPECIFICATIONS THROUGH CAREFUL COLLABORATION

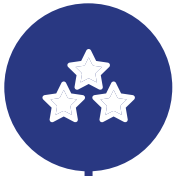
How Collaborative Methodology Led To Speedy USP Validation Before Introducing New Pharmaceutical Equipment To The Global Market

Before bringing a new filtration system to market, a leading international pharmaceutical and laboratory equipment supplier needed to complete global validation testing for the new system's filters. To do so, the company had to work hand-in-hand with laboratories around the globe to ensure the products met all global regulatory specifications. To meet USP regulations, the supplier chose to work with Azzur Labs microbiologists to develop the testing methodology for the validation of eight different filters.

Azzur Labs was responsible for sourcing and culturing the organisms used as well as for the quality control testing of all necessary testing material. 100mL of sterile buffer was inoculated with <100cfu of a USP panel of organisms. The buffer was then run through each filter type. The filters were then plated

onto multiple media types, specific to each organism, and the plates were incubated. In order to validate the test, the process was repeated five times for each of the eight filters, and tested with seven different organisms.

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THE CHALLENGE

Validation for and completion of microbial testing on new filters prior to going to market.



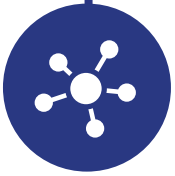
THE TEAM

Azzur Labs Headquarters



THE SOLUTION

In-house microbial testing methodology, execution, and reporting.



THE IMPACT

Development of testing methodology, execution, and validation of five separate tests, on eight different filters, for seven organisms—all completed within one month.

Testing for one to two organisms per day, the project was completed within one month. The results were then delivered directly to the client. In the end, each of the seven organisms were effectively recovered from the eight filters tested.



AZZUR LABS



At Azzur Labs, we bring together some of the brightest minds in life science to provide the innovations of tomorrow, today! We bring you full-scale, GxP-certified microbiology lab services, all complemented by Azzur Group's nationwide network of engineers and consultants.

LOCATIONS

HEADQUARTERS
484.550.7709

RALEIGH
919.342.8337

BOSTON
781.996.3223

[AZZURLABS.COM/LOCATIONS](https://www.azzurlabs.com/locations)