

It's time to say...

“I do.”



AvTech Laboratories, Inc.

• Experience. Results. Eurofins AvTech Laboratories, Inc.

At Eurofins AvTech, we know how important quality analytical testing is to your success. Let our success stories speak for themselves. Review these Case Studies and discover why our clients say “I Do.”

• Attention to Detail.

Our sponsor was prepared to pursue litigation with its contract manufacturer after the production of three unacceptable drug lots. Eurofins AvTech, out of dedication to the sponsor, investigated the production further. After focused research, our scientists noted a wider specification range for Canada, unknown to our sponsor, and suggested that the lots be used for Canadian manufacturing. The suggestion proved to be the perfect solution for the client and the CMO. Our efforts saved the sponsor millions of dollars by avoiding costly litigation and also enabled them to rescue the product from what seemed to be certain disposal, saving both time and money.

• Technical Experience.

Our sponsor, aware of Eurofins AvTech's specific expertise with complex analytical testing, requested identification of several polar degradants detected in the presence of their degraded 1 mg tablets. One degradant of particular interest appeared to form only after the initial hydrolysis of the parent drug, and then only in the presence of lactose. Eurofins AvTech's scientists hypothesized that the final product formed as a result of the Maillard reaction between the intermediate degradant (an aryl amine) and the reducing sugar. This was proven by direct reaction of the hydrolysis product and lactose, followed by mass spectral confirmation. Scientific expertise, technical experience and swift resolution allowed our sponsor to continue the tablet formulation without delay.

• True Problem Solvers.

After performing several residual solvents tests, Eurofins AvTech observed unexpectedly variable data for the test formulation. We performed an in-depth investigation and concluded there was a problem in the drying process of our sponsor's product. The trend in results indicated that the variability was due to the length of time the product's package was open. With the data and advice provided by analytical staff, the sponsor changed the drying technique to give more consistent, quality results. This ultimately saved the client both time and money since the issue was identified early, allowing the client to rectify the problem before release of the product.

• Exceptional Service.

A very unusual HPLC method for an immunosuppressant coating on cardiac stents was transferred to Eurofins AvTech. In spite of the client's issues working with other CROs who could not validate the method appropriately, Eurofins AvTech was able to complete the method transfer and validation both quickly and flawlessly. We worked around-the-clock to meet the client's tight deadline to submit stability data to the FDA, which included the incorporation of a custom report and data format. In addition, we also resolved a key problem with content uniformity testing of the first clinical lot samples—meeting a tight deadline and allowing the development plans to stay on track.

Discover why clients adore us and never want to leave.



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