



	PARTICULAR EQUIPMENT	TEAM WORK	QUALITY DATA	FLEXIBILITY	TRANSFER AND DEVELOPMENT
CHRISTIAN	RANGE  DSC TGA STABILITY CABINETS XRPD		X  Suitable for presentation  Cross data comparisons	X  Extended study  Supported when materials needed at labs	

## **Stability Study To Demonstrate The Efficacy Of A Novel Amorphous Drug Delivery Technology**

### **BACKGROUND**

The client, a company with a novel drug delivery technology which aims to stabilise the amorphous state of an active drug via encapsulation within a biodegradable matrix, wanted to demonstrate the benefits of their technology via a series of stability studies, the data from which could be used in both academic posters and marketing presentations.

### **OUR APPROACH**

We held a series of meetings with the client in which we worked with them to identify the key performance parameters and success criteria for their product. It was agreed that the encapsulation of two model compounds should be targeted, and a program of work was initiated at Agenda1 to develop analytical methods of sufficient sensitivity to detect the physical form (amorphous, crystalline) of those compounds within the client's matrix.

Our support was based around the use of our Vindon stability cabinets, Bruker-AXS D8 Advance X-Ray Diffractometer, PerkinElmer Pyris1 Differential Scanning Calorimeter, PerkinElmer Pyris1 Thermo Gravimetric Analyser, FEI Quanta 400 Environmental SEM, and Jasco FTIR-420, plus our extensive previous experience in managing stability studies for both R&D purposes and in support of clinical trials.

### **IN MORE DETAIL**

One of the key requirements of the project was that the overall work plan remained cost-effective for the client. Thus, whilst the methods developed needed to be suitably robust and of appropriate quality, it was important to keep the extent of method development and subsequent validation stage-appropriate. That is, this was a proof of concept study, and the data generated was to be incorporated posters / presentations, and was not destined for regulatory submission.

During the project we developed a close working relationship with the client. This was particularly important as, whilst the stability study and the majority of sample analysis was conducted at Agenda1, the client was responsible for carrying out one of the key product performance tests. A high level of cooperation and communication was required to ensure stability samples were pulled, shipped, tested and reports issued within acceptable time windows. Also, thanks to forward planning at Agenda1,



we were able to extend the study for an additional 3 months when requested to do so, and to supply additional samples to the client at short notice when key test equipment failed during use.

## **RESULTS**

The study was successfully completed and demonstrated the benefits of the encapsulation of active compounds in the novel matrix in two ways. Firstly, it revealed that the physical stability of both amorphous drugs investigated was significantly improved when encapsulated in the matrix compared to control samples, and secondly the study indicated that the chemical stability of the active drugs was not negatively impacted by intimate contact with the matrix.

The data generated from the study has been presented at a number of conferences; subsequently, the client has secured significant additional external funding for the project.

The client commented: *“The service provided by Agenda1 was of an excellent quality providing complete confidence in the data attained. The project involved working with research materials and as such late stage modifications to both protocols and methods were easily accommodated.”*