

Quality Control Laboratory Puts a New GC Workhorse Through Its Paces

The innovative Thermo Scientific TRACE 1310 GC System

“ The user-exchange of the instant connect injector and detector modules is quick and functional. The low temperature of the injection head has the practical advantage of replacing a new liner without losing any time. The simple and quick adaptation from liquid to head-space sampling is a great advance and is very helpful for daily user operations. Overall, the TRACE 1310 GC is very flexible and user-friendly for a wide range of applications... ”

Dr. Dietrich Hilke
Head of Laboratory, Quality Control / Technology,
Sanofi-Aventis, Deutschland GmbH, Frankfurt



Dr. Hilke is Head of a Pharmaceutical Quality Control Laboratory at Sanofi-Aventis in Frankfurt, Germany. This laboratory is responsible for conducting quality control of excipients, drug substances, and drug products during the many stages of manufacturing, including production, in-process control of semi-finished goods, and non-packaged finished goods. Subject to compliance with a myriad of country regulations, the pharmaceutical lab plays a decisive role in the launch of drug products and their continual supply to the market.

Analytical procedures in their lab span a variety of technologies—spectroscopy (AAS, ICP-OES, ICP-MS), electrochemistry, microscopy, and chromatography (LC, GC, GC-MS, LC-MS). Analytical work is performed either according to the current pharmacopoeias (EP, USP, JP) for known drug substances or according to the validated analytical methods registered with the

authorities (e.g. EMA, FDA, and others) for new active ingredients and the finished drug products.

Dr. Dietrich Hilke was initially part of a team of GC experts and users who participated in a “Voice of the Customer” event, a regularly occurring meeting hosted by Thermo Fisher Scientific to elicit customer input in the early new systems development phases. He then accepted to become a test site for the new Thermo Scientific™ TRACE™ 1310 Gas Chromatograph (GC), which was being designed from the ground up to innovate routine analysis and to provide users with much more flexibility and redefining GC usability.

The new TRACE 1300 GC and TRACE 1310 GC systems were introduced at PittCon 2012. These innovative, high-performance GC platforms offer groundbreaking instant connect injector and detector modules that allow the user to tailor the GC configuration to the application workload or to perform routine maintenance off-line while the GC is running, with the use of spare modules. The TRACE 1300 Series GC systems are built for the reliability, robustness, ease of use, and productivity required in the routine lab.

As a test site, the Sanofi-Aventis pharmaceutical QA/QC lab put the new TRACE 1310 GC system through its paces.

In this laboratory, the average workload for GC analyses is between 500 and 700 batches per year. For this, they have many GC systems in the lab to compare with, including several Thermo Scientific systems.



TRACE 1310 GC

“ There is often a demand for robust chromatographic methods with the highest throughput and the quickest possible response times,” Dr. Hilke commented. “We are always interested in new analytical and chromatographic technologies! ”

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The lab has a long list of requirements for new equipment: all instruments in the regulated QC laboratory must conduct Operational Qualification and Performance Qualification (OQ and PQ), and all methods must be validated. For GC analysis, the official methods used include European Pharmacopeia, US Pharmacopeia, and validated Sanofi Methods.

The Sanofi-Aventis lab tested the new TRACE 1310 GC system by analyzing routine products for precision and robustness, also running a complete method revalidation, and comparing data with other manufacturer's systems. The new TRACE 1310 GC system often provided better results compared to the other systems.

At first, precision and robustness were tested by analyzing ethanol in an injection solution and cholesterol in the excipient wool alcohol ointment. Results showed that the precision of the new TRACE 1310 GC system was better than the comparable test equipment providing an RSD of 0.9 % versus 3.0 %, while the results for the ethanol content were the

same between the two systems providing ethanol: 1.1 % on the TRACE 1310 GC system versus 1.2 % on the comparable system.

Next, a complete method revalidation on creams and ointments (benzyl alcohol in Batrafen® Cream) was made testing precision, linearity, selectivity and accuracy (see Figure 1), with results shown in Table 1.

Table 1. Results Comparing Revalidation of Creams and Ointments		
	TRACE 1310 GC	Comparable GC
Precision (RSD)	0.3%	0.8%
Linearity (Correlation Factor)	0.99997	0.99965
Accuracy (Recovery Rate)	103.5 %	101.3 %
Resolution	2-propanol/phenol=56.5 phenol/benzyl alcohol=16.4	2-propanol/phenol=39.4 phenol/benzyl alcohol=17.1

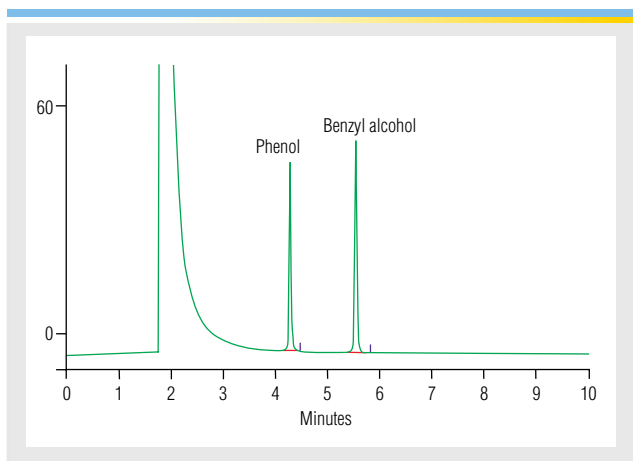


Figure 1: Benzyl alcohol determination in cream.

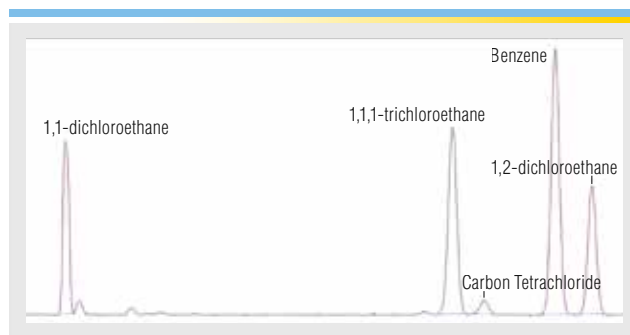


Figure 2: Example chromatogram for residual solvents determination in drug products, according to USP 467.

In his laboratory's experience, Dr. Hilke explained the following:

“ Using the TRACE 1310 GC, method development was minimal because all methods used for other GC systems were directly transferable to this gas chromatograph. The system operation and user-friendliness are very effective. The local touchscreen is very immediate, with its menu intuitive and easy to operate. The ability to directly control the GC is very useful for a rapid error analysis and correction during method development.

The user exchange of injector and detection units is also very quick and functional, as it doesn't require particular tools or training. The low temperature of the injection head has the practical advantage that the liner and septum replacement can be carried out without losing almost any time while the simple and quick adaptation from liquid to head space sampling is a great advance and is very helpful for daily operation.

Overall the TRACE 1310 GC is very flexible and user-friendly for a wide range of applications. We can recommend the acquisition of this GC with the Thermo Scientific TriPlus™ RSH Autosampler for the increase of flexibility to replace old equipment.”

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