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Simplifying Quality Control Testing with CUE Software

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Key Words

- Evolution 200 Series
- Acetaminophen
- CUE Scripts
- CUE Software
- Customized Analyzer
- Quality Control Testing
- US Pharmacopeia
- UV-Visible Spectrophotometer

Introduction

The quality control processes of a laboratory are critical to ensuring that high quality data is collected and reported accurately every time. A problem with any step in the process can lead to a multitude of consequences including out-of-specification results, delays in product release, and even product recalls. Some of the largest contributors to these problems arise from analyst errors and unplanned method deviations. This note will demonstrate a number of ways in which Thermo Scientific CUE software, included with every Evolution 200 Series UV-Visible spectrophotometer, can be used to reduce analyst error and unplanned method deviations while simplifying the overall quality control testing process.

We will consider four main components of a quality control method and demonstrate how customized CUE scripts can streamline and improve each using the US Pharmacopeia (USP) method for percent assay of acetaminophen as an example. These method components include:

- System Suitability
- Sample Measurement
- Data Analysis
- Result Reporting

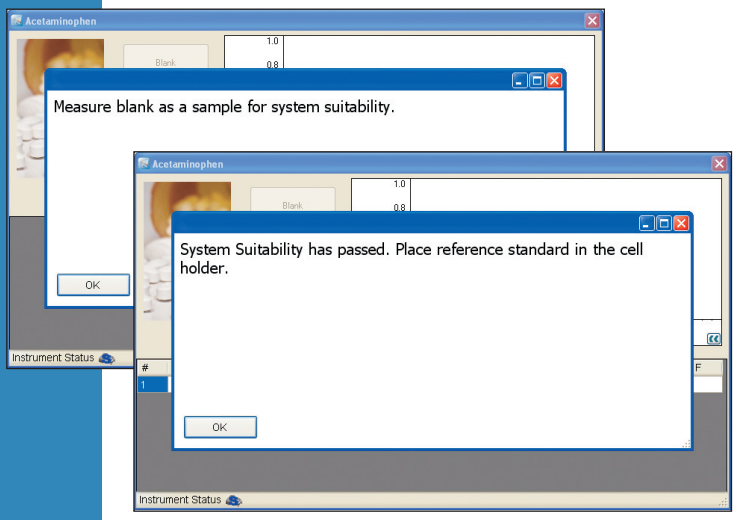

Figure 1: User prompts can be used to notify the user of an event and/or prompt them to perform specific actions at the appropriate time. Here, the user is prompted to measure the blank as a sample, notified that system suitability has passed, and then prompted to measure the reference standard.

System Suitability

System suitability is an important part of any quality control method. System suitability tells the user if the test system is functioning properly before and during the analysis. A common test for system suitability of a spectrophotometer is photometric stability or drift. This can be tested before beginning the analysis and/or at periodic intervals during the analysis by reading the blank as a sample, or using another suitable control. CUE is used in this example to both prompt the analyst to perform system suitability appropriately and to determine whether or not the system suitability test has passed (Figure 1). If the system suitability test passes, the analyst is prompted to measure a reference standard. If system suitability fails, the analyst is prompted to repeat the system suitability test and the script is stopped. Building these controls into the CUE software script ensures that sample analysis is not run until system suitability is achieved.

Sample Measurement

Sample specific information is often needed to process results or track specific qualities of the sample, such as lot number or expiration date. With CUE scripts, this information can be tied directly to the sample data and results through the use of interactive user prompts. Sample details can later be displayed in the result table or used in subsequent calculations and other steps in the sample analyses procedure. For added security, sample identification may be read directly into a CUE script with the use of bar codes and a compatible bar code reader. In this example, users are prompted to enter the actual weight of each sample used in the preparation of the sample solution (Figure 2). This information is then used in subsequent steps to perform calculations on the collected data which are required for complete analysis of the samples.

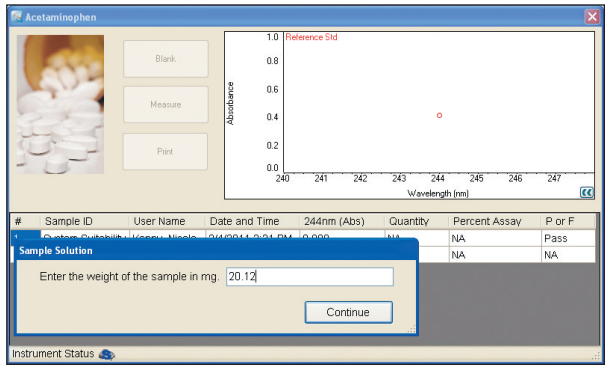

Figure 2: Specialized user prompts can be used to obtain additional information from the user, such as preparation-specific sample properties

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When the number of samples analyzed by a method varies, or a user wishes to have the option to repeat or verify a result, scripts can be programmed to ask the user if they have another sample to measure (Figure 3). In this example, if the user answers 'yes', sample measurement and analysis actions are performed for an additional sample, and the user may continue to make additional measurements as necessary. If the user answers 'no', the script stops and all of the data and results are saved into a single workbook file.

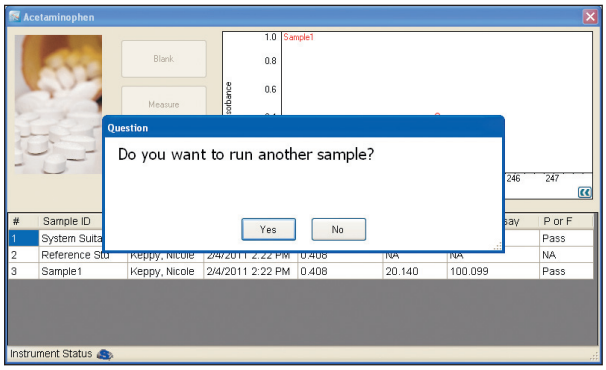

Figure 3: User decisions can be used to determine what action the script should do next, such as repeat or skip sections of a method which may vary from run to run

Data Analysis

To analyze a quality control sample for quantitative purposes, it is generally necessary to complete a set of mathematical calculations on the collected data and compare the results of those calculations to predetermined sample specifications. With CUE scripts, these analyses can be performed automatically according to method specifications and the user can be notified by a user prompt whether the sample passed or failed the pre-determined specifications (Figure 4). Additionally, the result can be reported and displayed in the appropriate results table. In this example, we calculate the quantity and percent assay of acetaminophen in the sample automatically using the following equations:

Quantity = RefWeight * (Asam/Aref)
Percent Assay = 100 * (Quantity/SamWeight)

The results are compared to the predetermined specifications outlined in the associated USP method. Here, the sample passes if the percent assay result is greater than 98% and less than 102%.

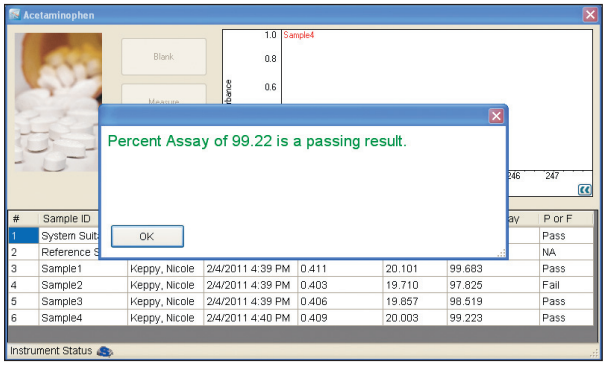

Figure 4: CUE scripts can be programmed to calculate, compare, and display results automatically to reduce errors and save time

Result Reporting

The reporting of results is a critical step in any analytical method. Several options are available for reporting results collected using CUE scripts including the ability to manually or automatically:

- Print result tables directly from a CUE script
- Export result tables directly from a CUE script
- Save results as a workbook that can be opened in Thermo Scientific INSIGHT or INSIGHT Security software – allowing access to full reporting capabilities (Figure 5)

When opened in INSIGHT Security software, saved workbook files can be electronically signed to assist with data management and compliance with 21 CFR Part 11 regulations.

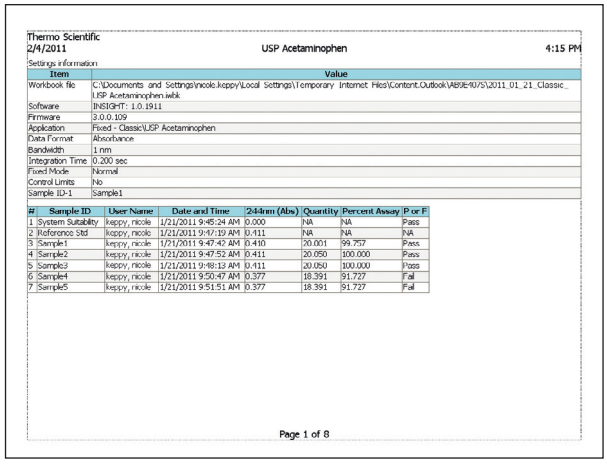

Figure 5: Complete reporting features are accessible through INSIGHT and INSIGHT Security software

Summary

Thermo Scientific CUE software provides a platform for you to create a customized analyzer for your quality control test methods. Whether you are working in a highly controlled regulated laboratory or with routine QA/QC analyses, customized CUE scripts can help you reduce analyst error and the occurrence of unplanned method deviations, while simplifying the overall quality control testing process for your technicians.

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