

Agilent 850-DS Sampling Station – Cleaning Validation

The procedure to establish a validated cleaning method for Agilent 850-DS Sampling Station.



Background

Validating a cleaning method is critical to prevent sample contamination as well as maintain the 850-DS Sampling Station in proper condition. Cleaning solutions and protocols should be determined on a method-specific basis, since different drugs and medium have different characteristics and therefore different requirements for rinsing.

Cleaning solutions

As a general rule, purified or DI water is the best solution for cleaning salts, sugars, and surfactants from the system. For polymers and other sticky substances, an alcohol such as ethanol or methanol tends to work better. For situations where both are present, a stepwise procedure is recommended that starts with water, then alcohol, and finish with water. The temperature of the water can also be elevated (e.g., up to 50°C) to improve rinsing. A purified water rinse should be the final step in the process.

Timing

Cleaning should be done as soon as possible after a run has been completed. If too much time is allowed to pass, leftover product or excipient may precipitate in the lines causing clogs. Over time, evaporation will also concentrate acidic media as well leading to corrosion any metallic components. Systems such as the 850-DS are capable of executing automated cleaning procedures immediately after run completion. This cleaning cycle should be incorporated into the setup of each dissolution method.

Procedure

Parameters

To determine the correct cleaning cycle parameters, the following should be considered:

- Cleaning solution(s)
- Cleaning volume
- Number of cycles

A bottle of your cleaning solution, or rinse media, is placed next to the 850-DS and connected to the Rinse Port via a length of tubing. It should be filled and readied prior to the test, but may be setup at any time prior to test completion.

While the cleaning cycle may be automatically attached to the end of each method, this procedure can also be performed on demand at any time. This is especially useful if multiple solutions are necessary or the system has been idle for an extended period of time. Refer to the 850-DS Operator's Manual for any specific instructions.

Validation

To validate the cleaning method, perform the following steps:

1. Perform a complete dissolution method using the Agilent 850-DS Sampling Station with the active drug sample and media as specified in the method.
2. Clean the system with your solution(s), volume, and number of cycles according to previous experience or manufacturer recommendations (see *Note*).

3. Once the cleaning cycle has completed, refill the vessels with the same dissolution media. Prepare as if another test was to be performed.
4. Without introducing any active product, take a sample using the autosampler. This can be done with a simple, single-timepoint method, or alternative by using the Diagnostics function.
5. Compare the results of the "blank" media sample to the final timepoint of the dissolution by the suggested method of analysis.

Note

Recommended typical starting conditions:

- Rinse Media - Purified / DI H2O
- Volume - 10 mL
- # of cycles - 2

Acceptance criteria

Acceptance criteria for carryover from the previous experiment to the blank media should be < 1% for each vessel position. The acceptance criteria of < 1% may need to be reduced if the dissolution system is used for testing of multiple products. Other products tested on the dissolution system may be lower dose drugs, or ones with poorer chromophores. A 1% carryover from a 100mg tablet would look like a 10% carryover for a run with 10mg, for example. Internal SOPs may also govern what the appropriate acceptance criteria should be.

Procedure

If carryover is still seen after multiple (e.g., 3-5) cycles of the 850-DS with DI Water and/or alcohol, then you should contact Agilent for further recommendations (dissolution.hotline@agilent.com). Carryover may become worse if tubing is old or worn, or other internal components such as valves, are in need of replacement. A proper preventative maintenance schedule can help to avoid such issues.

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