

Vision® G2 AutoPlus™

5 mL to 10 mL Syringe Upgrade

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Introduction

The Teledyne Hanson Vision G2 AutoPlus system is a very important addition to the Teledyne Hanson line of dissolution testers. Vision AutoPlus autosamplers allow users to collect samples automatically during tests from a dissolution system at predefined time intervals. Precise and consistent sample collection is required by those methods; therefore, the replacement of dissolution media is very important to obtain accurate test data. With recent advancements in technology and increased regulatory requirements in mind, Teledyne Hanson Research has developed an upgrade to the Vision AutoPlus from standard 5 mL syringes to 10 mL syringes. This upgrade was perfected in our engineering and analytical laboratory through a process of rigorous testing and evaluation.

Background

Historically, the Vision AutoPlus was available with standard 5 mL syringes connected through a syringe pump having either 6 or 8 syringes in a series. Hanson Research sold various models of dissolution testers such as the Classic 6, the Vision Elite 8, the CD 14, etc. The CD 14 autosampler is already equipped with 10 mL syringes; however, the other dissolution testers that use an autosampler have 5 mL syringes installed. But when collecting frequent samples, or when collecting a large volume of samples, the 10 mL syringe is very useful. Therefore, when ordering a new Vision G2 AutoPlus autosampler, users now have the options of 5 mL or 10 mL syringes.



Figure 2: 5 mL and 10 mL syringes



Figure 1: Vision G2 AutoPlus system.

Procedure

The kit to purchase for this upgrade depends on the number of 5 mL syringes currently installed on a Vision G2 AutoPlus. The 10 mL Syringe Kit part numbers for a 6-sample and 8-sample autosampler are 61-107-066 and 61-107-068, respectively. The 10 mL upgrade is very simple and is easily installed in the laboratory. Afterwards, the instrument can easily meet GMP qualification standards. The upgrade will allow users to perform various sampling techniques meeting the timing requirements of the 2% time window demanded by the current United States Pharmacopeia (USP).¹ This 2% reflects actual time required to collect the sample into a syringe for the desired volume pull. Later, the sample will be dispensed into a test tube or HPLC vials; media replacement is not part of the sampling time. The entire cycle to complete the sampling procedure might be longer, but the most important factor to consider for the time window requirement is how much time the syringe pump took to collect the sample solution. For a product with a single time point, a sample will be collected as specified by the procedure at the end of the test; however, during the method development, frequent sampling will be required.²

With a 10 mL syringe upgrade, the following benefits can be achieved in the laboratory when sampling from dissolution baths:

A. For one dissolution system connected to one autosampler:

1. 5 mL sample collection at 2-minute intervals is possible with a 7 mL rinse volume without replacement of dissolution medium.
2. 5 mL sample collection at 3-minute intervals is possible with a 7 mL rinse volume with 5 mL replacement of dissolution medium.
3. 10 mL sample collection at 3-minute intervals is possible with a 7 mL rinse volume without replacement of dissolution medium.
4. 10 mL sample collection at 5-minute intervals is possible with a 7 mL rinse volume with 10 mL replacement of dissolution medium.

Note: 5 ml sample collection in a syringe requires 16 seconds, while 10 mL sample collection in a syringe requires 26 seconds. Rinsing is performed prior to sampling time, and displacement into test tube or vial occurs after collection in syringe. Users should not confuse the total cycle time with the sampling time.

B. For two dissolution systems connected to one autosampler:

The sample collection time for the autosampler remains the same as mentioned in Section A above; however, the Tester Offset Time should be considered very careful depending on the sampling time points and time intervals for the two dissolution systems based on dissolution method. The Tester Offset Time should be set properly for accurate rinse, collection, and displacement cycles to be completed by each dissolution system. If a time points conflict occurs between two systems, the autosampler may alert the user to this by displaying a message on the autosampler prior to starting the test. The sampling time mentioned above is true for the individual system as well.

References

1. United States Pharmacopeia (2022). *General Chapter, <711> Dissolution*. USP-NF. Rockville, MD: United States Pharmacopeia. DOI: https://doi.org/10.31003/USPNF_M99470_02_01
2. United States Pharmacopeia (2022). *General Chapter, <1092> The Dissolution Procedure: Development and Validation*. USP-NF. Rockville, MD: United States Pharmacopeia. DOI: https://doi.org/10.31003/USPNF_M643_05_01

Note: The actual sample collection time is within the USP requirements of a $\pm 2\%$ time window for the dissolution test length of 15 minutes when a 5 ml sample collection is performed, or for the 30 minute test length when a 10 ml sample collection is performed. For a shorter test time, a staggered start and manual sampling using cannula is recommended.

About Teledyne Hanson

Teledyne Hanson is a global technology company specializing in analytical test instruments for the pharmaceutical industry. Founded by the innovator of modern dissolution test technology, Teledyne Hanson helps ensure the world's pharmaceuticals are pure, safe, and effective by manufacturing equipment that sets the global standard for quality, innovation, and long-term value. Teledyne Hanson instruments are used by scientists in over 75 countries worldwide and are supported by the industry's top customer service team. For more information, please visit teledynehanson.com.

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