

## Automated Dissolution of Salicylic Acid with the MultiDose G3

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### Introduction

*Salicylic Acid is commonly used in laboratories as a dissolution bath calibrator. Manual dissolution is very time intensive process, and hence automation of this technique is commonly used. In this study, the MultiDose G3 Workstation is used to automate the dissolution process by heating the media, filling vessels, dropping tablets and timing the dissolution process. This allows the analyst to use the MultiDose G3 Workstation as a tool to perform the necessary dissolution studies. In addition to reducing the hands-on time involved in dissolution, the MultiDose G3 Workstation provides a 21CFR Part 11 compliant documentation of the automated dissolution process. The objective of this study is to determine the equivalency between manual dissolution sampling and analysis and automated dissolution sampling and analysis using the Salicylic Acid calibrator tablet.*

### Materials and Methods

#### *Instrumentation*

All testing was performed using a MultiDose G3 Workstation (Caliper Life Sciences) and VK7000 dissolution bath (VanKel) with paddles. Batch On-line UV analysis was used with an 8453 UV/Vis Spectrophotometer (Agilent) with 1.0 cm flow through cells.

#### *Reagents and Standards*

The 7.4 pH phosphate buffer was prepared according to USP specifications. The Salicylic Acid standard Lot J was prepared according to the USP specification. The study was run using non-disintegrating USP Salicylic Acid 300-mg tablets, Lot N.

The manually sampled solutions were filtered by drawing 10 mL of sample solution through a through a 35 mm VanKel Full Flow Filter. For the automated sampling, a Millipore Automation Certified 1.0 mm glass fiber filter is used.

#### *MultiDose G3 Settings*

The MultiDose G3 settings used to be consistent with the manual method are described in Table 1.

MultiDose G3 Settings	
Media Storage Temperature	37° C
Auxiliary Media	yes
Dissolution Media	7.4 pH phosphate buffer
Density of Dissolution Media	1.0034 g/mL
Media Tank Degas	15 minutes
Number of Sampling points	1
Sampling Pump Flush Volume	30 mL
Filtration Flow Rate	12 mL/min
Total Run Time	30 minutes
Hot Wash Stage 1 and 2	1 cycle of each
Line Clean Vessel Volume	550 mL
Line Wash Volume	100 mL, 1 cycle

Vankel 7000 Bath Parameters	
Vessel Fill Volume	900 mL
Number of Vessels	6
Bath Type	VK 7000
Paddle Speed	100 rpm
Apparatus Type	USP II Paddles

Output Parameters	
Output Device	Agilent 8453 Spectrophotometer
Sample Wavelength	296 nm

Table 1. MultiDose G3 Automated Settings

### MultiDose G3 with Concurrent Manual Sampling

The MultiDose G3 performs the dissolution run by pre-heating the media, washing the vessels, filling the vessels, equilibrating the vessels to temperature, dropping the calibrator tablets, and timing the sampling point. When the sampling point is reached, the MultiDose G3 and an analyst sample from each vessel at the same time. Manual sampling is done from each vessel according to the USP manual method. Both the manual and automated samples are analyzed according to the procedure contained in the USP manual method on the same spectrophotometer.

## Results

The results are based on an UV standard reading before sampling. The results are shown in Table 2.

Vessel Number	Concurrent Manual Salicylic Acid % Dissolved	MultiDose G3 Salicylic Acid % Dissolved	Difference Manual - MultiDose
1	20	20	0
2	21	20	1
3	21	21	0
4	22	22	0
5	21	20	1
6	22	22	0
Mean	21	21	0
SD	1	1	
% RSD	3.6	4.7	

Table 2. Equivalency Study for Salicylic Acid Lot N at 100 rpm

## Discussion

The MultiDose G3 results for Salicylic Acid did not vary from the concurrent manual results for any one vessel at the 30 minute time point by more than 1% dissolved. At the 30 minute time point, the mean results and manual mean results for 6 vessels are identical

The MultiDose G3 Salicylic Acid passed the USP specification of 17-26% for percent dissolved at 30 minutes.

## Conclusion

Equivalency between manual dissolution sampling and analysis and automated dissolution sampling and analysis using the salicylic Acid calibrator tablet has been demonstrated.

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