Application Note

Automated Powder Transfer and Assay using TPW™ II

Jayne M. Brown, Lynn Jordan
Caliper Life Sciences Corporation, Applications Laboratory, Hopkinton, Massachusetts, USA

Introduction

Pharmaceutical companies are being required to test an increasing number of pharmaceutical granulations and blends. This is due to heightened FDA focus on uniformity in both process validation and in process control. Some powder blends can be difficult to manually transfer to a volumetric flask. These powder blends are just as difficult to transfer into the TPW II dispersion vessel. Powders can fall from the test tube onto the rim of the vessel during the tipping operation and they can stick to the test tube due to static electricity resulting in low or variable recovery. To prevent this, the powder blends can be contained in a cellulose thimble. In this study, the TPW II Workstation is used to automate a blend assay by dispersing the blend contained in a cellulose thimble. This allows the analyst to use the TPW II Workstation as a tool to perform the necessary blend assay studies without interference from the cellulose thimble on recovery. The objective of this application note is to document the results of a blend assay with and without a cellulose thimble.

Materials and Methods

Instrumentation

All testing was performed using a TPW II Workstation (Caliper Life Sciences) with the optional Large Tube Conversion Kit (for 20 x 150mm test tubes). On-line UV analysis was used with an 8453 UV/Vis Spectrophotometer (Agilent) with 0.5 cm flow through cells.

Materials

Cellulose Extraction Thimbles (Whatman, 10mm x 50mm) were used for the experiments. See Figure 1.

Figure 1

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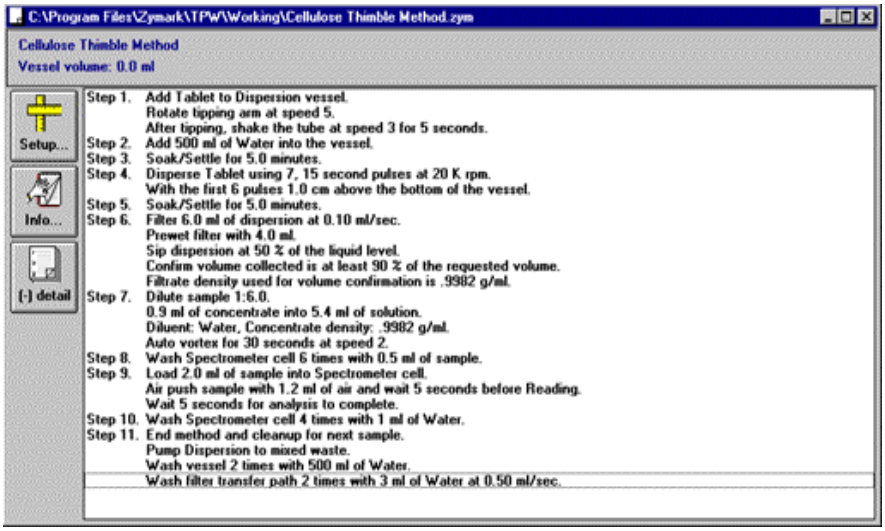
TPW II Method

For the TPW II method without the cellulose thimble, a 20 x 150mm glass test tube is filled with 2.5 grams of powder blend.

Before the TPW II method is started, the empty thimbles are tared on a 4-place analytical balance. Next, 2.5 grams of powder blend are placed in the thimble with a spatula and the top of the thimble crimped closed. The cellulose thimble is placed in a 20 x 150mm glass test tube and then placed in rack one. When the test tube is tipped, the cellulose thimble containing the blend is dropped into the TPW II dispersion vessel. A soak/settle for 5 minutes softens the cellulose thimble enough to allow dispersion of the blend and thimble. The TPW II disperses the blend powder and thimble in solvent, after which another soak/settle of 5 minutes lets the cellulose settle to the bottom of the dispersion vessel allowing aspiration of clear solution. After the blend is dispersed, the TPW II filters and dilutes the resulting solution then automatically sends the sample to an on-line UV/VIS spectrophotometer for analysis.



Results

The TPW II method of directly pouring powder blend material into the TPW II dispersion had an average of 96% recovery for six replicates. When the blend material was placed in a cellulose thimble and processed the mean of six assay samples was at 100.5% with a standard deviation of 0.9%.

Discussion

A powder blend can have different characteristics when the environment changes in the laboratory. Summertime has a high humidity that can cause the powder blends to stick and clump. In the wintertime lower humidity results in static electricity and the powder blends can fly through the air. In either case powder blends may stick to the glass test tube and not dump completely into the TPW II dispersion vessel. In this experiment we demonstrate that the TPW II and cellulose thimbles can be used to process powder blend assay samples without loss of sample or interference from the cellulose thimble on recovery.

Conclusion

Use of the cellulose thimble provides a superior method for processing powder blends that demonstrate low recovery using the TPW II Workstation.

Caliper LifeSciences

US Office

Corporate Headquarters

Caliper Life Sciences, Inc.
68 Elm Street
Hopkinton, MA 01748-1668
Telephone: 508-435-9500
Fax No: 508-435-3439
Website: www.caliperLS.com

Worldwide Offices

France
Caliper Life Sciences S.A.
ZAC PARIS-NORD II
13 rue de la Perdrix
BP 40016
95911 Roissy Charles de Gaulle Cedex
France
Telephone: +33-1-48-63-71-35
Fax No: +33-1-48-63-71-53

Benelux
Caliper Life Sciences NV/SA
Klapstraat 13
B-1790 Teralfene
Belgium
Telephone: +32-53-66-26-70
Fax: +32-53-66-27-32

Germany
Caliper Life Sciences GmbH
Eisenstr. 9c
DE-65428 Rüsselsheim
Germany
tel. +49 6142 834 93-0
fax: +49 6142 162 821

Japan
Caliper Life Sciences Japan
Saito-Bldg. 2F
Yushima 2-17-15, Bunkyo-ku
Tokyo 113-0034
Japan
Telephone: + 81-3-5840-6551
Fax: + 81-3-5840-6554

Switzerland
Caliper Life Sciences AG
Nordstrasse 17
CH-4665 Oftringen
Switzerland
Telephone: + 41-62-788-7000
Fax: + 41-62-788-7017

United Kingdom
Caliper Life Sciences Ltd.
1 Wellfield
Preston Brook
Runcorn, Cheshire WA7 3AZ
United Kingdom
Telephone: +44-1928-711448
Fax No: +44-1928-791228

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