Number 1

NITROGLYCERIN TABLET ASSAY USP METHOD 23

The Alcott Chromatography Applications Laboratory has completed a study, comparing the use of the Alcott Chromatography FilterCaps with hand filtering using Whatman GF/F glass filters for the USP Method 23 assay of Nitroglycerin tablets. The tabulated results of the study are presented on the reverse side.

Three sample solutions were prepared as per the procedure described in the USP 23 assay. Each solution consisted of 25, weighed Nitroglycerin Tablets dissolved in 100 mL of the 50/50 Methanol/Water Mobile Phase. The weights of the tablets for each solution were as follows:

Solution #1: 0.8110 g
Solution #2: 0.8035 g
Solution #3: 0.8154 g

Six autosampler vials were prepared from each of the sample solutions, for a total of nine vials. For each sample solution, three vials contained unfiltered sample and were sealed with a FilterCap . The remaining three vials were filled with sample that had been hand filtered using the Whatman GF/F, 25 mm glass fiber filter and capped with a standard vial cap.

The samples were chromatographed using the following conditions:

Column:	Spherisorb ODS II, 5 μm, 150 mm × 4.6 mm ID.
Mobile Phase:	50/50 Methanol/Water, continuously Helium sparged
Flow Rate:	1.0 mL/min
Detector:	UV at 220 nm.
Integrator:	Spectra-Physics ChromJet 4400

The results for all three solutions are summarized in Table 1.

Table 1 lists the Nitroglycerin Peak Areas for each sample along with the Peak Area Average, Standard Deviation (Std Dev), and Relative Standard Deviation (RSD (%)) for each set of vials. The RSD values indicate the injection precision, which is exceptional for this sample. The bottom row on the table list the Percent Differences (% Diff) between the Peak Area averages for each of the sample solutions filtered with the FilterCap and those hand filtered with the Whatman GF/F disks. These numbers are well below 0.5 % indicating that there is no statistical difference between samples filtered with the FilterCap and those manually filtered with the Whatman GF/F disks. This indicates that the use of the Model 708 Autosampler, combined with the FilterCap, should have no statistical difference with the manual Nitroglycerin tablet assay, and would greatly reduce sample preparation time allowing the laboratory to process more samples with a higher degree of precision.

TABLE 1
Nitroglycerin Tablet Assay
Filter Comparison

	Sample # 1		***Sample # 2***		***Sample # 3***	
	GF/F	***Filtercap***	***GF/F***	***Filtercap***	***GF/F***	***Filtercap***
	1366037	1370421	1350712	1356296	1381568	1391016
	1365632	1361543	1345493	1356326	1383828	1388802
	1365804	1365388	1346240	1358073	1383480	1393321
	1367719	1365845	1355368	1354467	1390239	1388393
	1375401	1363897	1352051	1358286	1384369	1404488
	1370030	1360674	1357273	1353805	1390461	1387973
	1368401	1363847	1355554	1358577	1390955	1389054
	1370052	1368013	1360799	1354391	1391488	1402863
	1370203	1362850	1349475	1348571	1387107	1388367
Average	1368808.8	1364719.8	1352551.7	1355421.3	1387055.0	1392697.4
Std Dev	3094.26	3091.46	5123.70	3128.32	3826.21	6457.77
RSD (%)	0.23	0.23	0.38	0.23	0.28	0.46
% Diff	0.30		-0.21		-0.41	