

Hypertensive Drug Assay, USP Method Comparison

A comparative study was conducted by Elan Pharmaceutical on the use of FilterCaps™ versus manual filtering in the analysis of a hypertensive, calcium channel blocker drug. The assay procedure used was the standard USP method for analysis of the drug as described in the USP Standard Methods Manual. After the sample has been prepared in the describe method, it is ready for analysis by HPLC. The final sample preparation step is to filter the sample. The chemist who conducted the study found that the average time expenditure for the manual filtering procedure was about 1.5 minutes for each sample. When the FilterCaps were used, the total time expenditure for the filtering was less than 30 seconds per sample. In addition to the time savings, a large laboratory supplies cost savings was realized because the need for disposable beakers, syringes, as well as the filter cartridges was no longer necessary.

A partial listing of the results of the comparison study is shown in Table 1. The code numbers in the column labeled Sample Description is the drug batch number. The second column is the Sample Number. The primed Sample numbers are those samples filtered by the FilterCap. The Third Column is the Assay Value or the potency value of the sample. The forth column is the average Assay Value for each sample. Finally, the last column is the Percent Difference of the Assay Value between the samples filtered by hand and those filtered by the FilterCap. The average Percent Difference is less than 0.5% for most of the samples indicating that there is no statistical difference in the samples processed by FilterCaps compared to those filtered manually.

Table 1: ELAN PHARMACEUTICAL DATA

SAMPLE DESCRIPTION	SAMPLE #	ASSAY	ASSAY AVG.	% DIFFERENCE
3N127	1'	428	429	-0.92
	2'	429		
3N128	1	435	436	-0.23
	2	431		
	3'	434		
	4'	437		
3N131	3	435	437	-0.23
	4	438		
	5'	436		
	6'	439		
3N132	5	436	439	-0.45
	6	441		
	7'	445		
	8'	449		
3N129	7	447	449	-0.45
	8	451		
	9'	443		
	10'	446		
3N133	9	445	447	-0.23
	10	448		
	11'	443		
	12'	438		
3N134	11	442	442	0.23
	12	442		
	13'	440		
	14'	441		
3N140	13	438	440	-0.67
	14	441		
	15'	442		
	16'	444		
3N144	15	444	446	-0.22
	16	447		
	17'	444		
	18'	447		
3N135	17	445	447	0.00
	18	449		
	19'	448		
	20'	451		
3N137	19	449	450	-0.23
	20	451		
	21'	443		
	22'	440		
3N138	21	443	443	-0.44
	22	443		
	23'	447		
	24'	449		
3N139	23	449	450	-0.68
	24	451		
	25'	437		
	26'	442		
3N244	25	441	443	0.22
	26	445		
	27'	454		
	28'	458		
3N142	27	451	455	1.33
	28	458		
	1'	460		
	2'	455		
3N143	1	453	456	1.11
	2	451		
	3'	454		
	4'	458		
3N144	3	449	451	1.77
	4	452		
	5'	461		
	6'	456		
3N145	5	451	451	1.80
	6	450		
	7'	453		
	8'	452		
4A304	7	444	445	-1.16
	8	445		
	17'	438		
	18	416		
	17	442	432	
	18	421		