EVALUATION OF THE ROYCO 367 SMALL VOLUME SAMPLE FEEDER FOR ESTIMATION OF PARTICULATE CONTAMINATION IN AMPOULES

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Particulate contamination standards are the subject of monographs in many pharmacopaeias including the B.P. and U.S.P. In general the standards allow for a range of instrumental techniques to be used but this in itself creates some difficulties (Davies et al, this conference) due to the differences in methodology. The techniques available usually require a large sample volume which necessitates the addition of diluting fluid to the sample when small volumes only are available. Recently Tsuji & Lewis (1978) examined over 100 small volume parenterals to see the extent of any contamination. In this study a Royco 367 small volume sample feeder has been used. This is capable of withdrawing 0.5, 1.0, 2.0 or 5.0 ml from an ampoule and passing the liquid through a Royco 342 sensor. A fixed flow rate of 25 $ml.min^{-1}$ is used which means that sampling time is short and large numbers of ampoules can be readily examined. In order to carry the liquid through the system without air bubbles, clean ballasting water is used

A number of batches of water for injection have been examined, the results are shown in Table 1. It can be seen that the degree of variation is quite small indicating a good reproducibility for the unit. Care has to be taken if the surface tension is low, as the suction appears to cause small gas bubbles to be released. This happened with sample A and is shown as a high count at the 2 μm size level. When tested by other techniques this sample had significantly lower counts at the same level.

In conclusion, the Royco 367 represents a rapid method of assessing particulate contaimination levels in ampoules without having the problems attendant on the use of dilution techniques.

Acknowledgements to Gelman Hawksley Ltd, Royco Instruments Inc. and Mr. D. Haslop for support in this study.

Sample		A			B			C			D	
No. of ampoules		50			50			49			49	
Ampoule vol(ml)		5			2			2			2	
Test vol(ml)		2			1			1			1	
Counts per ml at size greater than	$\bar{x}$	ν	σ	$\bar{x}$	ν	σ	$\bar{x}$	ν	σ	$\bar{x}$	ν	σ
2 μm	782	42	5.7	334	53	16.1	222	34	15.5	110	11	10.3
5 μm	117	14	12.2	134	14	10.8	10.5	16	16.2	66	7	11.0
10 μm	55	10	19.4	55	6	12.0	52	7	14.8	39	4	10.6
20 μm	24	3	20.3	20	2	11.7	23	2	10.6	20	2	11.0
50 μm	6	0	18.5	3	0	13.9	6	0	10.9	4	0	13.3

$\bar{x}$ = mean count; σ = standard deviation; ν = coefficient of variance

Tsuji, K. & Lewis, A.R. (1978) J.Pharm.Sci. 67, 50-55