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A comparative study of BP and USP rotating basket dissolution apparatus

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The difference between BP and USP rotating basket dissolution apparatus was investigated by applying both methods to a range of commercial formulations and the NCDA Performance Standard II. No significant differences were obtained between the two sets of apparatus for the commercial tablets. However appreciable difference was observed with the NCDA calibrator.

In the early 1960s criticism of the tablet disintegration test as an indicator of product performance generated a search in the USA for a better method. Initially attempts were made to improve the disintegration test apparatus, however, by the mid-1960s it had been suggested that the disintegration test should be phased out in favour of a dissolution test.

A joint United States Pharmacopeia/National Formulary (USP/NF) expert panel was formed and details of the rotating basket apparatus were published in the USP XVIII and NF XIII (1970). A dissolution test was specified in six monographs of the USP XVIII and subsequently the application of the test has been widened to encompass the monographs of the USP XX.

The USP Convention proposed in 1980 that all tablet and capsule monographs should include a dissolution test. A general specification of 75% content of active substance dissolved in 900 ml of water in 45 min using either USP apparatus No. 1 (rotating basket) at 100 rev min^{-1} or apparatus No. 2 (paddle) at 50 rev min^{-1} was proposed and has been adopted for most relevant USP monographs. While the rotating basket dissolution apparatus has been criticized on the basis of poor reproducibility and lack of correlation with in-vivo data, it is still widely used.

In Australia, in the absence of any relevant national standards, dissolution requirements for pharmaceutical products are determined by the appropriate monographs of the British Pharmacopoeia (BP) or the specifications agreed between the Department of Health and the manufacturer. A total of 18 dissolution specifications were included in the BP 1980 which became official for Australian testing purposes on 1 August 1981. The only significant differences between the test apparatus described in the BP 1980 and that of the USP is the shape of the base of the vessel. The base of the BP 1980 vessel is flat while that of the USP XX vessel is hemispherical.

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As most local pharmaceutical manufacturers have adopted USP XX apparatus, the study reported here was carried out to determine if the results obtained using the BP 1980 and USP apparatus No. 1 (rotating basket) test procedures are comparable.

Method

Dissolution rates were determined for six commercially available products and the USP prednisone calibrator using the rotating basket apparatus with USP and BP vessels. Commercially available tablets containing phenylbutazone, quinine sulphate, quinine bisulphate, warfarin sodium, prednisone and prednisolone were examined using appropriate test conditions (Table 1). In each test 1 litre of degassed dissolution medium was used.

A Hanson Research model QC72S six spindle dissolution apparatus was used throughout the program. Three USP and three BP dissolution vessels were employed in each determination to minimize errors due to fluctuation in rotational speed and vibration of the apparatus.

Samples of dissolution media were taken sequentially via an Altex six way sample valve at approximately 1 min intervals. The interval between sampling cycles was 6 min for all samples except prednisolone and prednisone 5 mg tablets when it was 3 min. Content of

Table 1. Conditions of test.

Product	Dissln medium	Speed (rev min^{-1})	No. of tabs per basket	Detection path length (mm)	γ
Phenylbutazone 100 mg	1	100	1	1	264
Quinine sulphate 300 mg	2	100	2	1	317
Quinine bisulphate 300 mg	2	100	2	1	317
Warfarin sodium 5 mg and 7·5 mg	3	100	1	10	360–306*
Prednisone 5 mg	4	50	2	10	242
50 mg	4	50	1	1	242
Prednisolone 5 mg	4	100	2	10	246

Media
1. Phosphate buffer pH 7·5. 2. 0·1 M hydrochloric acid. 3. Phosphate buffer pH 6·4. 4. Water.
* The difference between the absorbance at 360 nm and 306 nm is determined.

Table 2. Content of active substance released.

Product	Brand	USP vessel				BP vessel			
		30 min	45 min	SD30[a]	SD45[a]	30 min	45 min	SD30[a]	SD45[a]
Phenylbutazone tablets 100 mg	A	20	49	8	12	17	39	5	6
	B	90	98	9	9	91	100	3	2
	C	1	15	1	7	1	2	2	9
Quinine sulphate tablets 300 mg	D	99	101	4	5	98	101	4	2
Quinine bisulphate tablets 300 mg	D	—	105	—	3	94	105	15	4
Warfarin sodium tablets 5·0 mg	F	101	103	1	2	100	103	2	1
	G	46	58	2	3	45	56	3	4
7·5 mg	F	95	96	1	1	94	95	1	1
Prednisone tablets 5 mg	E	95	100	5	5	99	100	7	5
50 mg	H	59	70	4	5	57	71	4	6
Prednisolone tablets 5 mg	E	45[b]	103	7	4	40[b]	100	10	5

[a] SD—Standard deviation (for 6 results). [b] Tested after 20 min (USP XX requirement). [c] Standard deviation (for 6 results) after 20 min.

drug substances in the dissolution media was determined by ultraviolet (uv) spectrophotometry. The sampling pump, six way valve and uv detector were controlled by a Commodore CBM 3032 minicomputer. Dissolution rate profiles were presented on a visual display unit as well as being printed to produce a permanent record.

Results and discussion

For each determination the time taken for the dissolution of 10, 20, 30, 40, 50, 60, 70 and 75% of the content of drug substance was calculated. The percentage of active substance dissolved after 30 and 45 min was also calculated for each experiment (Table 2).

No significant differences were observed between the results obtained using both types of dissolution vessel other than the data obtained with brands A and C of the phenylbutazone formulations. Minor differences were observed between the initial dissolution rates determined for particular products using the BP and USP vessels. However, it would appear that the shape of the vessel is not a significant factor in determining compliance of the products tested with the general dissolution rate requirement of the BP, which specifies sampling at a single point 45 min after commencement of the test. There are, however, advantages in using the USP vessel since this is suitable for use with both the USP No. 1, BP rotating basket and USP rotating paddle apparatus.

Since this study was completed Cox et al (1982) have reported that the shape of the vessel could result in significant differences in dissolution rate for some formulations. The prednisone 10 mg formulation used by Cox et al (NCDA, Prednisone, Performance Standard II) was tested and the results obtained confirm a difference of about 6% in dissolution rate between the BP and USP vessels at 30 min, with the two sets of apparatus producing a mean release of 68·7 and 74·7% respectively.

Particles from the NCDA calibrator were observed to fall through the basket and settle on the floor of the vessel. The distribution pattern of these particles was dependent on vessel shape with a cone of sediment being formed in the bottom of the USP vessels while the particles in the BP vessels had a tendency to accumulate in the corners.

Conclusion

There was no significant difference in the dissolution rates, determined using the BP rotating basket apparatus with BP or USP vessel, for the commercially available formulations included in this study.

The results obtained indicate that the vessel shape may effect the dissolution rate of some types of tablet when determined with the rotating basket apparatus. None of the commercial tablets tested by this laboratory have exhibited this behaviour but caution should be exercised in interpreting results if tablet fragments accumulate on the bottom of the vessel during the dissolution test.

REFERENCES

British Pharmacopoeia (1980) Her Majesty's Stationery Office, London: pp A114–1A115

Cox, D. C., Wells, C. E., Foxman, W. B., Savage, T. S., King, A. C. (1982) J. Pharm. Sci. 71: 395–399

Pharmacopoeial Forum (1980) 6(5) September–October pp 510–511

United States National Formulary, Thirteenth Edition (1970) Mack Publishing Company, Easton Pa, pp 802–803

United States Pharmacopeia, Eighteenth Revision (1970) Mack Publishing Company, Easton Pa, pp 934–935

United States Pharmacopeia, Third Supplement to the Twentieth Revision (1982) Mack Publishing Company, Easton Pa, pp 310–311