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COMMUNICATIONS

A disintegration test for vaginal tablets: comparison with BP test

MASATOSHI YAMAGUCHI, KEIKI TANNO*, KENJI SUGIBAYASHI**, YASUNORI MORIMOTO**, *Department of Pharmacy, Niigata Prefectural Muikamachi Hospital, Muika-machi, Niigata 949 66, * Department of Pharmacy, Niigata University Hospital, 1-754 Asahimachidori, Niigata-shi 951, and ** Faculty of Pharmaceutical Sciences, Josai University, 1-1 Keyakidai, Sakado, Saitama 350-02, Japan*

Abstract—To improve the disintegration test for vaginal tablets described in the British Pharmacopoeia (BP), a monitoring apparatus was added, and tested with seven effervescent and five non-effervescent tablets. A tablet was placed on the metal disc of the BP disintegration apparatus, and the guided plate was placed on the tablet. The guided plate moved downward smoothly in a cylinder as the tablet disintegrated. The movement was recorded by using a kymograph. The end-point and process of disintegration of the tablet were automatically recorded and the results obtained suggest that the modified test is a useful tool for the quality control of vaginal tablets.

The British Pharmacopoeia (BP) describes a disintegration test and apparatus for vaginal tablets. Although this method is generally suitable, it is often difficult to determine an exact time required for complete disintegration of the tablet and to observe the progress of disintegration during the test. While it is not always necessary to measure exact individual times for disintegration, such information can be of value in examining batch-to-batch variation.

In the present study, a monitoring apparatus previously reported by us (Yamaguchi & Tanno 1986) was added to a BP disintegration apparatus and end-point and process of disintegration measured.

Materials and methods

Materials. Seven effervescent and five non-effervescent tablets were assessed. They were from different manufacturers and on the Japanese market in 1987. Distilled water was used as disintegrating medium in all experiments.

Apparatus for the disintegration test of vaginal tablets. The BP disintegration apparatus (Erweka, West Germany) for vaginal tablets was used (B and C in Fig. 1). The monitoring apparatus consisted of a cross shaped guided plate, E within a cylinder, F, made of a 50 mL plastic disposable syringe (Termo Co., Tokyo, Japan). Four plates of 2, 4, 6 and 8 g were used.

Disintegration test procedure. The BP disintegration apparatus was placed in a vessel of approximately 11 cm in internal diameter containing water at 37 ± 0·5 C. The level of water was adjusted by gradual addition of warm water until the perforations in the metal disc were just covered by a uniform layer of water. A tablet was placed on the centre of the perforated plate and a guided plate was placed on the tablet. The plate moved smoothly downward in the cylinder as the tablet disintegrated and movement was recorded by a kymograph. When the tablet disintegrated completely, the guided plate touched the surface of the perforated plate and the recording showed a horizontal line. This defined the completion of disintegration. Disintegration profiles were observed over 120 min.

The test procedure was carried out strictly according to the BP test. Whether the tablet disintegrated completely or not was examined after 10, 30, 60, 90 or 120 min by using a glass rod. The test was carried out five times using one tablet and stopped when all tablets showed the complete disintegration.

Results and discussion

To find out the optimum weight of the guided plate, the effect of

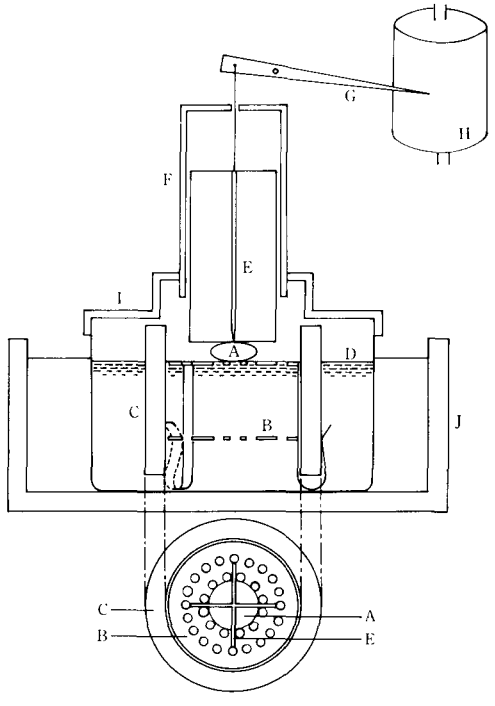

FIG. 1. Apparatus for the disintegration test of vaginal tablets. A, vaginal tablet; B, metal disc; C, plastic sleeve; D, water surface; E, guided plate; F, plastic cylinder; G, writing lever; H, kymograph; I, plastic cover; J, thermostat.

Correspondence to: M. Yamaguchi, Department of Pharmacy, Niigata Prefectural Muikamachi Hospital, Muika-machi, Niigata 949-66, Japan.

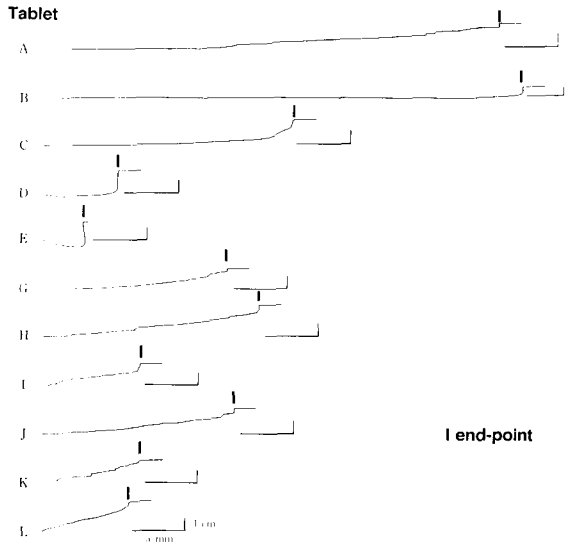

FIG. 2. Kymographic recordings of the disintegration of vaginal tablets. Weight of the guided plate; 6 g. No end-point was found for tablet F in 120 min. Tablets A, B, C, D and E were non-effervescent, and others effervescent tablets.

the weight of the guided plate on the disintegration of vaginal tablets was investigated. In general, the disintegration times showed a tendency to decrease with increasing weight of the guided plate, although Tablet F showed no end-point within 120 min, even when the 8 g guided plate was used. A 6 g plate was found to be most satisfactory and Fig. 2 shows the typical patterns of kymographic recordings. The swelling of the tablet was observed in the recordings of Tablets D and E. The disintegration time of each tablet determined was:

A, 43·4±2·2 min; B, 62·2±6·2 min; C, 23·5±2·4 min; D, 7·6±0·5 min; E, 4·9±0·6 min; G, 17·9±0·6 min; H, 20·7±1·4 min; I, 9·1±0·5 min; J, 19·3±1·8 min; K, 10·4±1·0 min; L, 9·9±2·1 min.

Table 1. Disintegration test for vaginal tablets of British Pharmacopoeia.

	Time (min)				
Tablet	10	30	60	90	120
A	0/5	0/5	5/5		
B	0/5	0/5	2/5	5/5	
C	0/5	5/5			
D	5/5				
E	5/5				
F	0/5	0/5	0/5	0/5	0/5
G	0/5	5/5			
H	0/5	5/5			
I	5/5				
J	0/5	5/5			
K	3/5	5/5			
L	3/5	5/5			

Values represent the number of tablets. Each numerator represents the number of tablets which showed the complete disintegration at prescribed times.

Each value represents the mean±s.d. of five experiments.

Table 1 shows the results of the BP disintegration test and they agree well with those obtained by using a 6 g guided plate. This suggests that the limit of the test for the proposed method can be set at 30 min, as that adopted for the BP test.

From the results obtained, this modified method has the advantages of a sharp end-point providing an exact disintegration time and continuous assessment of the disintegration process.

References

Yamaguchi, M., Tanno, K. (1986) Design and evaluation of a new disintegration test apparatus for vaginal tablets. Yakugaku Zasshi. 106: 228–232