J. Pharm. Pharmac., 1967, **19**, 329–331 Received November 9, 1966

Apparatus for studying the disintegration of tablet coatings

W. ANDERSON AND A. SAKR

A new apparatus has been designed to assess rates of disintegration of tablet coatings and the availability of coated tablet contents. Random movement of the coated tablet in a known volume of mildly turbulent disintegrating fluid at a standard temperature is achieved in a perforated Perspex drum made to revolve slowly in the fluid which moves up and down in its container at the same time. The procedure eliminates the tendency for coatings to stick together or to the grid during a test, which is seen with present pharmacopoeial designs and which causes large variability in the results.

SYSTEMATIC examination of the disintegration or dissolution rates (herein called disintegration rates) of tablet coatings, with the possible exception of the "enteric" coating, has received scant attention.

The test of the British Pharmacopoeia (1963) for the coated tablet is the test for the uncoated tablet with extended time. The apparatus is such that the coating of a tablet can be unevenly abraded by falling many times onto the grid with the same side downmost. Also, with the five coated tablets which are used in this test, the chance of the wetted coatings sticking to each other or to the grid is much greater than is likely with the uncoated tablet. Sticking is due to the presence of gelatin, acacia and similar substances in the coating. The presence of five coated (or uncoated) tablets in the stomach or in one small section of the intestine at any point in time is unlikely, hence the sticking which frequently occurs in the disintegration apparatus is unlikely to occur in the gut.

Drugs may be incorporated in tablet coatings, and different layers of the coating may contain different drugs or different concentrations of the same drug, necessitating sequential release from the layers of coating in the gastrointestinal tract. There is, therefore, a case for considering the disintegration of coated tablets singly in an apparatus where factors causing uneven disintegration rate of the coat or a part of the coat are absent and in which disintegration occurs layer by layer.

During the development of a spray-pan coating method (Anderson & Sakr, 1966) we had occasion to study disintegration rates of the tablet coatings produced by this method and to compare them with the tablet coatings produced using the traditional method. We concluded that the B.P. apparatus was unsatisfactory for this purpose.

THE APPARATUS

The new apparatus (Fig. 1) consists of a cylindrical disintegration drum of Perspex, 3 cm diameter, 3·2 cm long, perforated with 140 equally spaced holes each 0·24 cm diameter, and fitted internally with a trip bar to minimize contact with the sides of the drum and to ensure that the coated tablets tumble in the fluid and do not slide round the inside. The tablet is placed inside the drum (the cap can be removed) which is then made to revolve by a pulley drive 10 times/min within a disintegration tube of 300 ml capacity, 5·5 cm diameter, 14 cm in height, containing the

From the Department of Pharmacy, University of Strathclyde, Glasgow, C.1.

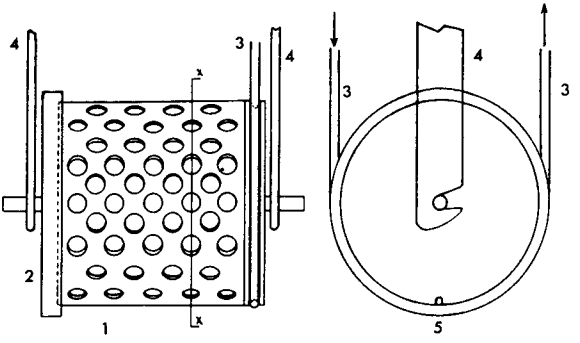

FIG. 1. Disintegration drum. 1. Drum; 2. Cap; 3. Drive; 4. Supporting shafts; 5. Trip bar. The drum revolves in a disintegration tube which moves up and down and contains fluid.

desired disintegration fluid. The disintegration tube is made to move up and down 25 times/min so that the revolving drum just fails to break the surface of the fluid at the bottom of the stroke of the tube, and just fails to touch the bottom of the tube at the top of the stroke. The revolving of the perforated drum, and the vertical up-and-down movement of the fluid in the tube, ensure that the tablet tumbles in a mildly turbulent fluid; contact with the inner surface of the drum is minimal and, because of the tumbling, random. A tap may be fitted to the disintegration tube to allow sampling of the fluid. Temperature control can be obtained by using a jacketed disintegration tube, or by having a thermostatically controlled heater in the tube, or by housing the apparatus in a cabinet with a thermostatically controlled atmosphere.

Blue coatings containing Sky Blue 1900 [Williams (Hounslow) Ltd.] were deposited on white core tablets by the spray-pan method which has been shown to yield evenly deposited layers of coating (Anderson & Sakr, 1966). The contrast in colour between core and coat allowed easy visual determination of the end-point which was complete removal of blue coating. The dye liberated as the coating disintegrated was determined spectrophotometrically at 635 mμ.

DISINTEGRATION STUDY

For disintegration study, one, two and five tablets were used and 20 determinations were done in each case. The new apparatus and the B.P. apparatus were both used at 37°; different samples of the same batch of tablets were used. Release rate of the dye from the coating using single tablets in the test is shown in Fig. 2. The use of up to five tablets in a test did not significantly affect the rate. Results for release rate in the B.P. test are not included because of the uneven disintegration rate of the coating. It frequently happened that the core on one side had begun to disintegrate before all the coating on the other side had been removed.

This uneven disintegration is not allowed for in the B.P. test which considers only the total disintegration time of the whole tablet, and it renders the B.P. test of little value when information about the disintegration rate of the coating is required. A uniform release rate and a

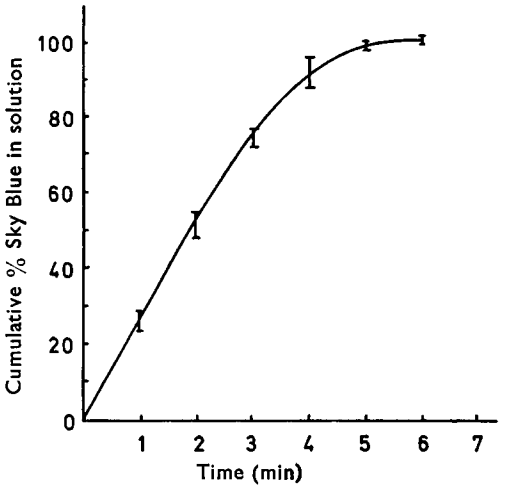

FIG. 2. Rate of release of Sky Blue 1900 from tablet coating. Each point is the mean of five determinations, using single tablets.

disintegration time with small error are necessary for the determination of total availability, with time, of the contents of the coating.

TABLE 1. VARIABILITY OF DISINTEGRATION OF TABLET COATINGS IN THE TABLET DISINTEGRATION APPARATUS OF THE BRITISH PHARMACOPOEIA AND IN A NEW APPARATUS

	Mean disintegration time (min)		Coefficient of variation (%)	
Number of tablets per test	B.P. apparatus	New apparatus	B.P. apparatus	New apparatus
1	3·4	2·4	15·6	2·4
2	3·2	2·5	10·5	1·6
5	2·9	2·8	9·8	1·4

Each mean includes 20 determinations with the relevant number of tablets.

Results of the disintegration tests (Table 1) using the new apparatus show less variability than those obtained with the B.P. type of apparatus. This is due to two factors: elimination of the sticking together of the coatings during the test, and of uneven disintegration of the coatings caused by failure of the tablets to tumble and present both sides with equal frequency to the grid in the B.P. apparatus.

The new apparatus is suitable for release rate studies involving whole coatings, and, as a result of uniform disintegration, different, distinguishable layers of one coating.

Acknowledgement. We thank Mr. I. Aird for help in construction of the disintegration apparatus.

Reference

Anderson, W. & Sakr, A. (1966). *J. Pharm. Pharmac.*, **18**, 783–794.