

NEW APPARATUS

A NEW APPARATUS FOR THE B.P. TABLET DISINTEGRATION TEST

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Under the heading "Disintegration Test" the British Pharmacopœia states as follows:—

"Disintegration Test.—Five tablets are used for the test. Place each tablet in a test-tube, 6 in. long and 1 in. in internal diameter, containing sufficient water heated to 37° C. to fill the tube almost completely, so as to leave about half an inch of air space when the tube is closed. Close the tube, place it in a water bath maintained at 37° C., and repeatedly invert it at such a speed that the tablet travels through the water without striking the ends of the tube; the time required for the tablet to dissolve, or to disintegrate, or to soften throughout so that it disintegrates on a slight touch, is not more than 15 minutes, unless otherwise stated in the monograph. All five tablets should comply with the test. If one tablet fails to comply, the test may be repeated, using five tablets from the same sample; all must comply with the test."

In practice, the inversion of 5 tubes in a water bath at 37° C. presents certain difficulties. If the inversion is carried out by hand, the test is tedious in any case and if required for appreciably longer than the 15 minutes, it becomes very monotonous besides being a waste of time. The number of tests that can be carried out simultaneously is restricted and individual differences arise between operators. If the inversion is performed mechanically, a water bath is not very suitable as a medium for maintaining the temperature of the tubes. No standard apparatus is available and various devices, e.g., vacuum jacketed tubes have been used in the past. The apparatus described below and illustrated in the diagram is simple to construct and has proved very satisfactory for routine use.

The tubes are mounted radially on clips, on a rotating disc in a shallow cupboard maintained at 37° C. by a thermostat and heated by warm air. The cupboard is enclosed by a perspex panel and the progress of the disintegration can be followed all the time through this observation door. The disc is rotated by a fast running motor geared down to rotate the disc at a speed which allows the tablets to fall slowly through the water and the method of inversion ensures that the tubes turn over evenly and that the tablets are not knocked about. In the model shown, 10 tubes, equivalent to 2 tests, can be mounted together and this number can be greatly increased by increasing the diameter of the disc and placing the clips closer together. The other end of the motor armature carries a suction fan which takes the air through the short tube shown

projecting on the right, and this air is pumped through a half-inch metal duct into the bottom of the cupboard. The short tube contains a 250-watt element which heats the air as it passes through and which is automatically cut out through the action of the thermostat in the cupboard when the temperature of the air inside reaches 37°C . In this way the temperature of the air inside the cupboard is maintained between 36° and 38°C .

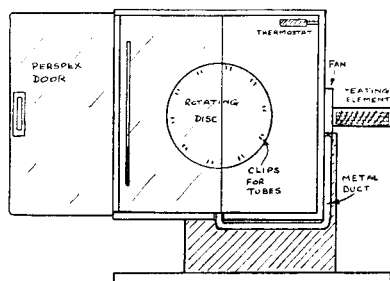


FIG. 1.

In use the cupboard is allowed to attain a steady temperature and test tubes with B.24 ground glass stoppers containing the tablets are filled with water at 37°C ., leaving a small air space. The motor is then switched off, the tubes placed in the clips and the apparatus restarted. The progress of the disintegration can then be followed continuously or a timing clock can warn the operator after any desired interval of time. Tests on tablets with abnormally long disintegration times, or special tests, for instance, in the examination of enteric coatings or hardened gelatin capsules, can be continued for hours without further attention and any tube can be removed quickly at any time to allow closer examination of the contents. The results obtained are reproducible and agree with those obtained by manual methods.

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