Precision Apparatus for Dissolution Rate Determinations

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An apparatus particularly useful for intrinsic dissolution rate determinations by the rotating disk method is described. It affords precision speed control, wide range of rotation rates, good shaft concentricity, and maintains constant speed over extended periods of time. The apparatus is particularly useful for dissolution rate studies at very low rates of rotation.

THE USEFULNESS of the rotating disk method for intrinsic dissolution rate determinations based either on periodic assays of the medium (1) or on determination of weight loss of the disk (2) has been demonstrated and discussed in a number of recent publications (1–7). It is frequently necessary to determine the dissolution rate of a given drug at different rates of agitation in order to characterize fully its dissolution behavior and to elucidate the mechanism governing the rate of dissolution (6, 8). This makes it desirable to have available an apparatus which affords rates of rotation encompassing as much as two orders of magnitude. The stirrer shaft must be free of vibration and other extraneous (nonconcentric) motion, particularly at higher speeds, and the apparatus must maintain a given rate of rotation accurately for extended periods of time, despite motor heating. The latter requirement is particularly important at the lower speeds, in view of the marked effect of rate of rotation on dissolution rate at lower rotation rates, and the longer duration of experiments performed at low rotation rates. These requirements are not satisfied by the usual commercial stirrers which we have examined. The electronically controlled stirrer which we have used in previous studies (9) permits precision speed control, but is not functional at very low speeds and does not offer a vernier device for rapid regulation of speed. The apparatus to be described in this communication was designed to fulfill the stated needs.

A model T-8 Sigmamotor pump[1] consisting of a 1/8 hp., 110 v., 60 cycle, 1725 r.p.m. single phase explosion-proof motor connected to a model 14 Revco Zero Max speed changer (with vernier control), which in turn is connected to a Sigmamotor pump head, provided the basic equipment. The pump head was removed, and two vertical support rods were attached to the base of the unit in its stead. A vertical sliding bar was attached to the support rods. Clamps were provided to secure the vertical bar at any desired height. A heavy duty flexible shaft (the speedometer cable from a truck) was coupled to the output shaft of the speed changer. The flexible shaft terminates at the cross-bar, where it was coupled to a short (9 cm.), 0.75 cm. diameter, rigid stainless steel shaft. Vertical motion of the latter was prevented by a sleeve at the cross-bar, while nonconcentric motion was minimized by keeping the steel shaft short. A disk holder (1) can be attached to the end of the steel shaft with another accurately machined sleeve. The disk holder can be removed easily by loosening two setting screws in the sleeve. Immersion of the disk holder into and removal from the dissolution medium are accomplished by lowering and raising, respectively, of the cross-bar. The apparatus is shown in Fig. 1.

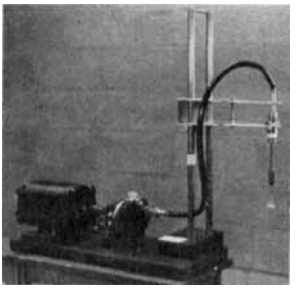

Fig. 1.—Precision apparatus for dissolution rate determinations. (See text for detailed description.)

The vernier speed control is calibrated readily by means of a suitable tachometer (at higher speeds) or by stop-watch (at lower speeds). The equipment has been operated continuously for up to 48 hours without difficulty. Dissolution rate experiments at speeds as low as 4 r.p.m. and of 6 hours duration have been carried out without measurable variation in rate of rotation, evidenced by periodic direct speed determinations and by the constancy of the dissolution rate data. The range of rotation rates of the apparatus is approximately 3 to 400 r.p.m.

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[1] Manufactured by Sigmamotor, Inc., Middleport, N. Y.

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