# Gasket Insert Modification of U.S.P. Tablet Disintegration Apparatus

*Sir:*

The U.S.P. XVI apparatus for tablet disintegration testing specifies a basket rack assembly consisting of six open glass tubes each 7.75 cm. long and having an inside diameter of approximately 21.5 mm. Each tube is provided with a slotted and perforated cylindrical disk 9.5 mm. thick and 20.7 mm. in diameter.

The procedure directed for disintegrating uncoated and plain coated tablets is to place one tablet in each of the six tubes of the basket, add a disk to each tube, and then operate the apparatus as indicated in the tablet disintegration test monograph.

It has been our experience that many tablets will lie flat on the bottom wire screen, or because of gummy and gelatinous ingredients or ingredients of an adhesive character, either will adhere to the rising and falling disks, or will adhere to the bottom stainless steel wire cloth. In any case, the tablet disintegration system intended by the U.S.P. does not apply. Instead, the net result may be a flattening out of the tablet core caused by the constant action of the falling disk on the same point of the tablet surface. With other tablets, an indeterminate soft mass results which makes exact timing of the disintegration end point difficult.

We have found that by inserting a thin, flexible rubber gasket in the bottom of the glass tubes in contact with the lower stainless steel wire cloth, an increased turbulence is effected in the immersion fluid as the basket rack assembly rises and falls. This turbulence causes the tablets to "bob" up and down, increases the rate of flow of fluid around the tablets, creates more uniform attrition to all of the tablet surfaces, and prevents adhesion of the tablets to the bottom wire cloth. Thus it has served to obviate the use of the disks in tablet disintegration testing in most cases.

As an additional application, the introduction of these gasket inserts permits the use of the U.S.P. disintegration apparatus for establishing *in vitro* disintegration patterns for timed-release and sustained-action tablets. The rate of flow of the fluids around the tablets simulates the flow rate realized in the rotating bottle method (1) recommended by Krueger and Vliet to the P.M.A. Contact Section (2).

The dimensions of the flexible rubber gasket inserts are as follows: external diameter, 21.5 mm.; internal diameter, 15.0 mm.; wall thickness, 3.25 mm.; gasket thickness, 3.5 mm.

(1) Souder, J. C., and Ellenbogen, W. C., *Drug Standards*, **26**, 77(1958).
(2) Krueger, E. O., and Vliet, E. B., THIS JOURNAL, **51**, 181(1962).

LEONARD L. KAPLAN
JOHN A. KISH

Walker Laboratories, Inc.
Mt. Vernon, New York

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# *Book Notices*

*Los Colorantes Sinteticos en Bromatologia y Farmacia.* By J. M. PLA DELFINA. Sociedad Española de Farmacotecnia, Barcelona, Spain, 1961. 372 pp. 16 × 23 cm. Paperbound. Price 200 pesetas.

This monograph (Spanish) includes a brief summary of the legal status of colors used in different countries; it classifies the various colors and describes properties, uses, and methods for detection and determination of coloring materials.

*Organic Syntheses.* Vol. 41. Edited by JOHN D. ROBERTS. John Wiley & Sons, Inc., 440 Park Ave. South, New York 16, N. Y., 1961. ix + 118 pp. 15 × 23 cm. Price $4.

This volume includes methods for 28 compounds. The smallest-scale synthesis yet given is for 0.0005 mole of cholestanyl methyl ether. More than a third of the reactions and compounds described in this volume were unknown five years ago. One illustrative procedure, for the extraordinary conversion of carboxylic acids to trifluoromethyl groups by sulfur tetrafluoride, is included within 18 months after its original publication.

*Textbook of Organic Medicinal and Pharmaceutical Chemistry.* 4th ed. Edited by CHARLES O. WILSON and OLE GISVOLD. J. B. Lippincott Co., Medical Dept., East Washington Square, Philadelphia 5, Pa., 1962. xvi × 883 pp. 18 × 25.5 cm. Price $14.

This established textbook utilizes chemical and pharmacologic classifications to present its text material that has been revised to include the latest available medicinal compounds and other materials of pharmaceutical importance. A Chapter on Physicochemical properties in relation to biologic action has been included. Products in U.S.P. XVI, N.F. XI, N.N.D. 1961, and A.D.R. 1961 have been covered in this edition.