

$\theta = 0.039$. The approximation that we have made then gives an error of 0.05%.

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Elimination of Tablet Air Entrapment Using USP 1 Rotating-Basket Dissolution Apparatus

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To the Editor:

Dissolution testing using the USP 1 rotating-basket apparatus (1) is subject to variability due to an artifact of the method. For certain dosage forms, this artifact results in entrapment of the test specimen in an air bubble at the top of the basket assembly. This air bubble is entrapped if the 2-mm vent hole in the top of the basket assembly is blocked by the tablet as the assembly is lowered into the dissolution fluid or if the bubble is positioned elsewhere on the top of the assembly and does not migrate toward the vent.

Since the rim around the detachable part of the basket

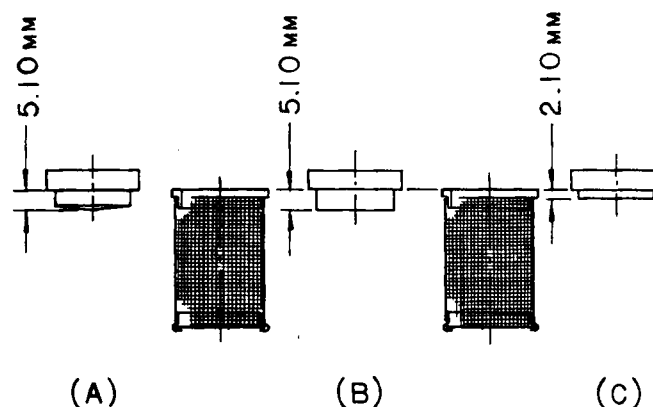


Figure 1—Conical head design (A), extended head design (B), and conventional head design (C).

protrudes below the top of the assembly by about 3 mm, a dead space is available to prevent the bubble from migrating out of the basket at the edge (Fig. 1C). When a tablet is entrapped in this way, the apparent dissolution rate is very low and the dissolution run is invalid.

It was noted in our laboratories that this air entrapment occurred occasionally during dissolution tests on the nondisintegrating USP dissolution calibrator salicylic acid 300-mg tablet. A basket top was fabricated to eliminate the dead space around the basket rim (Fig. 1B), and this simple modification essentially eliminated the problem. However, the problem recurred during testing of an experimental film-coated tablet. For the film-coated tablets, the problem was so severe that several runs were needed to obtain valid six-tablet results. Use of the modified design (Fig. 1B) did not totally eliminate the problem.

To circumvent air entrapment with the film-coated tablets, the top of the basket assembly was modified further by fabricating a slight conical shape such that the center protrudes about 1 mm below the edge. This shape imparts enough of a slope to permit an entrapped bubble to escape and to allow the tablet to return to the bottom of the basket (Fig. 1A). The improvement is dramatic. For example, in one series of six-tablet runs, seven of 18 USP salicylic acid calibrators were air entrapped with the conventional head while the conical head design completely eliminated the problem. For the experimental film-coated tablets, 10 of 18 tablets were air entrapped with the conventional head but only one of 18 was air entrapped with the conical head design.

The conical head modification of the basket top design (Fig. 1A) may be of sufficient utility to warrant general use. It is not inconsistent with the present apparatus description (1); however, it may be advantageous to define explicitly the dimensions in the USP to permit its use.

(1) "Fifth Supplement to USP XIX and NF XIV," United States Pharmacopeial Convention, Rockville, Md., 1979, pp. 221, 222.

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