

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0365]

DDM

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Certifier A. Corbin

**Draft Guidance for Industry on the Use of Mechanical Calibration of  
Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice;  
Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (CGMP).” The draft guidance is intended to aid drug manufacturers and ancillary testing laboratories in using mechanical calibration as an alternate approach to the use of calibrator tablets in calibrating an apparatus used for dissolution testing. The guidance provides references to information on critical tolerances that should be achieved with mechanical calibration.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD

20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Albinus D'Sa, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301-827-9044.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

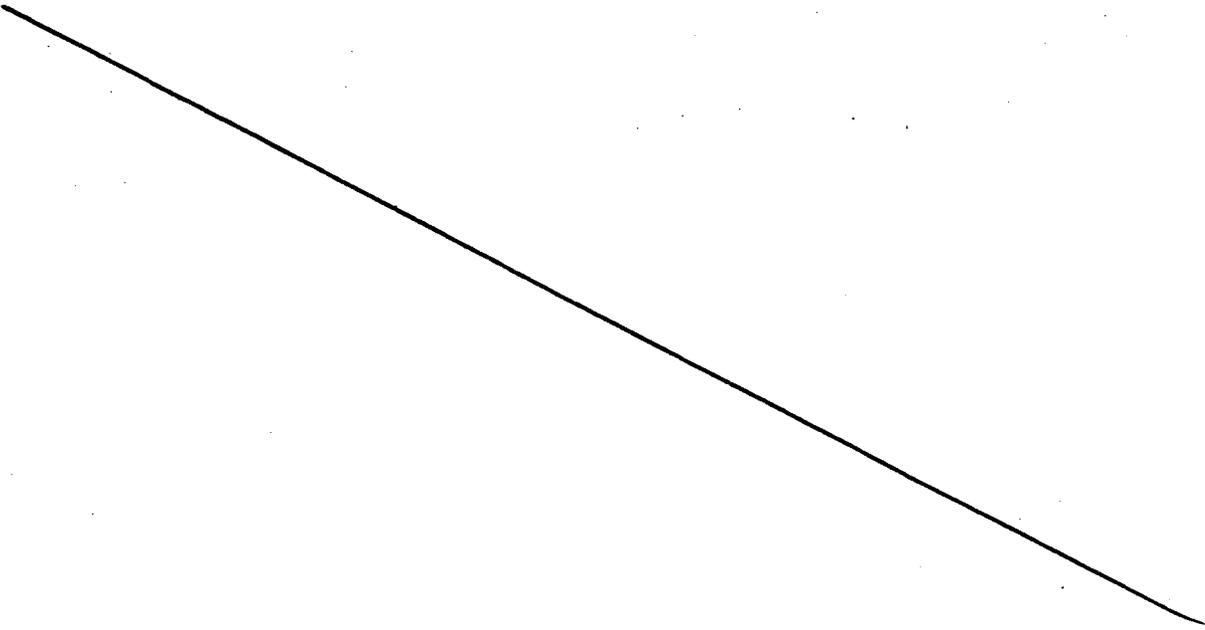
FDA is announcing the availability of a draft guidance for industry entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (CGMP)." FDA regulations require that laboratory apparatus be calibrated at suitable intervals in accordance with established written specifications (21 CFR 211.160(b)(4)). Historically, both chemical and mechanical means have been used in calibrating dissolution apparatuses. Since 1978, chemical calibration has been the predominant method of calibration, consistent with chapter 711 of the U. S. Pharmacopeia (USP), which describes the use of calibrator tablets. Chemical calibration of an apparatus is usually performed, in addition to mechanical calibration, every 6 months. Because the use of USP chemical calibration tablets can lead to variability in the dissolution measurement system, FDA is providing guidance on mechanical calibration as an alternate approach to calibrating dissolution equipment. As stated in the draft guidance, instead of using an external calibrator tablet, a

firm can use an appropriately rigorous method of mechanical calibration as an alternative to ensure ongoing acceptability of the dissolution apparatus.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the use of mechanical calibration of dissolution apparatus 1 and 2 as related to CGMP. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

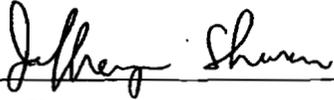


### III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: OCT 15 2007

October 15, 2007.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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