

FDA Update

FDA Publishes Dissolution Test Database

FDA has made public the database containing the dissolution conditions for products approved by the agency. The website was created on November 2, 2005

The website address is www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm

The database will be updated quarterly and if there is a USP monograph for a particular product, the dissolution conditions for this particular product will not be listed in the database.

One can search the website using the generic name for the drug, and a printable PDF file list of all the drugs in the database is available.

The Dissolution Methods Database has been prepared by the Division of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug

Administration. The dissolution methods contained in the database are recommended methods that are not binding on FDA or others. FDA will consider alternate methods when supported by appropriate data. FDA recognizes that the database contains a large amount of material, and methods and specifications may change over time. The FDA welcomes comments or suggested changes to the database. The web site will be revised in an ongoing basis.

The FDA instructs to send suggested changes to this database, along with supporting documentation to:

Division of Bioequivalence (HFD-650)
Office of Generic Drugs
7500 Standish Place
Rockville, MD 20855