(2) Digoxin tablets: Any person marketing digoxin tablets, in addition to complying with all of the requirements of paragraph (a)(1) of this section, shall include in their abbreviated new drug application:

(i) A statement that the applicant will establish procedures to test each lot of digoxin tablets prior to releasing the batch for distribution to assure that the batch meets all of The United States Pharmacopeia (USP XVIII) requirements for digoxin tablets including, but not limited to, potency, content uniformity, and dissolution and that the quantity of digoxin dissolved at one hour is not more than 95 percent of the assayed amount of digoxin or that the quantity of digoxin dissolved at 15 minutes is not more than 90 percent of the assayed amount of digoxin.

(ii) A statement that finished product specifications shall be established to include provisions to assure that the range of average one-hour dissolution values among batches of digoxin tablets does not exceed 20 percent.

(3) Before releasing for distribution any batch of digoxin tablets manufactured after (insert date of publication in the FEDERAL REGISTER), the manufacturer shall:

(i) Test a sample of the batch to assure that the batch meets all of the requirements of The United States Pharmacopeia (USP XVIII) including, but not limited to, potency, content uniformity, and dissolution and that the quantity of digoxin dissolved at one hour is not more than 95 percent of the assayed amount of digoxin or that the quantity of digoxin dissolved at 15 minutes is not more than 90 percent of the assayed amount of digoxin.