(ii) Submit a sample of the batch to the Food and Drug Administration according to the procedures set forth in paragraph (g) of this section. Results of tests conducted on the batch by or for the manufacturer and the batch production record shall accompany the sample.

(iii) Withhold the batch from distribution until he is notified by the Food and Drug Administration that the sample was tested and found to meet all of the requirements in The United States Pharmacopeia (USP XVIII) for 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.