

**10- DRUG SAMPLING SCHEDULES**

(Does not include Antibiotic Preparations)

STERILITY TESTING VITAMINS, DEVICES, & DRUGS

Type of Product	Sample Size <sup>1</sup>	
	INV Sample <sup>2</sup>	Official [702(b) & Check] <sup>3</sup>
DRUGS	36	86
DEVICES	46	106

LEGEND:

<sup>1</sup>Double sample size requirements when individual containers are 2 ml (2 g) or smaller.

<sup>2</sup>INV sample includes units (30 for Drugs & 40 for devices) for examination and 6 units for bacteriostasis.

<sup>3</sup>Official Sample includes units (30 for drugs & 40 for devices) for examination, units (30-40) for check, 20 units for 702(b) [21 U.S.C. 372(b)] and 6 for bacteriostasis.

Note: If a lot is aseptically filled into 200 finished units or less, sample no less than 10% of lot.

DISSOLUTION TEST - USP & NF

Unless directed otherwise by your assignment or supervisor, submit samples to your normal servicing laboratory.

SAMPLE SIZE

Collect a 200 tablet portion for drug potency analysis by the collecting district lab, plus a separate 100 tab portion to be split for dissolution testing.

MICROBIOLOGICAL EXAMINATION OF DRUGS (Other than for Sterility)

PRODUCT	<u>MINIMUM SAMPLE SIZE (Includes 702(b) portion)</u>	
	<u>Sub Size</u>	<u>Nos. of Subsamples</u>
Dosage Form Drugs (See #1 below), Bulk Drugs, or Raw Materials for Manufacturing	90 g or 90 ml	10

SAMPLING INSTRUCTIONS

1. Contact the laboratory (which has microbiological testing capabilities) serving your district for sample size requirements before sampling dosage form drugs containing less than 3 grains, 200 mg, or 25% of the suspect ingredient.
2. Use aseptic technique when collecting samples from raw materials or bulk containers. Implements and sample containers used must be sterile. Submit controls. See IOM 4.3.6 through 4.3.6.5.
3. Submit samples to the laboratory with microbiological testing capabilities which serves your district unless directed otherwise.