

10350 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-106-8700 (Mod. No. 2)

"Assay (in duplicate):

Transfer an accurately weighed sample (about 1.0 Gm) to a 1000 ml volumetric flask. Dissolve in and dilute to volume with distilled water. Record the ultraviolet absorption spectrum of the solution from 300 to 220 millimicrons on a Cary Recording Spectrophotometer, or other suitable instrument giving comparable results, using the following operating conditions: 1 cm cells, distilled water in the reference cell, low speed, large gear, slit width - not more than 0.15 mm at 257 mu. Record a baseline under the same conditions with distilled water in both cells.

Calculations:

$$\frac{(A_{257} - A_{285}) \times 0.995 \times 1000 \times 100}{\text{Sample Wt. (mg)}} = \% \text{ purity}$$

*0.995 = mg dextroamphetamine sulfate/ml/unit - A

Limits: 98 to 102 percent.

"All other ingredients entering into the preparation or manufacture of the tablets shall comply with 85.1."

S6.4.2.1 Uncoated tablets. Delete in its entirety and substitute:

"S6.4.2 Color. Uncoated tablets shall be white,"