

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10327

6505-116-9325 (P.D. #3)

Treat each aliquot alike as follows:

Filter without delay through a 2-1/4 inch Whatman No. 4 paper, or equivalent. Transfer without delay, exactly 2.0 ml of the filtrate to a glass-stoppered test tube, add exactly 10.0 ml of chloroform, then 0.5 ml of diluted hydrochloric acid (10% HCl), and shake for 2 minutes. Centrifuge at about 1000 r.p.m. for 5 minutes to clarify the chloroform layer. Transfer exactly 5.0 ml of the chloroform solution, free from contamination with the aqueous phase, to an extraction flask. Evaporate to dryness on a steam bath under a current of air, reducing the application of heat as dryness is approached. Dissolve the residue in exactly 50.0 ml of 95 percent ethanol. With a suitable spectrophotometer, determine the absorbance of the solutions prepared from the sample, A_u , and the absorbance of the standard solution, A_s , at 220 mμ, using a suitable spectrophotometer, 1 cm cells, relative to 95 percent ethanol as the blank.

Calculate the percent completion of dissolution as follows:

% completion of dissolution =

$$\frac{A_u}{A_u (1 \text{ hr})} \times 100$$

Where: A_u is the absorbance of the respective aliquots, and
 $A_u (1 \text{ hr})$ is the absorbance after 1 hour

Calculate the percent of label claim in solution after 60 minutes, as follows:

% of label claim after 60 minutes =

$$\frac{A_u (1 \text{ hr})}{A_s} \times 100$$

Where: A_u is the absorbance after 1 hour
 A_s is the absorbance of the reference standard.*

*Available upon request from Directorate of Medical Materiel, Technical Operations Division, Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, Pa., 19101, Attention: Material Standards Branch, DPSC-ATSB-1.