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Serum Theophylline Levels.

The average of the serum theophylline levels shall be not less than 150 micrograms percent (1.5 micrograms per milliliter) at 30 minutes, and not less than 300 micrograms percent (3.0 micrograms per milliliter) at 240 minutes. The average shall be based on determinations from not less than thirty (30) patients. In addition, not more than three of the serum theophylline determinations shall be less than 100 micrograms percent (1.0 micrograms per milliliter). All patients shall show serum theophylline concentrations. When the concentration is less than 100 micrograms percent (1.0 micrograms per milliliter) a value of 0.0 micrograms percent (0.0 micrograms per milliliter) shall be used in determining the average. Any individual values which are abnormally high (i.e., more than two and one-half times the respective originally-calculated 1/2 hour and 4 hour averages) shall be eliminated from the calculations.

Note: Not more than six patients may be eliminated from the study due to interferences in the serum, illness of patients, errors in analysis, etc., provided determinations from at least thirty patients are performed. Lack of serum theophylline content shall not be cause for elimination from the study. Results of all patients entering into the study, except those eliminated due to illiness, serum interference, or analysis errors, shall be reported.

S6.4.6 Hardness. The hardness of the tablets shall be not less than 3 when tested by the Stokes Hardness Tester. Twenty (20) tablets shall be tested and not more than 2 tablets may fall below the hardness requirement stated herein, or not less than 5 when tested by the Strong-Cobb hardness tester.

S6.4.7 Scoring. Tablets shall be scored.

S6.4.9.1 Disintegration, Disintegration time shall be not more than 4 minutes using purified water as the immersion fluid at a temperature of 37° C. ± 2° C.