

10334 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

FEDRAL

DEFENSE MEDICAL PURCHASE DESCRIPTION		NUMBER	DATE						
		7	6 October 1970						
FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT							
6505-753-4766	THEOPHYLLINE, EPHEDRINE HYDROCHLORIDE AND PHENOBARBITAL TABLETS, NF, 1000s	Bottle							
Shall be Theophylline, Ephedrine Hydrochloride, and Phenobarbital Tablets, N. F., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 140a, dated 31 October 1966, and Amendment 1, dated 25 March 1970, together with the options and additions stated herein: S2 Classification. Shall be type I, class 1. S5.2 The following additional requirements and tests are added to this paragraph: Shall contain the following formula per tablet, within the applicable assay limits: <table> <tbody> <tr> <td>Theophylline, (Hydrous) -----</td> <td>0.130 Gram</td> </tr> <tr> <td>Ephedrine Hydrochloride -----</td> <td>0.024 Gram</td> </tr> <tr> <td>Phenobarbital -----</td> <td>0.008 Gram</td> </tr> </tbody> </table> The Ephedrine Hydrochloride used in the manufacture of the tablets shall be of N. F. grade, and the Theophylline (Hydrous) and Phenobarbital shall be of U. S. P. grade. All other ingredients used in the manufacture of the tablets shall comply with S5.1. <u>BLOOD LEVEL STUDY</u> <u>Clinical Laboratory.</u> State licensed clinical laboratory or general clinical laboratory of a hospital accredited by the Joint Commission on Accreditation of Hospitals. <u>Qualifications of Investigator.</u> Licensed Medical Doctor with active clinical laboratory experience. <u>Supervision of Clinical Test.</u> The testing shall be performed under the supervision of the Head of the Clinical Laboratory. The findings shall be reported on stationery of the clinical laboratory.				Theophylline, (Hydrous) -----	0.130 Gram	Ephedrine Hydrochloride -----	0.024 Gram	Phenobarbital -----	0.008 Gram
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