

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10287

Serpasil

DEFENSE MEDICAL PURCHASE DESCRIPTION		NUMBER	DATE
		7	10 June 1971
FEDERAL CHECK NO.	ITEM IDENTIFICATION	UNIT	
6505-290-0022	RESERPINE TABLETS, USP, 0.25 mg, 1000s	Bottle	

Shall be Reserpine Tablets, U.S.P., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 140a, dated 30 October 1966, and Amendment-1, dated 25 March 1970, and as specified herein:

S2. Classification. Shall be type I, class 1.

S5.2 The following additional requirements and tests are added to this paragraph:

Shall be tablets containing 0.25 mg of Reserpine per tablet, within the applicable assay limits for the tablets.

The Reserpine powder used in the manufacture of the tablets shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto, and, in addition, shall comply with the following:

Description. Shall be white or pale buff to slightly yellowish, odorless, crystalline powder.

Identification. The infrared absorption spectrum (graph) of the powder in a Nujol dispersion shall compare qualitatively with the spectrum (graph) of the U.S.P. Reserpine Reference Standard.

Specific rotation. Shall be between -115° and -121° when determined as follows:

Accurately weigh about 100 mg of powder previously dried at 60°C . for 3 hours, into a 10-ml volumetric flask. Dissolve in, and dilute to volume with chloroform. Determine the optical rotation of the solution in accordance with the U.S.P. procedure, at 25°C ., using a 1-decimeter tube and the D line of the sodium spectrum. Calculate the specific rotation.

Paper chromatography. The reserpine sample shall show a homogeneous spot comparable in size, and having the same Rf value as the reference standard, except that a trace impurity may remain at the origin and another trace impurity at approximately Rf 0.04. The procedure to be employed shall be as follows:

BRITISH PHARM. SAYS -113° to -123° determined at 20°C - Not Dried -

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USP HAS NO SUCH REQUIREMENTS

WHAT IS THIS SUPPOSED TO DO FOR THEM? - DID THIS

SSC-1

COME FROM THEIR FAVORED SUPPLIER 60