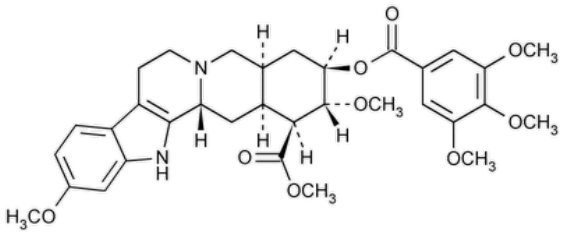
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-B450DCD6-10FE-453D-B86D-189B0D2AF7DC_2_en-US
DOI: https://doi.org/10.31003/USPNF_M73170_02_01
DOI Ref: yxr7p

Reserpine



$C_{33}H_{40}N_2O_9$ 608.68

Yohimban-16-carboxylic acid, 11,17-dimethoxy-18-[(3,4,5-trimethoxybenzoyl)oxy]-, methyl ester, (3β,16β,17α,18β,20α)-.

Methyl 18β-hydroxy-11,17α-dimethoxy-3β,20α-yohimban-16β-carboxylate 3,4,5-trimethoxybenzoate (ester) CAS RN®: 50-55-5; UNII: 8B1QWR724A.

» Reserpine contains not less than 97.0 percent and not more than 101.0 percent of $C_{33}H_{40}N_2O_9$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.

USP Reference standards ⟨11⟩—

USP Reserpine RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020)

B: [Note—Conduct this test promptly, with a minimum exposure to light.] Dissolve 25.0 mg of it, previously dried, in 0.25 mL of chloroform; mix with about 30 mL of methanol previously warmed to 50°; transfer the mixture with the aid of warm methanol to a 250-mL volumetric flask; cool the solution to room temperature; dilute with methanol to volume; and mix. Pipet 10 mL of this solution into a 50-mL volumetric flask, add 36 mL of chloroform, dilute with methanol to volume, and mix: the UV absorption spectrum of a 1 in 50,000 solution so obtained exhibits the same maxima in the range of 255 nm to 350 nm as that of a similar solution of USP Reserpine RS, concomitantly measured; and the respective absorptivities, determined with reference to a mixture of 36 volumes of chloroform and 14 volumes of methanol as the blank, at the wavelength of maximum absorbance at about 268 nm, do not differ by more than 3.0%.

Loss on drying ⟨731⟩—Dry it at 60° for 3 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.1%.

Assay—

Mobile phase—Prepare a filtered and degassed 1:1 mixture of acetonitrile and ammonium chloride solution (1 in 100). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩). The pH is about 5.6.

Standard preparation—Dissolve an accurately weighed quantity of USP Reserpine RS in *Mobile phase,* and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 10 µg per mL.

Assay preparation—Transfer about 10 mg of Reserpine, accurately weighed, to a 100-mL volumetric flask. Dilute with *Mobile phase* to volume, and mix. Dilute 1.0 mL of this solution with 9.0 mL of *Mobile phase,* and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 268-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the column efficiency determined from the analyte peak is not less than 1500 theoretical plates; the tailing factor for the analyte peak is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{33}H_{40}N_2O_9$ in the portion of

Reserpine taken by the formula:

$$C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Reserpine RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
RESERPINE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 42(6)

Current DocID: GUID-B450DCD6-10FE-453D-B86D-189B0D2AF7DC_2_en-US

DOI: https://doi.org/10.31003/USPNF_M73170_02_01

DOI ref: yxr7p