

Xiao'er Kechuan Granules (*Xiao'er Kechuan Keli*) – 小儿咳喘颗粒

Sample source

Commercially available Xiao'er Kechuan Granules

Chemical reference substances

ephedrin hydrochloride (National Institute for the Control of Pharmaceutical and Biological Products)

Preparation of test solution

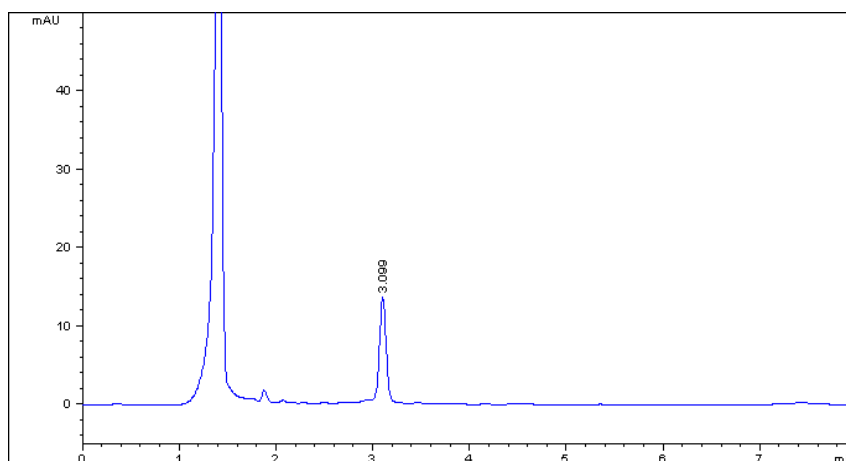
Grind 1 package of the granules to a fine powder, accurately weigh 2.0 g, add 120 mL of 5 mol/L sodium hydroxide and shake well. Add 7.5 g of sodium chloride, treat ultrasonically for 10 minutes, distill, transfer 95 mL of the distillate to a 100 mL volumetric flask, containing 5 mL of 0.5 mol/L hydrochloric acid, add water to volume, and shake well. Accurately transfer 10 mL to a 25 mL volumetric flask, add 1 mL of periodic acid (0.25 g in 10mL) and 2.5 mL of 0.25 mol/L sodium hydroxide, shake well, allow to stand for 30 minutes, adjust to pH 7 with 0.5 mol/L hydrochloric acid, add methanol to volume, shake well, filter and use the filtrate as the test solution.

Chromatographic conditions

- Column: ZORBAX SB C18 4.6×150 mm, 5 µm (883975-902)
- Column temperature: 25 °C
- Mobile phase: methanol-water (58:42)
- Detector wavelength: 254 nm
- Flow rate: 1.0 mL/min
- Injection volume: 10 µL

Chromatographic system

- Agilent 1200 Series quaternary pump with vacuum degasser
- Agilent 1200 Series high-performance autosampler
- Agilent 1200 Series thermostated column compartment
- Agilent 1200 Series variable wavelength detector
- System control through Agilent ChemStation revision B.01.01



Components	k'	Ret Time (min)	Height (mAU)	Area (mAU*s)	n	USP T
Ephedrin	1.582	3.099	13.27	62.6	10264	1.01