ABSTRACT

METHOD FOR ANALYZING RELATED SUBSTANCES IN FEQUESETIDE PREPARATION

A method for analyzing related substances in a fequesetide preparation. In the method, high-performance liquid chromatography is used for determination, wherein the chromatographic column used therein is a YMC-Triart C18 chromatographic column, 4.6 × 150 mm, 3 μm; the column temperature is 35°C; the sample size is 100 mL; the detection wavelength is 210 nm; the mobile phase A is a 0.1% aqueous trifluoroacetic acid; the mobile phase B is 0.1% trifluoroacetic acid-acetonitrile; and gradient elution is used, and the elution program is as follows: at 0 min: the volume ratio of the mobile phase A to the mobile phase B is 100:0; at 8-13 min: the volume ratio of the mobile phase A to the mobile phase B is 85:15; and from 13 min to 20 min: the volume ratio of the mobile phase A to the mobile phase B is 100:0. In the present analysis method, the degree of separation between a main peak and impurity peaks is good, the peak pattern, tailing and number of theoretical plates are good, and the detection time is short; therefore, an effective method is provided for formulating quality standards for products of this type.

FIG. 7