The synthesis and quality control of fexofenadine

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A simple, easy control, low coast, highly productivity synthesis process has been established. With 2-2-dimethyl phenyl acetic acid as a starting material which was reduced first by $LiAlH_4$, then following the procedure of patent US5631357 and finally reduced with $NaBH_4$, we obtained 19.9% of total productivity of fexofenadine. While the HPLC-UV method for the routine quality control of fexofenadine hydrochloride in synthesis products has also been established. By using triethylamine-phosphoric acid aqueous solution (0.10 mol/L) / methanol (45:55) mobile phase (flow rate 1.0 mL/min) and ODS column at ambient temperature, fexofenadine hydrochloride can be well separated from its 3 major synthetic intermediate impurities in 15 minutes. The representative linear equation of the method was $Y = 1.103x10^3X - 1.186x10^3$, where X is the concentration of fexofenadine hydrochloride and Y is the peak area, with correlation coefficient(R) of 0.9999 (n=3) . The limit of quantitation (LOQ) and limit of detection (LOD) of the proposed method were 180 ng and 60 ng, respectively. The RSD of intra- and inter-day precision test of the method were 0.43% and 0.28%, respectively, which had shown great promise in the quality control routine analysis of fexofenadine hydrochloride . The proposed method was demonstrated in degradation test of fexofenadine hydrochloride.