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标题: Solid State Characterizations and Analysis of Stability in Azelnidipine Polymorphs
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摘要: Azelnidipine, a new dihydropyridine calcium ion antagonist, was protected by patent in Japan. In present study, identifications of the crystal phases, including two polymorphic and a pseudopolymorphic crystal forms of azelnidipine, were attempted using powder X-ray diffraction (PXRD), differential scanning calorimetry (DSC), IR-, Raman-, THz-, and ss-NMR-spectroscopy. PXRD identified three different crystal forms, while, spectroscopy analysis provided the information of crystal structure involving intermolecular interactions. The transition thermodynamics of the azelnidipine polymorphs were extensively investigated by solubility method. The solubility of the two polymorphs of alpha and beta in 50% ethanol at 25, 31, 37, 42, and 49 degrees C was investigated; the values obtained were used to calculate the thermodynamic parameters of the transition reaction. The temperature of polymorphic phase transition in 50% ethanol was 50.78 degrees C, and the values of Delta G(alpha,beta)(0), Delta H-alpha,beta(0), and Delta S-alpha,beta(0) at 25 degrees C were -1.18 kJ.mol(-1), -14.81 kJ.mol(-1), and -45.73 J.mol(-1).K-1, respectively. Form beta was proved to be thermodynamic stable form at room temperature and enantiotropically related with form alpha. The kinetics of the solid-state decomposition, studied using DSC analysis, showed that the activation energies of decomposition of the polymorphs alpha and beta at high temperatures were 148.67 and 151.93 kJ.mol(-1).
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