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1 Studies of phase transitions in the aripiprazole solid dosage form

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6 Graphical abstract

7 Highlights

- 8 • The polymorphic transition and an aripiprazole hydrate formation were detected in
9 tablets.
 - 10 • A DSC method was developed for a detection of polymorphic transition between
11 forms III and I in tablets.
 - 12 • The formation of aripiprazole monohydrate in tablets was controlled by powder
13 diffraction and Raman spectroscopy.
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18 **Keywords:** aripiprazole, active substance, phase transitions, solid dosage form

19 Abstract

20 Studies of the phase transitions in an active substance contained in a solid dosage form
21 are very complicated but essential, especially if an active substance is classified as a BCS
22 Class IV drug. The purpose of this work was the development of sensitive methods for the
23 detection of the phase transitions in the aripiprazole tablets containing initially its form III.
24 Aripiprazole exhibits polymorphism and pseudopolymorphism. Powder diffraction, Raman
25 spectroscopy and differential scanning calorimetry methods were developed for the detection
26 of the polymorphic transition between forms III and I as well as the phase transition of form
27 III into aripiprazole monohydrate in tablets. The study involved the initial 10 mg and 30 mg
28 tablets, as well as those stored in Al/Al blisters, a triplex blister pack and HDPE bottles (with

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