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Title:	Novel polymorph of ambrisentan: Characterization and stability
Authors:	Gupta, Vijay (/jspui/browse?type=author&value=Gupta%2C+Vijay) Mandal, S.K. (/jspui/browse?type=author&value=Mandal%2C+S.K.)
Keywords:	Polymorphs Phase transformation Solution crystallization Solubility Solution calorimetry
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Publisher:	Elsevier B.V.
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Abstract:	The present work highlights a novel polymorph (form II) of ambrisentan (AMT), a selective endothelin type A (ETA) receptor antagonist used in the treatment of pulmonary arterial hypertension (PAH). Form II was isolated by solution crystallization and characterised by differential scanning calorimetry, powder X-ray diffraction, solution calorimetry and aqueous solubility. The single crystal X-ray diffraction shows that it crystallizes in monoclinic system with space group P21/c different from the form I (commercial form). Form II was found to be enantiotropically related to form I. Apparent solubility of form II was performed in 0.1 N HCl (pH 1.2) was found to be higher (1.5 fold) than of form I. Solution mediated and stress-induced phase transformation studies revealed conversion of form II to form I. Accelerated stability studies (40 °C & 75% RH) also reveal that form II converted to form I after one month. However, this does not belittle the improved solubility of a new solid form.

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