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Short Communication

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Drug Excipient Interaction Study with Polymorphic Forms of Tibolone

Gabriel L.B. ARAUJO [1]*, Helio SALVIO- NETO [1], Márcio H. ZAIM [2] & Jivaldo R. MATOS [3]

[1] *Departamento de Farmácia, Faculdade de Ciências Farmacêuticas, Universidade de São Paulo, SP, Brazil*
[2] *Sintefina Indústria e Comércio LTDA, Divisão Hormônios, São Paulo, SP, Brazil*
[3] *Departamento de Química Fundamental, Instituto de Química, Universidade de São Paulo, São Paulo, SP, Brazil*

SUMMARY. Powder mixtures (1:1) of tibolone polymorphic forms I (monoclinic) and II (triclinic) and excipients have been prepared and compacted. The samples were stored at 50 °C and 90% RH for one month and subsequently were evaluated using differential scanning calorimetry (DSC) and high-performance liquid chromatography (HPLC). The results indicate that during the compaction, the applied pressure reduced the chemical stability of tibolone in both polymorph forms. The triclinic form was more chemically unstable, both pure and in contact with excipients, than the monoclinic form. Lactose monohydrate was shown to reduce chemical degradation for both forms. Ascorbyl palmitate was shown to affect the tibolone stability differently depending on the polymorphic form used.

KEY WORDS: Drug-excipient interaction, Polymorphism of drugs, Solid-state characterization, Thermal analysis.

* Author to whom correspondence should be addressed. *E-mail:* gabriel.araujo@usp.br

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