

QUANTITATIVE PHASE ANALYSIS OF ISOTIBOLONE IN TIBOLONE RAW MATERIAL USING THE SCARLETT-MADSEN METHOD

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Tibolone is used for hormone reposition of post-menopause women and isotibolone is considered the major metabolic degradation product of tibolone. Isotibolone can also be present in API raw materials due to some inadequate synthesis. Its presence is then necessary to be identified and quantified in API products, before its use in the manufacturing of medicaments. In this work we present the indexing of isotibolone and the application of the Scarlett-Madsen method to quantify it in an API raw material of tibolone. The characterization of isotibolone sample by IR spectroscopy, elemental and thermal analyses were also performed. The crystallographic data are $a = 6.8068 \text{ \AA}$, $b = 20.7343 \text{ \AA}$, $c = 6.4487 \text{ \AA}$, $\beta = 103.571^\circ$, $V = 884.724 \text{ \AA}^3$ and space group $P2_1$. With the Scarlett-Madsen method it was possible to quantify 83.60 wt% of monoclinic $P2_1$ tibolone and 16.4 wt% of isotibolone.