

Modafinil Tablets

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Expert Committee: Monograph Development—Pulmonary and Steroids

In accordance with the 2005–2010 Rules and Procedures of the Council of Experts, the Monograph Development—Pulmonary and Steroids intends to revise the Modafinil Tablets monograph based on comments received. Under the test for Related compounds, it is proposed to change the limit of any individual unknown impurity from NMT 0.1% to NMT 0.2% pending final FDA approval for tentatively approved Abbreviated New Drug Application (ANDA) holders.

It is anticipated that the proposed revision will be published as a Revision Bulletin.

Should you have questions, please contact Mary Waddell (301-816-8124 or msw@usp.org).