Tadalafil Tablets

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Expert Committee	Small Molecules 5

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 5 Expert Committee has revised the Tadalafil Tablets monograph. The purpose of this revision is to add *Dissolution Test 3* to accommodate FDA-approved drug products with different dissolution conditions than the existing dissolution test(s). In addition, a new specified degradation product, “Desmethylene tadalafil”, with a limit of “NMT 0.5%” is added to the test for *Organic Impurities* to accommodate FDA-approved drug products with different acceptance criteria, as the limit is wider than that for unspecified, individual impurities, “NMT 0.2%”. A footnote has been added to *Total impurities* instructing that “Total impurities excludes desmethylene tadalafil.”

Additionally, minor editorial changes have been made to update the *Organic Impurities* test to current *USP* style.

The Tadalafil Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Brice Wagner, Documentary Standard Scientist (301-998-6832 or brice.wagner@usp.org).