Buprenorphine and Naloxone Sublingual Tablets

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In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 2 Expert Committee has revised the Buprenorphine and Naloxone Sublingual Tablets monograph. The purpose of this revision is to add *Dissolution Test 2* and *Dissolution Test 3* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). *Labeling* information has been incorporated to support the inclusion of *Dissolution Test 2* and *Test 3*. This revision also necessitates a change in the table numbering in the test for *Organic Impurities*.

- *Dissolution Test 2* was validated using the Zorbax SB C18 brand of column with L1 packing. The typical retention time for buprenorphine is about 11 min. The typical retention time for naloxone is about 3 min.

- *Dissolution Test 3* was validated using the Zorbax SB Phenyl brand of column with L11 packing. The typical retention time for buprenorphine is about 15 min. The typical retention time for naloxone is about 6.5 min.

The Buprenorphine and Naloxone Sublingual Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or yanyin.yang@usp.org).