Carbidopa and Levodopa Tablets

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Expert Committee	Small Molecules 4

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 4 Expert Committee has revised the Carbidopa and Levodopa Tablets monograph. The purpose of this revision is to add *Dissolution Test 3* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s).

- *Dissolution Test 3* was validated using the µBondapak brand of L1 column. The typical retention times for levodopa and carbidopa are about 4 and 11 min, respectively.

Additionally, the revision widens the acceptance criteria for methyldopa from NMT 0.6% to NMT 0.7% and for dihydroxyphenylacetone from NMT 1.0% to NMT 1% in the test for *Organic Impurities* to accommodate FDA-approved drug products with wider approved acceptance criteria.

The Carbidopa and Levodopa Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Claire Chisolm, Senior Scientist II (301-230-3215 or cnc@usp.org).