

Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules

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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 Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules monograph. The purpose of this revision is to add *Dissolution Test 2* 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*.

• Dissolution Test 2 was validated using an Accucore XL C18 brand of column with L1 packing. The typical retention times for clidinium and chlordiazepoxide are about 2.3 and 5.4 min, respectively.

The Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules 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).