

Doxepin Hydrochloride 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 Doxepin Hydrochloride Capsules monograph. The purpose for the 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 Agilent Zorbax SB C8 brand of L7 column. The typical retention times for the (E)- and (Z)- isomers of doxepin are about 4.4 and 4.8 min, respectively.

The Doxepin Hydrochloride Capsules Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Tsion Bililign, Senior Scientist II (301-816-8286 or tb@usp.org).