



U.S. Pharmacopeia
The Standard of Quality™

Effective date: September 30, 2004

NOTE: The specifications in this sheet supercede the previous specifications issued for this lot.

**USP DRUG RELEASE CALIBRATOR
For APPARATUS 3 (SINGLE-UNIT TYPE)
USP Chlorpheniramine Maleate Extended-Release Tablets RS
Lot G0B259
(16 mg nominal chlorpheniramine maleate content per tablet)**

This Drug Release Calibrator is provided for the USP General Chapter <724> DRUG RELEASE Apparatus Suitability Test.

Procedure - Follow the instructions in <724> DRUG RELEASE, unless indicated otherwise. Place 250 mL of deaerated purified water as the *Dissolution medium* in each vessel of a selected row of vessels, and equilibrate to $37.0 \pm 0.5^\circ$. Place one tablet in each reciprocating cylinder. Each reciprocating cylinder is equipped with a 20-mesh, 0.84-mm stainless steel screen on the bottom. Immediately operate the apparatus with the dip rates specified in the Table below. At the times indicated, withdraw a 10-mL sample aliquot from each vessel, and filter immediately. Use a filter type with a nominal pore size of 2.0 microns or less that has been evaluated for interference, and found suitable for use. Discard an appropriate amount of filtrate prior to collecting a sample. Cool the remaining filtrate to ambient temperature before analysis. Do not replace the medium taken at the first sampling time. Measure the amount of chlorpheniramine maleate dissolved from the filtered portions of the sample aliquots, suitably diluted with fresh *Dissolution medium*, if necessary, at the wavelength of maximum absorbance at about 262 nm in comparison with a Standard solution of USP Chlorpheniramine Maleate RS having a known concentration. Use purified water as the blank. For calculation at the second time point, use a dissolution volume of 240 mL, and also correct with the quantity of chlorpheniramine maleate removed by the first sampling.

Test Interpretation -The apparatus is suitable if each of the individual calculated values for each time interval at all indicated dip rates is within the specified ranges.

Notes: Bias introduced by automated methods is to be avoided.

These values apply only to Lot G0B259

Time in Hours	%Dissolved 5 Dips per Minute	% Dissolved 30 Dips per Minute
one	25-34	--
two	--	42-71
four	56-68	--
six	--	NLT 85

Founded in 1820, the United States Pharmacopeial Convention comprises representatives from colleges and national and state organizations of medicine and pharmacy. It revises and publishes *The United States Pharmacopeia* and *The National Formulary*, the legally recognized compendia of standards for drugs.