



U.S. Pharmacopeia  
The Standard of Quality<sup>SM</sup>

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**NOTE: Effective this lot there is a reduction in test requirements—  
calibration is now only done at 100 rpm  
USP DISSOLUTION CALIBRATOR,  
NON-DISINTEGRATING TYPE**

**Salicylic Acid Tablets, 300 mg**

**Lot N**

This USP Dissolution Calibrator is provided for the *Apparatus Suitability Test* in the General Chapters (711) and (724). **Do not expose to excessive humidity.**

*Procedure*—[See *Dissolution* (711) and *Drug Release* (724) in the current USP.] Determine the quantity of salicylic acid,  $C_7H_6O_3$ , dissolved at thirty minutes, for each spindle, expressed as percent of the labeled amount. Use 900 mL of deaerated 0.05 M phosphate buffer pH 7.40  $\pm$  0.05 (pH tested at room temperature) as the *Dissolution Medium*. The test is conducted at 37° and the apparatus are operated at each of the speeds indicated in the Table below. Measure the amount of salicylic acid in solution in filtered portions of the *Dissolution Medium*, suitably diluted with fresh *Dissolution Medium*, if necessary, at the wavelength of maximum absorbance at about 296 nm in comparison with a solution of known concentration of USP Salicylic Acid Reference Standard.

*Test Interpretation*—The apparatus is suitable if each of the individual calculated values for each apparatus at all indicated speeds are within the specified ranges, as shown in the Table.

*Notes:* An amount of alcohol not to exceed 1% of the total volume of the standard solution may be used to bring the salicylic acid standard into solution prior to dilution with *Dissolution Medium*. Filtering method must be checked for adsorptive loss of drug. In the case of membrane filters, do not use the first 2 mL of solution unless separate interference and recovery experiments have been carried out. Bias introduced by automated methods is to be avoided. These tablets are pure salicylic acid with no binders or fillers. Because of the physical properties of such tablets some sticking of the tablets may occur during storage. Gentle pressure or tapping of the bottle may be used to separate tablets. Cracked, "capped", or severely chipped tablets should not be used. However, tablets with minor surface flaws are generally acceptable for use. Powder on the surface of tablets should be removed prior to use of the tablets. **If equipment is dedicated for use with only one apparatus (basket or paddle), then the calibration is not required for both apparatus.**

See other side for helpful suggestions.

**These values apply only to Lot N**

Appara	% dissolved minutes
	100 rpm
1	23-29
2	17-26

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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.