HPLC Method Development and Validation for the Assay and Organic Impurities of Dopamine Hydrochloride
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Purpose
The current USP Dopamine Hydrochloride monograph uses titration procedures for the assay and lacks an organic impurities procedure. It has only a chromatographic purity procedure by TLC, and specifies a 1.0% limit for the sum of all impurities. In an effort to strengthen and modernize the monograph, a single HPLC method was developed for both the assay and organic impurities tests.

Methods
The separation was carried out on a C18 column, 10-cm x 2.1-mm, 1.9-μm, at 35º. The mobile phase consisted of 0.1% heptafluorobutyric acid (HFBA) in water and methanol (85:15). The flow rate was at 0.5 mL/min, and the detection was at 280 nm.

Results
The HPLC method separated dopamine and three specified impurities: 4-O-methyldopamine, 3-O-methyldopamine, and 2-(3,4-dimethoxyphenyl)ethanamine with a resolution of more than 5. The mobile phase was further adjusted to resolve a coeluting unknown peak detected in Dopamine HCl Injections. Forced degradation studies were carried out to demonstrate the stability-indicating ability of the method. The method was robust under all the variations allowed in USP General Chapter <621>. The validation results for both the Organic impurities and Assay procedures met all the acceptance criteria as per Draft General Chapter <1200>. A similar method was used to test and validate Dopamine in injection dosage forms (data not provided).

Conclusion
A single LC/MS compatible UPLC method was developed and validated for the assay and organic impurities procedures for USP Dopamine Hydrochloride monograph. It is currently under review by USP Expert Committee to be published in USP Pharmacopeial Forum.