HPLC Method Development and Validation for the Assay and Organic Impurities of Benzyl Benzoate
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Purpose
The current USP Benzyl Benzoate monograph uses titration procedures for both the assay and aldehydes limit test. In an effort to strengthen and modernize the monograph, a single HPLC method was developed for both the assay and organic impurities test.

Methods
The separation was carried out on a C18 column, 25-cm x 4.6-mm, 5-µm, at ambient temperature. The mobile phase consisted of 0.1% phosphoric acid and acetonitrile at gradient elution mode. The flow rate was 1.0 mL/min, and the detection was at 210 nm.

Results
The HPLC method separated benzyl benzoate, benzaldehyde, and three potential impurities: benzoic acid, benzyl alcohol, and benzyl ether with a resolution of more than 2.5. An isocratic mobile phase of acetonitrile and water (60:40) was initially found to be suitable; however, the retention time of benzoic acid was inconsistent later. Addition of phosphoric acid into the mobile phase reproduced the retention times. The method was further optimized by using gradient elution. Forced degradation studies were carried out to demonstrate the stability-indicating ability of the method. The final method was fine tuned with robustness study. The validation results for both the Organic impurities and Assay procedures met all the acceptance criteria for its intended uses.

Conclusion
A single HPLC method was developed and validated for the assay and organic impurities procedures for USP Benzyl Benzoate monograph. It is currently under review by USP Expert Committee to be published in USP Pharmacopieial Forum.