Stability of Epinephrine in Expired EpiPen Products from EMS Ambulances
A. Stonemen, A. Torres, H. Zheng, M. Brodeur
Albany College of Pharmacy and Health Sciences

Purpose
EpiPen® and EpiPen Jr® were developed as a convenient self-administered system for emergency treatment of anaphylaxis. They are routinely equipped in Emergency Medical Service (EMS) Ambulances, and most of them have to be replaced after expiration dates, despite their high cost and recent drug shortage. To access the quality and potential clinical value for these expired products, we studied the stability of epinephrine and remaining contents from expired EpiPens.

Methods
More than one hundred of EpiPen® and EpiPen Jr® were collected from ambulances of EMS agencies in Albany, NY. Their expiration dates ranged from 2002 to 2013. The auto injectors were dissembled. The drug solutions were taken for qualitative and quantitative analysis by UPLC-UV/MS/MS.

Results
Upon the USP standards, upgraded methods were developed using UPLC-UV/MS/MS high throughput method. Compared to traditional C18 columns, HILIC chromatography (ACQUITY UPLC® BEH HILIC Column, 2.1 x 150mm, 1.7µm) gave better resolution and separation of epinephrine from degradation products. The percentage remaining of epinephrine presented in the tested auto injectors was quantified, ranging from 12.6% to 31.1% of the labelled amount. The impurities or degradation products were also explored, but no major dominant degradation specie (more than 10% of detected epinephrine) were found by MS and UV detectors.

Conclusion
None of the tested samples held a clinically acceptable amount of active ingredient (90-110% of the label). Considering the extreme environment in EMS ambulances, this study also raised the question whether the EpiPen® products can retain a good stability and quality within the recommended shelf life, with enough active ingredients and without significant toxic degradation products. Further validation and investigations are needed to address these questions.