Stability of Cyanocobalamin (Vitamin B12) in Multi-vitamin/Mineral Preparations Containing Thiamine and Niacin and the Influence of Analytical Testing Conditions on Its Stability
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Purpose
Cyanocobalamin is a water soluble vitamin, one of the eight b-vitamins involved in cell metabolism and energy production. The instability of vitamin B12 in the presence of other b-vitamins upon storage and during analytical testing has been reported. As a result, most formulations contain very high overages to compensate for the loss. The purpose of this study was to understand the following: (i) the influence of niacin and thiamine on the stability of vitamin B12 in solid dosage formulations, (ii) the analytical testing conditions that promote further degradation of B12 during chemical analysis and (iii) identify analytical testing conditions that could prevent further degradation during the analysis.

Methods
Multivitamin/mineral tablets were manufactured under conventional methods. Tablets were stored in stability chambers at 40oC/75% RH and 25oC/65% RH and tested at various time points for the levels of each active ingredient including vitamin B12. In addition, four sets of powder blends were prepared into which a known concentration of vitamin B12 was added. Blend 1 contained only processing excipients, blend 2 contained excipients plus niacin and thiamine, blend 3 contained all other actives in the multivitamin/mineral formulation excluding niacin and thiamine and blend 4 contained all actives including thiamine and niacin. These blends were assayed for vitamin B12 levels and measured by HPLC. The effect of varying auto sampler temperature on the recovery of vitamin B12 was assessed.

Results
The presence of thiamine and niacin negatively affected the recovery of vitamin B12 in tablets and vitamin-B12 spiked blends. 100% of the added vitamin B12 was recovered in the blend that excluded thiamine and niacin while only 50% of the vitamin B12 input was recovered in the blend that contained thiamine and niacin. In addition, better recovery of vitamin B12 was reported when auto sampler temperature was maintained at 4oC.

Conclusion
Niacin and thiamine promote the degradation of vitamin B12 in multi-vitamin/mineral preparations. The recovery of vitamin B12 in these preparations can be improved by controlling the HPLC auto-sampler temperature.