

TL24 - Diuretics version 2.0

Summary of Major Modifications

The Technical Letter on the minimum reporting level for certain diuretics that are known contaminant of pharmaceutical products, TL24 – Diuretics version 2.0, has been updated to include guidance on how a finding for hydrochlorothiazide (HCT) shall be reported when it is detected in conjunction with its degradation product chloraminophenamide (ACB).

The Reporting Requirements section has been updated to include two examples on how an analytical finding shall be reported when HCT and/or ACB are present in a *Sample*:

- *Adverse Analytical Finding (AAF)*, where either HCT or ACB is present at an estimated concentration above (>) 20 ng/mL, or
- Negative Finding, where both HCT and ACB are present at an estimated concentration less than or equal to (\leq) 20 ng/mL.

This Technical Letter becomes effective immediately.