



"Thanks you! TAT
(turnaround time)
impressive" -
11/18/2020

"Thank you for getting
this out so quickly.
The team and I really
appreciate it." -
10/06/2020

Dear ,

Most of us will agree that 2020 was an unusually challenging and stressful year and be glad it is in our rearview. Unfortunately, it appears that we may not get back to some sense of normality until late 2nd or 3rd quarter of 2021. Nonetheless, please accept our heartfelt wishes for a less stressful, more manageable, and a rewarding 2021!

CHEMTOS specializes in Certified Analytical Reference Standards, so every compound we custom-synthesize or sell requires a comprehensive Certificate of Analysis (CoA). Have you given any thought to which analysis should be included in a CoA for any compound? It is convenient to split the analysis requirements into three categories based on the application of the compound: (1) the **WHO/WHAT** – to confirm identity; (2) the **HOW MUCH** – to determine potency; and (3) the **SHOULD NOT BE PRESENT** – to confirm absence of toxic or biologic impurities.

(1) the **WHO/WHAT**: Any compound used as a reference standard should have analytical data in its CoA that confirms its **identity** - this should be an absolute minimum requirement, ideally using at least two distinct analytical techniques. In some instances, this may be sufficient for qualitative use of a reference standard, such as Stable-Isotope Labeled (SIL) internal standard.

(2) the **HOW MUCH**: For use of compound as a quantitative internal standard, it is important to have accurate **potency** value. For compounds that are 100% pure and crystalline, this is relatively easy to determine. But when impurities are present, determination of potency is prone to errors, especially since *there is no analytical tool or detector that has a uniform response for each component or impurity that might be present* (this will be discussed further in a future newsletter and a case for use of quantitative proton NMR analysis for potency will be made).

(3) the **SHOULD NOT BE PRESENT**: Compounds that are ingested by humans or animals will often require additional **testing for trace toxics** (heavy metals, etc) **and biologics** (microbial testing) due to the potential for outsized biological response from these impurities. Compounds that are manufactured following strict GMP (Good Manufacturing Practices) protocols typically ensure absence of such impurities and will often be high purity monomorphic crystalline compounds that are packaged and sealed under controlled conditions. But compounds, whose manufacturing source, conditions, storage, packaging, etc is not definitely known or controlled, would typically require significant analytical effort to rule out presence of impurities with outsized biological response, if they are to be administered to humans or animals for biological response studies.

A presentation that covers some of this discussion can be found here:

https://www.chemtos.com/RefStd-CoA_discussion.pdf

Custom Synthesis of Ref Stds



With years of combined experience in varied chemical synthesis processes and isolation techniques, we have been able to synthesize and isolate compounds and metabolites at high purity, often in short time duration (typically less than 4 weeks). We find innovative ways to insert stable labels in the reference standards that we synthesize, even when others have struggled!

We are DEA licensed with quotas for manufacture of C-I through C-V compounds for use as analytical reference standards.

Analytical Services



Our standard GLP Certificate of Analysis includes (i) UV HPLC Purity assessment averaged over multiple absorbance wavelengths; (ii) LC-MS for confirmation of molecular weight; and (iii) Proton NMR analysis for molecular structure confirmation and residual protonated organic solvent determination. We also offer Quantitative proton NMR for potency value, KF titration for moisture content, Residue on Ignition for non-combustible inorganic salt content, Chiral HPLC and Optical Rotation analysis.

Catalog of in-stock Ref Stds

We carry a number of Certified Analytical Reference Standards in-stock (not for human consumption). All are accompanied by a comprehensive CoA that includes copies of the analytical data. We also offer DEA Exempt 1 ml solutions of analytical reference standards in flame sealed ampoules whose concentration has been confirmed using quantitative proton NMR analysis.



Our web catalog can be found at www.chemtos.com/xcart/. Use of Search bar on top right is quite effective in finding compounds by name or CAS number or SMILES.

Please do not hesitate to contact us if we can be of any assistance in fulfilling your Certified Analytical Reference Standard or Compound Re-certification needs. We are at your service whenever you need us.

Sincerely,

Chemtos Team



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