

# chemtos <sub>NEWS</sub>

#### VOLUME 21, NUMBER 1

Dear Sir/Madam,

Hopes of interacting with you at the WRIB meeting in Orlando, Florida were dashed when the Vendor Exhibition was postponed to 2022 due to inadequate fraction of inperson attendees!

In terms of recognition of our services, Pharma Tech Outlook, based on their customer survey responses, reported Chemtos to be one of the top 10 Analytical Services provider. The article may be found at the following link:

#### Pharmatechoutlook magazine August2021 issue

Previous Chemtos Newsletter in 2020 included a discussion on which analytical analysis should be included in a Certificate of Analysis of an organic compound. As mentioned previously, when impurities are present in a compound, determination of accurate potency value can be challenging. The traditional method of potency determination uses results from multiple analytical analyses to estimate the true weight percent potency of the active ingredient. This is like separately determining the size of various parts of an elephant (ears, trunk, leg, tail, etc) to determine the size of the elephant. Furthermore, a number of analytical measurements (e.g. HPLC) have mole proportional relative value of observable components (assuming uniform detector response), which is not necessarily weight fractional value - but can only be considered an estimated value due to underlying variables. Fortunately, there is one analytical technique that can independently determine weight fractional potency of an organic compound, provided molecular structure and molecular weight of compound is known with certainty - this is "Quantitative proton NMR (Nuclear Magnetic Resonance)" or "qNMR". NMR resonances are also mole proportional responses, but addition of known weight of a high purity compound as internal reference allows conversion of the mole proportional NMR responses (resonances) to a weight percent value, without necessarily identifying all the other impurities that might be present. This can be thought of as directly detecting the size of the elephant.

Accurate qNMR analysis for weigh percent potency is a non-trivial task. Errors can be introduced during weighing, due to inadequate magnetization recovery between RF pulses, H/D exchange of either reference standard or the compound of interest when in deuterated NMR solvent (especially the case for basic compounds), errors due to incorrect phasing, baseline corrections and integrations, etc.

We at Chemtos have spent more than five years optimizing our processes for accurate qNMR analysis using <5 mg of sample. We offer qNMR as analytical GLP recertification service for \$595 with turnaround time of 1-3 days. The process to submit sample for analysis is simple via a <u>web submission form</u>. <u>NMR Services at Chemtos</u>

A presentation that covers this discussion of CoA of organic compounds can be found here: <u>https://www.chemtos.com/RefStd-CoA\_discussion.pdf</u>



"You guys are fantastic!*" -*06/15/2021

"Thanks so much for your timely support! " - 05/13/2021

## **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 (qNMR) 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 (qNMR) analysis.



Our web catalog can be found at <u>www.chemtos.com/xcart/</u>. 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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news@chemtos.com To stop receiving such occasional communications, please advise by reply email.

"Thank you! I appreciate your team's resourcefulness to get this done." – 01/27/2021

"Thank you for always being reliable." – 07/30/2021