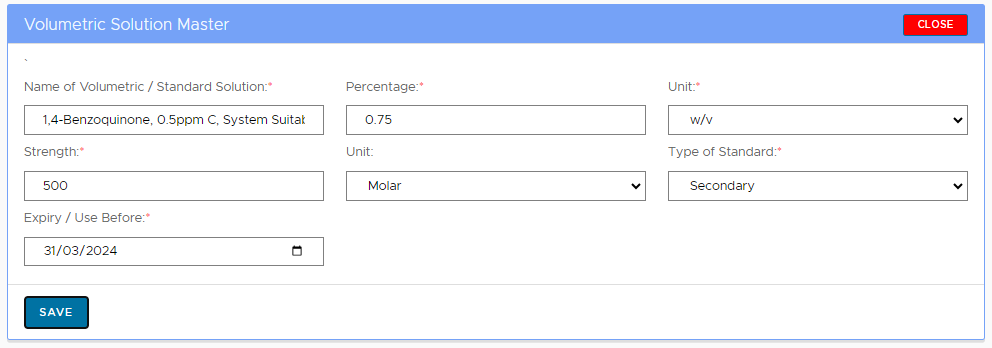
A trial entry was made into the Volumetric Solution Master. The following information was entered:



General Comments:

* The Volumetric Solution Master does not appear to have any functionality to enter the procedure for preparation of the solution.
* We need to be able to document preparation of solutions which may contain more than one chemical (for example HPLC Resolution Solution, containing Mannitol and Sorbitol).
* We need to be able to document preparation of sets of solutions for use as calibration curve standards (for example 0.1, 0.5, 1.0, 2.0, 3.0mg/mL Mannitol calibration curve standards for TM-005).
* We need to be able to document preparation steps (i.e. multiple dilutions) and record the balances, glassware and pipettes used during preparation.
* Our current procedures for preparation of volumetric solutions are documented using our Standard Reagent Preparation (SRP) template TE-007-05. (Note that functionality to perform calculations for exact concentrations for calibration curve standards is also required, this should be similar to test method calculations.) **Can you please update the Volumetric Solution Master Format to match our SRP requirements and allow us to document procedures for preparation of standard solutions (and sets of solutions)?**

Specific Comments for the current version of the Volumetric Solution Master form:

* Percentage and Unit are not required for most volumetric solutions we prepare.
* Strength and Unit are not required for most volumetric solutions we prepare.
* The drop down list for Type of Standard, will need to be updated to include ‘Calibration Curve Solutions’, ‘Reference Solution’, ‘System Suitability Solutions’ with the option to add additional types of solutions as needed.
* Expiry dates will be assigned based upon the date of preparation, however the master can detail the assigned expiry period. Storage conditions for the solutions should also be able to be documented.
* When I pressed the save button for the entered data, this did not save to the Volumetric Solutions Master List.

Comments for the Volumetric Solutions Master List:

* The Volumetric Solutions Master List should be the list of all approved solutions for use in the relevant test methods. We then need a separate list of individually prepared solutions.
* When a new Volumetric Solution Master is created, this should be reviewed and approved in accordance with the procedure for all new documents (refer to procedure for SOP review and approval).
* Each time a Volumetric Solution (or set of solutions) is prepared the relevant Volumetric Solution Master should be used to document preparation of the solution (set of solutions). The prepared solutions should be given an individual identifier and a log of prepared solutions should also be available. The Volumetric Solution Log in the QC section (https://arna.cpplgmp.com/#/qc/volumetric/log) reference Solution No. as well as the Master List. **Can you please advise if a Solution No. is given to each Master and how individually prepared solutions are identified?**