

CHATA Biosystems – Frequently Asked Questions

Has your facility been audited by the FDA?

CHATA manufactures raw materials, not drug products or medical devices. As a result, we are not subject to FDA audits, but are subject to vendor audits performed by the majority of our clients. Our facilities have been audited by nearly all the major North America pharmaceutical manufacturers.

What is the quality of your water?

The water used by CHATA for chemical solutions meets criteria for USP Pharmaceutical Grade Water and ASTM Type 1A Water. The water system is validated monthly.

What guarantee do we have that you will make our solutions according to our method?

Manufacturing cannot proceed until the required Product Definition form has been reviewed and signed by the customer. The Product Definition form includes information on solution formulation, packaging, labeling, any requested QC testing, and contact addresses. This form can also include a copy of your method. In addition, QA must sign off on the accurate transfer of the formula to the mixing instruction sheet. Both documents are part of the SOP controlled batch record.

What is the expected turnaround time on orders?

Normal turnaround time for new orders is 4-6 weeks plus shipping, which can vary from 3-7 days depending on your location. However, QC testing ordered for lot release can extend solution turn around times.

For customers with blanket orders, CHATA carefully monitors your inventory to manufacture the freshest solution for on-time delivery. Turnaround times should not affect your laboratory because your inventory is regularly replenished before it is exhausted.

How are solution expiration dates determined?

To determine the shelf life of your particular solution and to assign an accurate expiry, it is necessary to conduct a stability study. CHATA offers custom studies for mobile phases and dissolution media. The studies result in a data supported expiration date that is printed on each Certificate of Analysis and label for your solution. Please contact your local sales manager for more information on a custom study for your solution.

What information is printed on CHATA's labels?

Our labels include the Lot Number, Part Number, Product Name, Product Composition, CAS Numbers if required, HMIS codes, the expiration date dictated by your SOP or stability test, and CHATA contact information. Additional information can be added by request.

Does the CHEM+NECT™ system contain extractables?

Depending on the chemistry of the solution used in an isocratic application, it is possible for extractables to migrate out of the CHEM+NECT™ system at very low parts per million levels. Structurally, these extractables are similar to anti-oxidants. Over 70 pharmaceutical quality control laboratories have successfully used CHATA's pre-packaged solutions over the last five years without any problems due to extractables. If you would like to use the CHEM+NECT™ system for gradient applications, please contact your local sales manager for packaging information.

How do you determine batch volume?

CHATA recommends that your product be manufactured to provide your laboratory with a three to six month supply of solution, dependent upon the expiry. Based on your volume usage we can assist you in determining what this batch volume would be. The final calculations of the batch volume are included in batch record. Before manufacture can begin on your first lot, you must check these calculations and approve the Product Definition sheet.

What information is included in the Batch Record?

All batch records contain complete traceability on chemicals and materials used in the manufacturing process, HMIS information, a Formula Sheet, volumetric to gravimetric conversion calculations, complete label accountability, and a Notice of Batch Release. In each step of the manufacturing process, there is a double witness sign-off.

Depending on the solution and specified manufacturing tests, the Batch Record may also contain temperature readings, pH test results, dissolved oxygen readings, filter integrity test results, and QC test results selected for lot release.

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Do you provide a Certificate of Analysis?

A Certificate of Analysis is provided with each lot and includes the product name, catalog number, lot number, manufacturing date, expiration date if a stability study has been performed, general packaging information, general manufacturing procedures, and the results of any analytical tests performed.

What if our SOP requires a specific raw material or vendor?

CHATA is happy to accommodate customer requests to use specific raw materials or vendors. Only HPLC grade solvents and ACS grade salts are used in the manufacture of CHEM+NECT™ pre-mixed solutions. CHATA purchases all chemical raw materials from approved vendors and assigns expiration dates according to SOP. Please note that requiring a specific vendor can increase the cost of your product.

Do you validate your equipment?

CHATA manufactures according to cGMP methods. Therefore, all critical equipment is validated and/or certified according to a schedule set by our internal SOPs. Calibration of balances and pH meters used in solution preparation are done at point of use and recorded in the batch record with double witness sign-off.

How do you ensure lot-to-lot consistency?

All lots are made according to a batch record produced using cGMP guidelines. CHATA's QA Department issues this batch record to the manufacturing department. All weights, volumes, and in-process measurements are double verified during manufacturing and recorded in the batch record. All equipment used for the production of the product is calibrated at time of use with NIST traceable standards and weights and recorded in the batch record. The raw materials and standards used in the manufacture of product are recorded in the batch record, thereby providing complete traceability on all components.

Does CHATA degas mobile phases?

Yes, all mobile phases packaged in closed system CHEM+NECT™ bags are degassed unless directed otherwise by the customer. Mobile phases in open system packaging such as CHATA's CHEM+PROTECT™ bottles can be degassed at the customer's request. CHATA's mobile phases are helium sparged or filter sparge our mobile phases. The dissolved oxygen content is also measured and recorded in the batch record with double witness sign-off.

What type of filtration is available?

Our standard filter is an in-line 0.22-micron PVDF filter. However, other filter sizes are available upon request. This filtration process does not cause loss of organics in the solution, allowing CHATA to filter your entire solution for the purest product.

What if we don't have enough storage space for a three-month supply?

CHATA can help arrange storage in our warehouse or one more local to your facility. You can elect to have shipments from your inventory arrive according to a regular schedule. Sending CHATA a shipping schedule allows us to manufacture your solution on a timely basis to guarantee an uninterrupted supply. CHATA offers a monthly inventory and usage update via email, should you request one.

How are CHATA products shipped?

CHATA uses several carriers depending on the type of shipment and destination. In all cases, we attempt to use the lowest price service. It is also possible to use a customer's shipping account if it is specified on the purchase order.

Do you have a catalog?

CHATA custom prepares hundreds of solutions, and most solutions are made according to customer specifications. Therefore, a catalog is not applicable. Instead, please complete a Quote Request form, which provides us with the information necessary to determine the most appropriate packaging, accessories, and pricing for your specific solution.

We do offer a select number of dissolution media and mobile phases made to order. Please ask your sales representative for a complete listing of current off-the-shelf mobile phases and dissolution media supported by stability data.

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How is solution dispensed from the CHEM+NECT™ 100L system?

Pumps and other accessories will help you create a custom workstation that meets your laboratory needs. It is possible for you to connect CHEM+NECT™ directly to your automated dissolution system. Contact your representative for details on what accessories you will need.