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Residual Solvents Testing

Pharmaceutical companies are increasingly demanding full residual solvent screening, with method validation, due to more complex formulations, complicated active ingredient structures, and high product safety requirements.

Residual Solvents are separated into three classes based on their potential toxicity level. The requirements of the screening methods change according to this potential toxicity level. Class 1 residual solvents are known to cause unacceptable toxicities. Class 2 residual solvents are associated with less severe toxicities and Class 3 residual solvents are considered the least toxic.

Testing should be performed for those residual solvents that are used or produced in the manufacture or purification of drug substances, excipients or drug products. For finished products, the client may choose to test either all the individual components or the final finished product.

Eurofins BioPharma Product Testing's network of laboratories offers many testing options to satisfy each customer's needs. Testing options range from a residual solvent screen, which may evaluate classes of solvents, to a very specific method that was developed and validated specifically for the solvents of interest in a particular sample matrix.

Why Choose Eurofins BioPharma Product Testing?

We have extensive experience in all classes of solvents, using direct injection GC, Headspace GC and HPLC approaches.

The flexibility we offer for systems, customized approaches and deliverables allows us to meet each client's unique needs.

We have extensive experience with compendia methods that can be used for general residual solvent screening or analyzing specific solvents of interest.

We offer a self-validating approach that allows validation elements to be built into the analysis, allowing for a lower cost for a sample type that only needs to be analyzed once or twice a year.

We offer protocol driven studies to support formal establishment of a residual solvent method

Differences between Ph. Eur. and USP Residual Solvents

The Ph. Eur. and USP general chapters for residual solvents testing are very similar in methodology and classification of solvents, but there are a few minor differences. The differences do not impact the overall intent of the procedure in which each general chapter provides a means of evaluating the amount of residual solvents in a sample matrix to ensure that residual solvents are below a certain level to be deemed safe for the patient. The choice of method will depend on several criteria, for example, the solubility of the analyte, the type and boiling point of the solvent, limit values, or readily available standards. Due to the logistic requirements for compendia specific standards and the potential to ship overseas and Eurofins site location, each

Eurofins site may default to a specific compendia so that standards are readily available.

Information Needed for Residual Solvent Testing

1. What is the sample? Excipient/Drug Substance/Drug Product/API?
2. Is sample water-soluble or water-insoluble? If unknown, we may require additional testing to determine solubility.
3. List any known residual solvents expected. This information may be provided by the vendor of the sample material.
4. The default approach for your testing strategy, Limit or Quantitative evaluation. This may require verification testing under protocol.
5. What specification to apply for each solvent of interest?