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USP Residual Solvents <467>

USP Residual Solvents <467> is separated into three classes based on their 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 product, the client may choose to test either all the individual components or the final finished product. The USP has stated that a company does have the option to develop and validate their own internal method for determining residual solvents rather than using the USP Residual Solvents <467> method.

Why Choose Eurofins Biopharma Product Testing?

- With a pricing structure that is specific to each USP testing regiment, you will pay only for the amount of work needed based on solvent "hits."
- We offer a self-validating approach that allows all 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, rather than cost surrounding a full method validation for each sample matrix.
- We have extensive experience in all classes of solvents, using direct injection GC, Headspace GC and HPLC approaches.
- We offer protocol writing capabilities to support projects.
- The flexibility we offer for systems, customize approaches and deliverables allows us to meet each client's unique needs.

Information Needed for Residual Solvent Testing

1. What is the sample? Excipient/Drug Substance/ Drug Product?
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, including any Class 1, 2 or 3 as well as ethylene oxide or any other residual solvents.
4. The default approach for Class 1 and 2 (Mix A and B) solvents is Procedure A/B (Limit Test). Indicate if you require a quantified result and would like us to proceed with procedure C. This may require verification testing under protocol.
5. Can a minimum of 1 gram of sample be provided for release testing? Verification testing will require an additional 5 grams of material.

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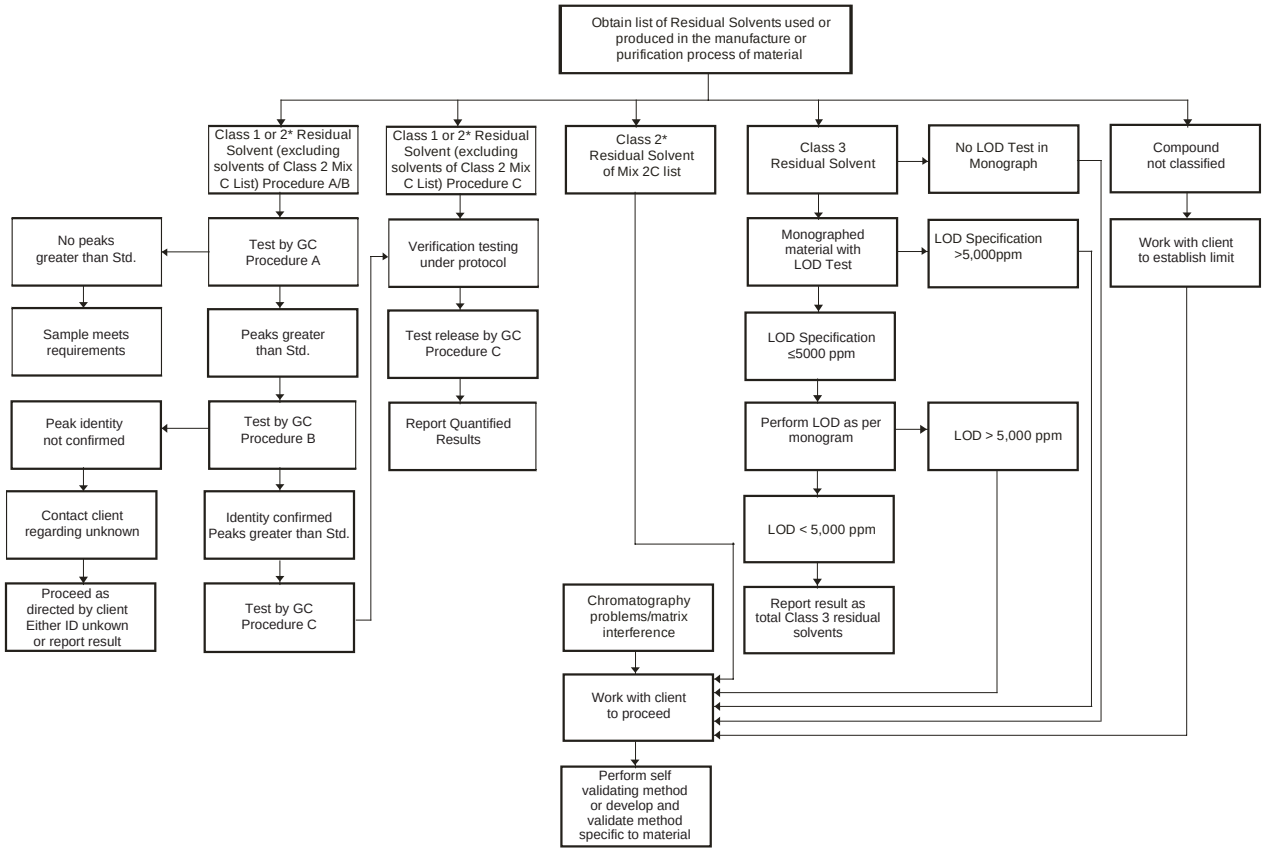
Flow Chart for Testing Residual Solvents by USP <467>



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