



QUALITY CHEMICAL LABORATORIES

Sample Submission Form

Submitting Company _____

Client Contact _____

Telephone # _____

Fax # _____

E-mail _____

Sample Name _____ Number of Samples _____

Lot Number (s) _____

Deliver COA to:	Contact Name	Address	e-mail

Comments /Specific Client Info (Report Information)

(List additional required information for C of A.)

Testing Methodology/Monograph Name

- USP _____
 ACS _____
 EP _____
 Other _____
 JP _____

Client Supplied Method Transfer Required Method Transfer NOT Required

Required Tests

- Full Monograph
 Other (Please list)

Due Date Standard (10-15 Business Days) Rush (Prior Approval Required)

Requested Date _____

Sample Disposition Discard Return

Raw Data Required (check if applicable) (not part of standard turn around)

Storage Conditions Ambient Refrigerate Other _____

Special Safety Precautions

Submitted By _____

Purchase Order# _____

USP<467> Residual Solvents Addendum for Sample Submission

Your answers to the following questions will determine the testing format:

See “USP<467> Residual Solvents Test Approach” on page 3 for a definition of “Full Testing”

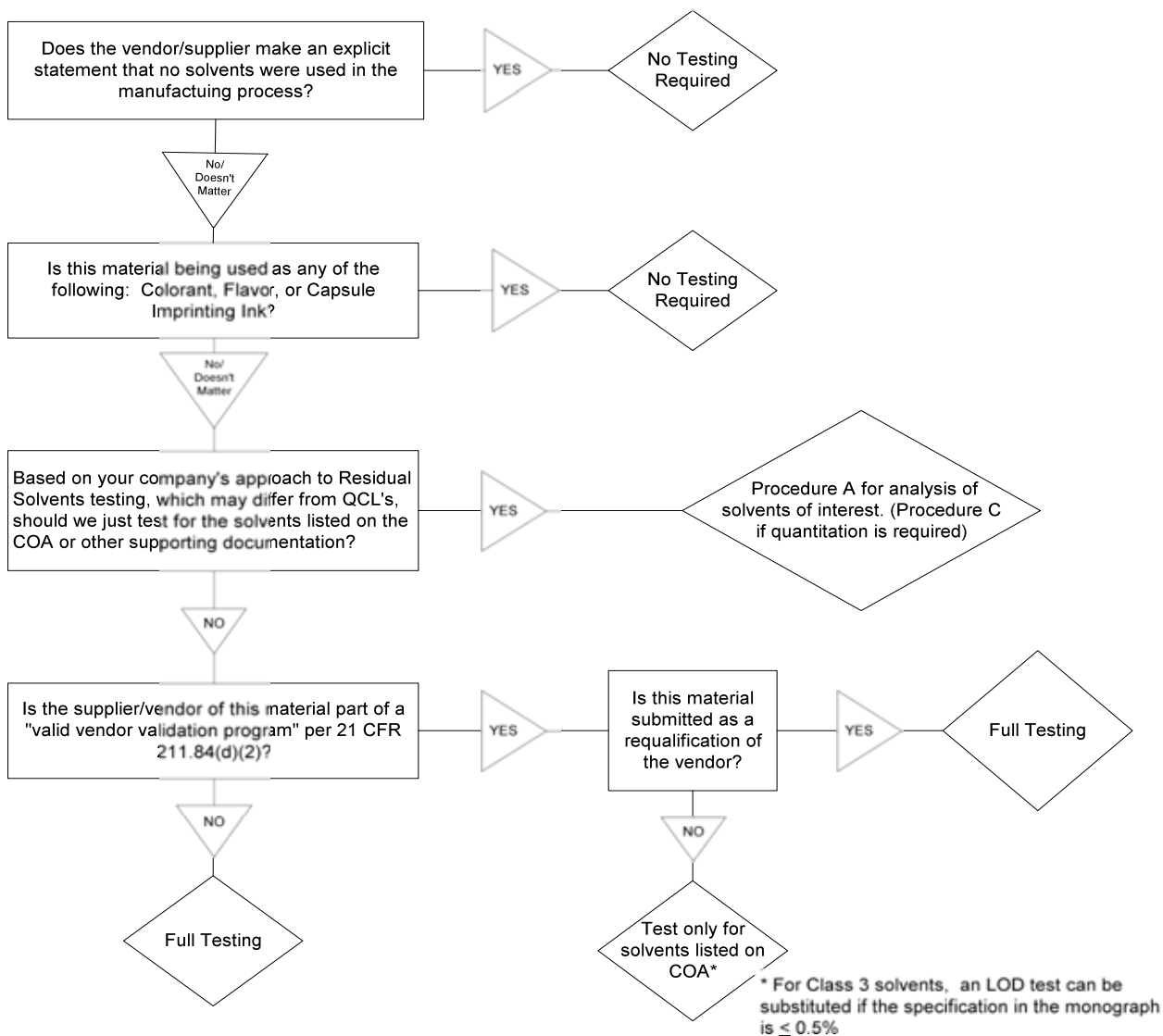
1. Does the vendor/supplier make an explicit statement that no solvents were used in the manufacturing process?
 - Yes (Residual Solvent testing is not required)
 - No/ Doesn't Matter (Testing will be based on the answers supplied)
2. Is this material being used as any of the following: Colorant, Flavor, or Capsule Imprinting Ink?
 - Yes (Residual Solvent testing is not required)
 - No/ Doesn't Matter (Testing will be based on the answers supplied)
3. Based on your company's approach to Residual Solvents testing, which may differ from QCL's, we should:
 - Screen for the solvents listed on the COA or other supporting documentation (skip questions 3 and 4)
 - Screen for all Classes of solvents, following QCL's procedures based on the answers supplied in this questionnaire.
4. Is the supplier/vendor of this material part of a “valid vendor validation program” per 21 CFR 211.84(d)(2)?
 - Yes
 - No (Full Testing, starting with Procedure A)
5. What is the reason for submitting this material?
 - Qualify/Requalify the vendor/supplier (Full Testing, starting with Procedure A)
 - Yearly Retest of the material (Testing will depend on the answer to Question 1)
 - Other, specify: _____
6. Are there alternative limits, other than USP<467>, that need to be applied for specific solvents likely to be present?
 - Yes. Specify: _____
 - No (The USP<467> limits will be applied)
7. Results for any class 1,2, or 3 solvents detected below the limits stated in USP<467> are reported as Less than the specification for each solvent since Procedures A and B are non-quantitative limits tests. If a quantitative result is required, please indicate here so that Procedure C is performed. (Note: Quantitative results are generally not required unless the solvent concentration is expected to exceed the limits stated in USP)
 - Yes, a quantitative result is required even if the sample is expected to be below the USP limit.
 - No, a quantitative result is not required.
8. Solubility of material:
 - Water Soluble
 - Water Insoluble
 - Unknown
9. Please provide a COA from the manufacturer/supplier when available. Knowing any Class 3 or unclassified solvents that may be present prior to testing will save significant time and labor.

*Note: Class 2 solvents formamide, 2-ethoxyethanol, 2-methoxyethanol, ethylene glycol, N-methylpyrrolidone, and sulfolane are not analyzed for during Full Testing as these solvents are not detectable by static headspace analysis. Method Development/Validation would be required to test for these solvents if an alternative method is not available. Testing for Ethylene Oxide is conducted only where specified in the individual monograph (This may be USP, EP, or JP)

Submitted By _____

Phone Number/Email _____

USP<467> Residual Solvents Test Approach



Full Testing consists of:

1. Analyze for all Class 1 and 2* solvents according to USP Procedure A (B and C, if needed)
2. Analyze for all listed class 3 solvents using Procedure A or B. An LOD test can be substituted, if listed in the monograph, and the limit is ≤ 0.5%.
3. If present, analyze for all listed unclassified solvents stated on the COA based on limits supplied by the client.

*Note: Class 2 solvents formamide, 2-ethoxyethanol, 2-methoxyethanol, ethylene glycol, N-methylpyrrolidone, and sulfolane are not analyzed for during "Full Testing" as these solvents are not detectable by static headspace analysis. Method Development/Validation would be required to test for these solvents if an alternative method is not available from another source. Testing for Ethylene Oxide is conducted only where specified in the individual monograph (This may be USP, EP, or JP)