



821 CORPORATE DRIVE • LEXINGTON, KY 40503 • PHONE: 859-224-2844 • FAX: 859-296-3033 • WWW.RMTCNET.COM

Substance Identification Form – Verification of Label Ingredients

Laboratory		Contact Info:	
Sample Origin		Date Submitted	
Generic Name (if applicable)		Trade Name	
Manufacturer/ Compounder		Lot Number (if applicable)	

Active Label Ingredients:

Label Photograph:

APPENDIX A

Testing Performed:

Listed Active Ingredient	Fit for Purpose Test Performed	Result

Comments:

Please attach a copy of the laboratory report and any associated data to this document for transmittal to RMTC.



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Protocol for Verification of Label Ingredients

Purpose:

This protocol is to be used to verify the label ingredients in a product and to identify any other active ingredients in the product. This protocol should not be used to identify components of unlabeled products or those that bear incomplete or inadequate labels.

Procedure:

1. Review the active ingredient list on the product label. Identify appropriate tests to identify and quantify each of the active ingredient(s) on the product label.
2. Perform fit for purpose analysis of listed active ingredient(s) to confirm that they are contained in the product.
3. Perform fit for purpose testing to quantify the listed active ingredient(s) which were identified in paragraph 2. The accuracy and precision of the method used to quantify the active ingredients should be adequate to determine whether the concentration of each active substance in the product is within 85-115% of the label claim.
4. Perform a fit for purpose screening test to determine whether other regularly tested substances are present in the product.
5. If active ingredients are not identified or if unknown substances are detected but not identified, treat the product as an unknown and utilize the Unknown Sample Protocol to test the product.
6. Complete the Substance Identification Form – Label Comparison document and email it to RMTC