

ANALYTICAL CHEMISTRY METHODS: DEVELOPMENTS AND VALIDATION

IZET M. KAPETANOVIC¹ AND ALEXANDER V. LYUBIMOV²

¹*NIH NCI Division of Cancer Prevention, Chemoprevention Agent Development Research Group, Bethesda, Maryland*

²*University of Illinois at Chicago, Chicago, Illinois*

Contents

- 1 Introduction
 - 1.1 Background
 - 1.2 Purpose
- 2 Analytical Method Development
 - 2.1 Sampling and Handling
 - 2.2 Sample Preparation
 - 2.3 Analytical Techniques for Method Development
- 3 Analytical Method Validation
 - 3.1 Installation, Operation, Performance Qualification, and Maintenance of Instrumentation
 - 3.2 Validation Parameters and Definition
 - 3.3 Guidelines: ICH, FDA, AOAC, USP, ISO 9000, and ISO 17025
 - 3.4 Good Laboratory Practice (GLP)
 - 3.5 Method Validation Protocol
- 4 Conclusion
 - References