

POLICY ON MANUAL INTEGRATION

INTRODUCTION:

This document provides the policy for manual integration in Chromatography data with a high degree of assurance that will consistently ensure and safeguard the integrity of the data generated.

SCOPE:

This policy applies to the Chromatography data generated through instruments in and its associated units falling within the scope of GxP regulations.

POLICY DETAILS:

- ✧ There shall be procedure in place describing the documentation requirement, specific chromatographic situations where the manual peak integration is required.
- ✧ Manual peak integration shall not be done to meet the specification.
- ✧ Manual peak integration shall be used only when the automated quantitation procedures in the chromatographic software do not integrate peaks properly.
- ✧ The privilege of Manual Integration shall not be given to any user.
- ✧ Manual integrations shall be clearly identified in the software and on the Chromatographic data.
- ✧ Manual integration shall be formally approved, documented and shall be performed by assigning the privilege only for specific chromatographic data.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION:

Not Applicable

ABBREVIATIONS:

GxP : Good X Practices where x stands for manufacturing, laboratory, clinical, distribution.

REFERENCES:

Not Applicable