POLICY ON EXTRANEOUS PEAK

INTRODUCTION:

This document provided a policy for extraneous peaks observed during performing chromatographic analysis.

SCOPE:

This policy is applicable to all cases where any extraneous peaks are observed during chromatographic analysis by HPLC or GC method at …… and its associated unit.

POLICY DETAILS:

- ✧ Extraneous peak should not occur in the product manufactured under cGMP environment.
- ✧ A written procedure shall be in place for handling of extraneous peak during chromatographic analysis.
- ✧ In HPLC/GC chromatogram, extraneous peak called when it is greater than limit of quantitation or more than 0.010% in case of HPLC and S/N ratio more than 10 in case of GC.
- ✧ Any extraneous peak observed during chromatographic analysis shall be investigated to determine the identity and source of the peak.
- ✧ Based on cause identified, derive appropriate corrective and preventive action.
- ✧ Efforts shall be made to identify the extraneous peak through advanced tools e.g. PDA detector, LCMS, GCMS etc. with the help of analytical development laboratory.
- ✧ If the source of extraneous peak in not identified from the laboratory, then production review shall be initiate for identification of source as per the defined procedure.

AMENDMENT AND WAIVER:

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

DEFINITION: Not applicable

ABBREVIATIONS:

cGMP	:	current Good Manufacturing Practices
GC	:	Gas Chromatography
GCMS	:	Gas Chromatography Mass Spectroscopy
HPLC	:	High Performance Liquid Chromatography
ICH	:	International Conference of Harmonization
LCMS	:	Liquid Chromatography Mass Spectroscopy
PDA	:	Photo Diode Array
S/N	:	signal to noise ratio
%	:	Percent

REFERENCES:

ICH, Q3A, (R2) : Impurities in new drug substances