

Supplementary Materials

Development and Validation for Quantitative Determination of Genotoxic Impurity in Gemfibrozil by Gas Chromatography with Mass Spectrometry

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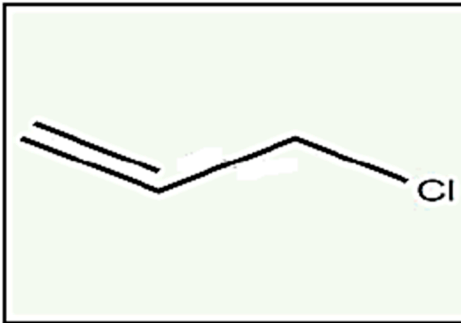
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1. Allyl chloride standard Qualification data:

Product Name : ALLYL CHLORIDE		
Chemical Name : 3-Chloro-1-propene 2-Propenyl chloride		
Synonyms : NA		
CAT No. : OT1610000		
CAS No. : 107-05-1		
Molecular Formula : C ₃ H ₅ Cl		
Molecular Weight : 76.52 g/mol		
Storage Condition : Store at 2°C to 8°C		
Shipping condition : Ambient		
		
ANALYTICAL INFORMATION:		
Sr No	TESTS	RESULTS
1	DESCRIPTION	Colourless Liquid
2	IDENTIFICATION 1. 1H-NMR 2. MASS 3. IR	Conforms to the structure Conforms to the structure Conforms to the structure
3	CHROMATOGRAPHIC PURITY (By GC, area Normalization)	99.23 %
4	Solvent content by NMR	NIL
5	DEFINED POTENCY (By Mass Balance Method)[(100 - Solvent Content) x GC Purity/100]	99.23 %

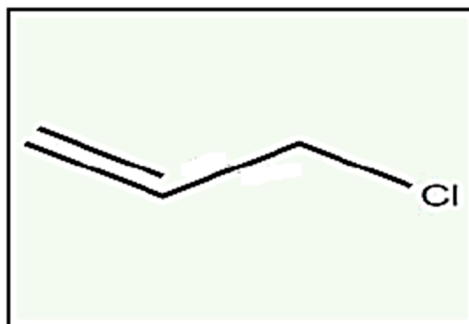


Figure S1. Allyl chloride standard certificate of analysis.

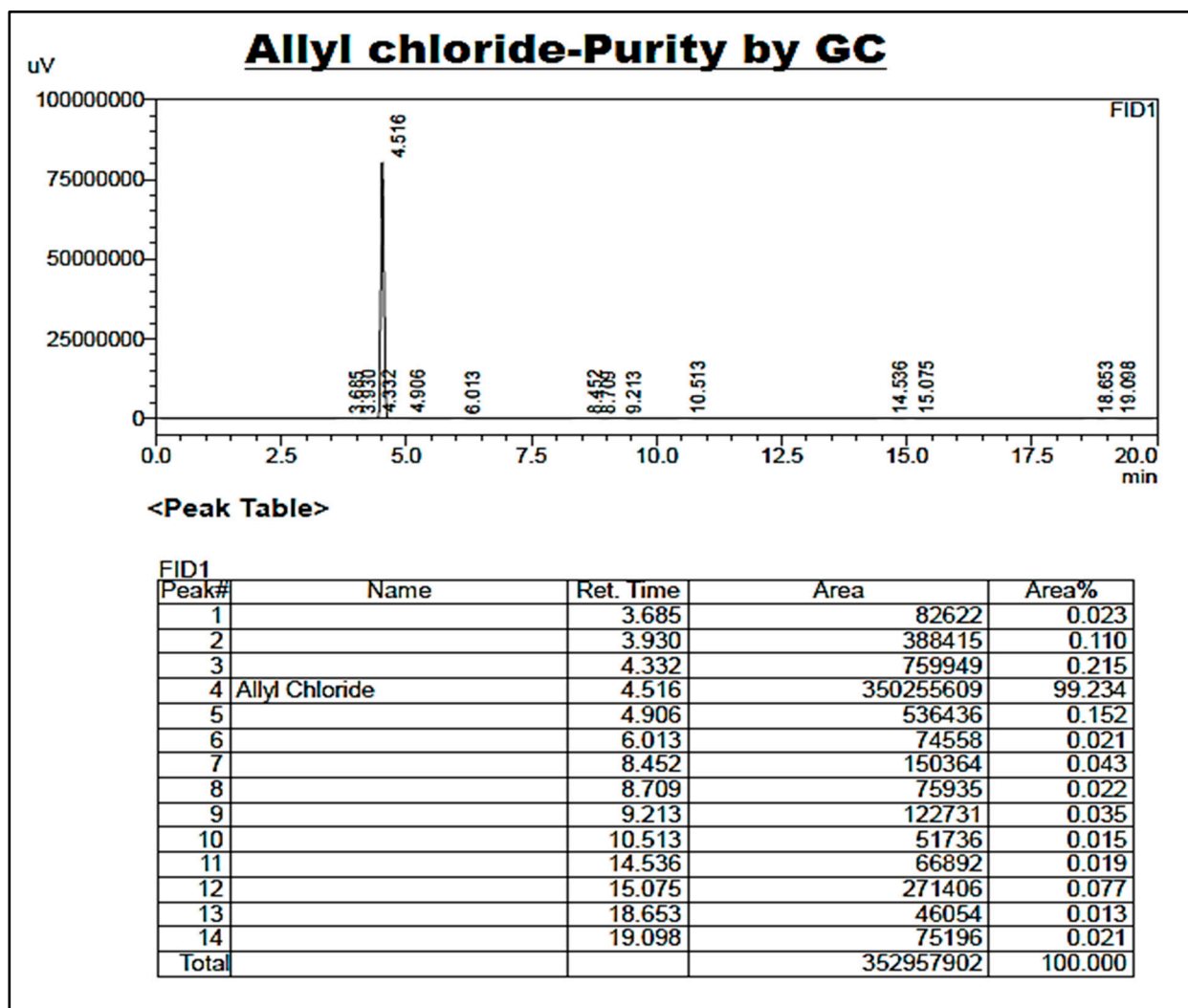


Figure S2. Allyl chloride standard purity by GC analysis.

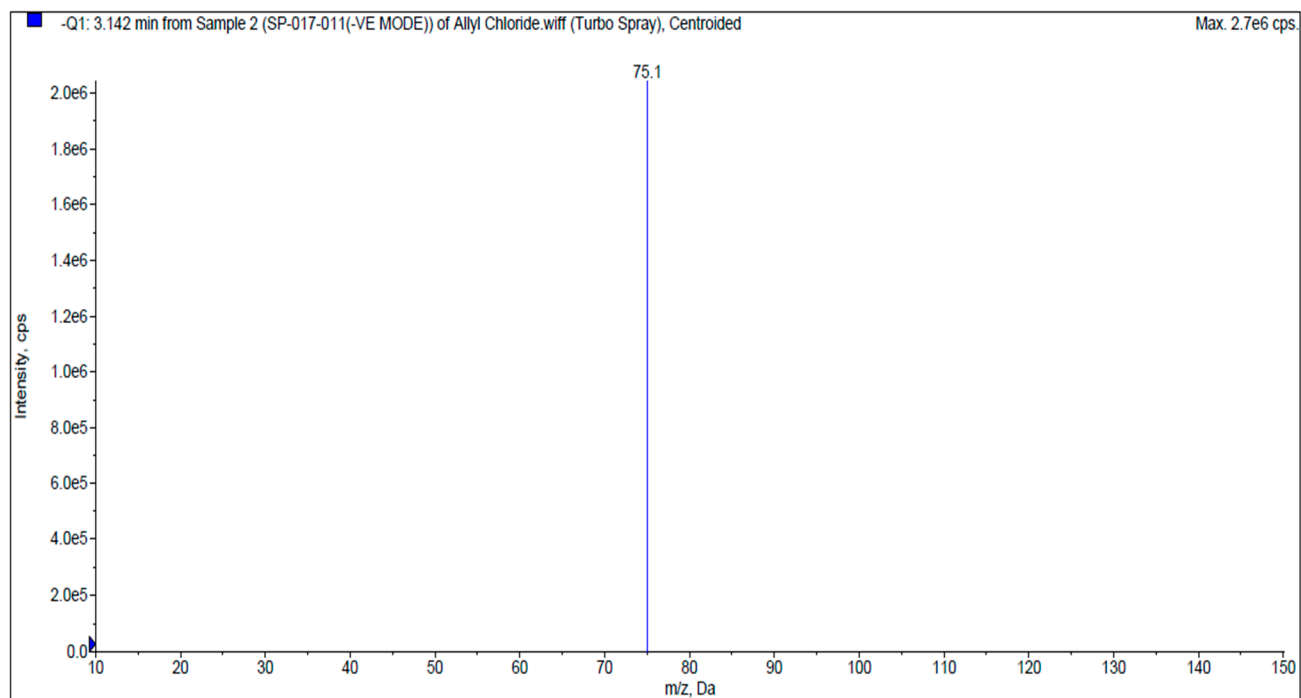


Figure S3. Allyl chloride standard Mass data.

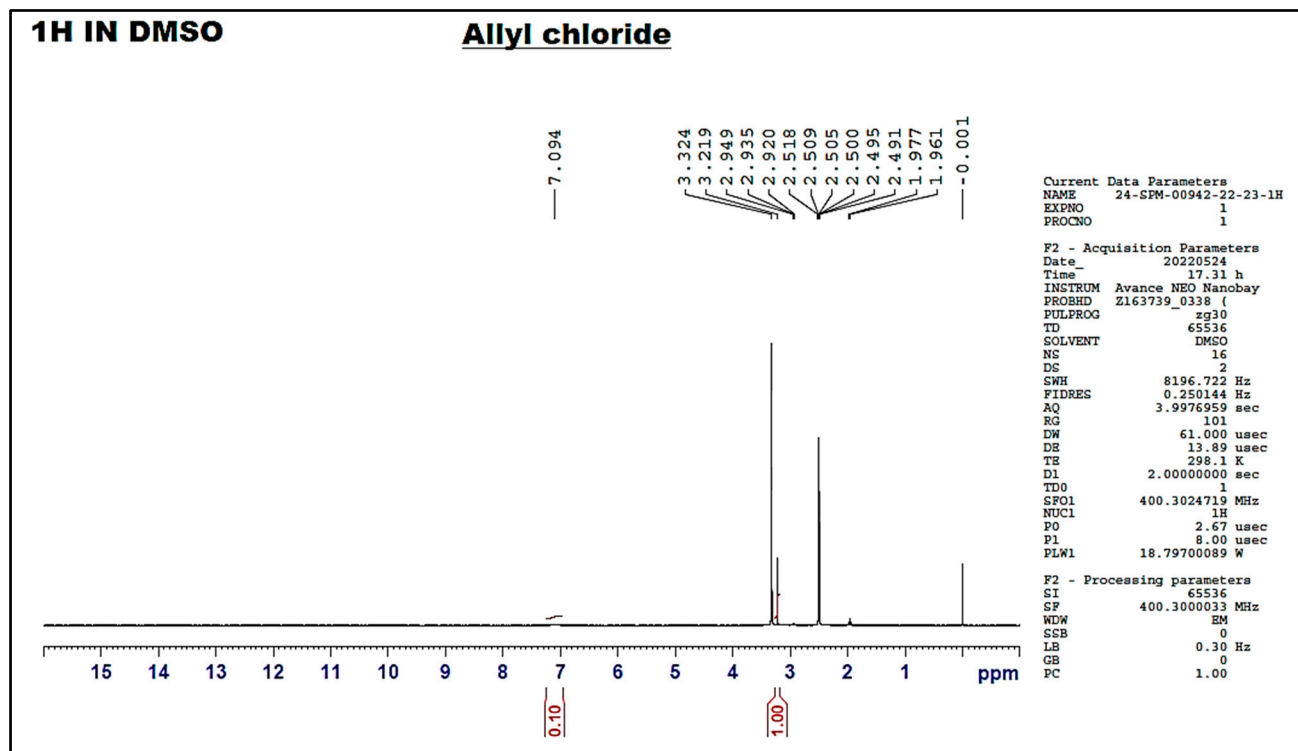


Figure S4. Allyl chloride standard ¹H-NMR data-1.

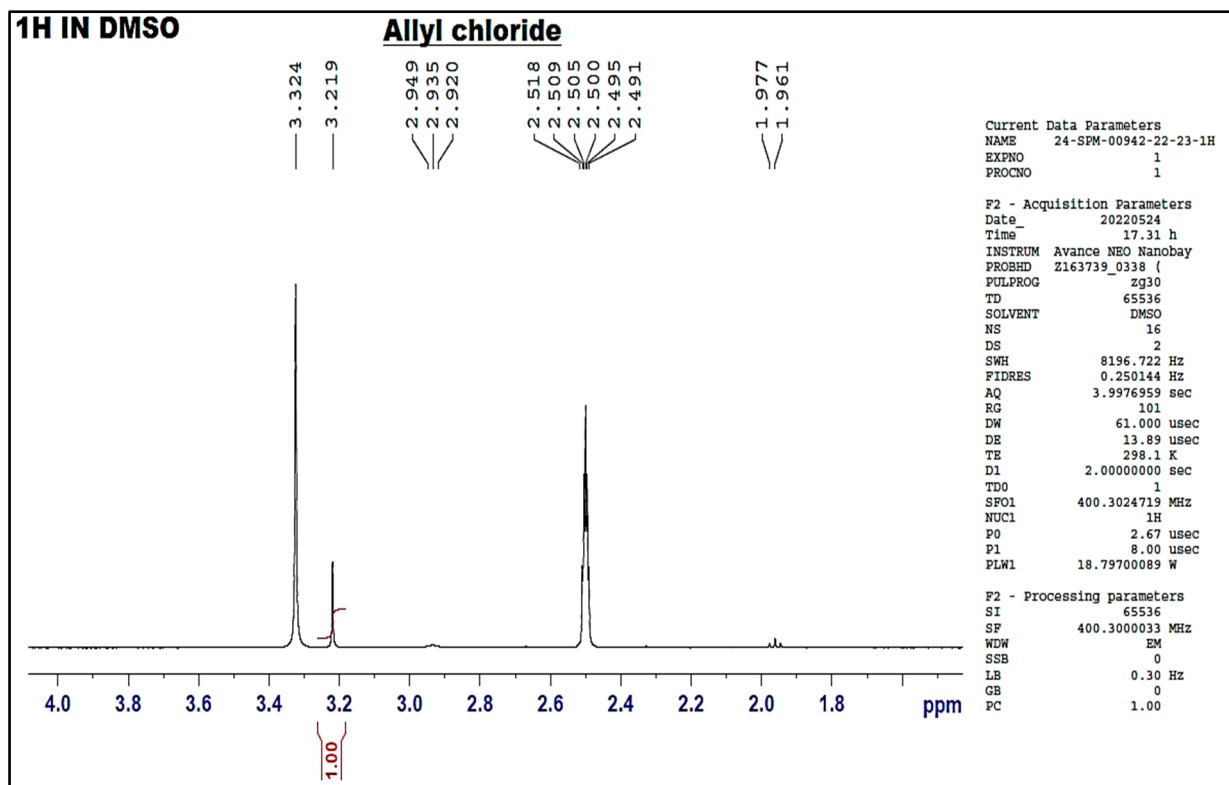


Figure S5. Allyl chloride standard 1H-NMR data-2.

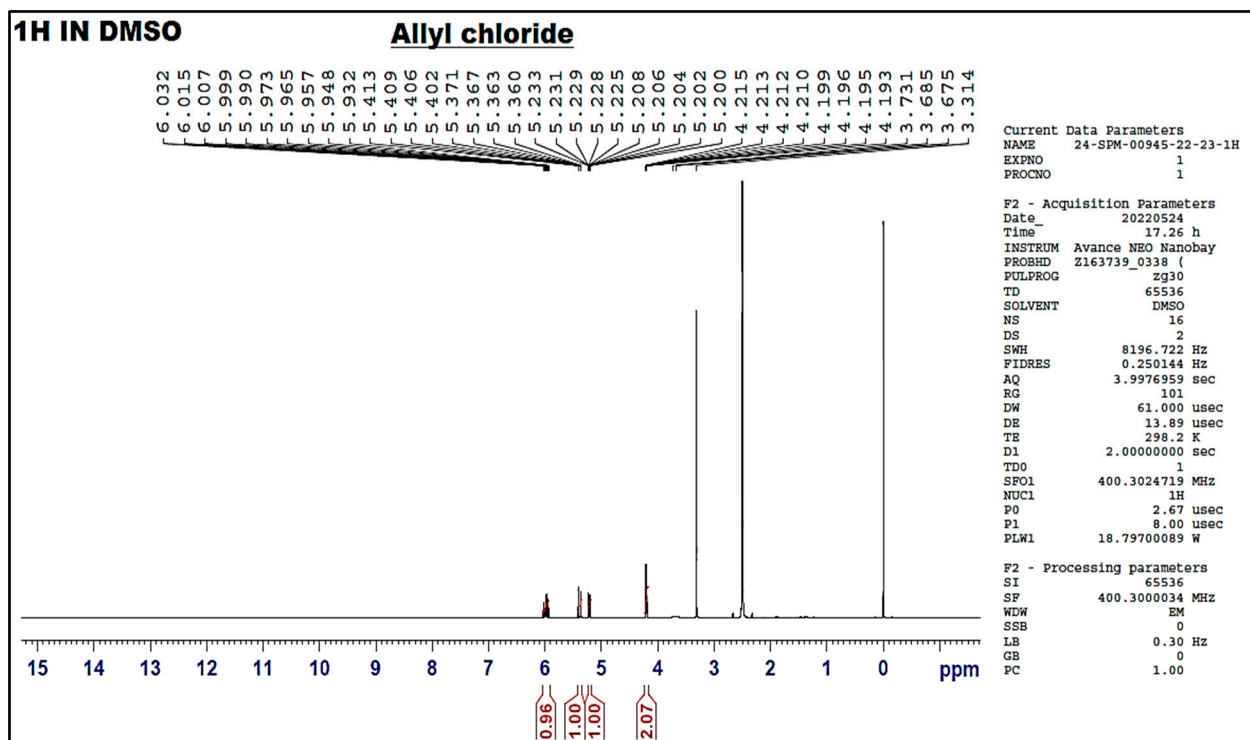


Figure S6. Allyl chloride standard 1H-NMR data-3.

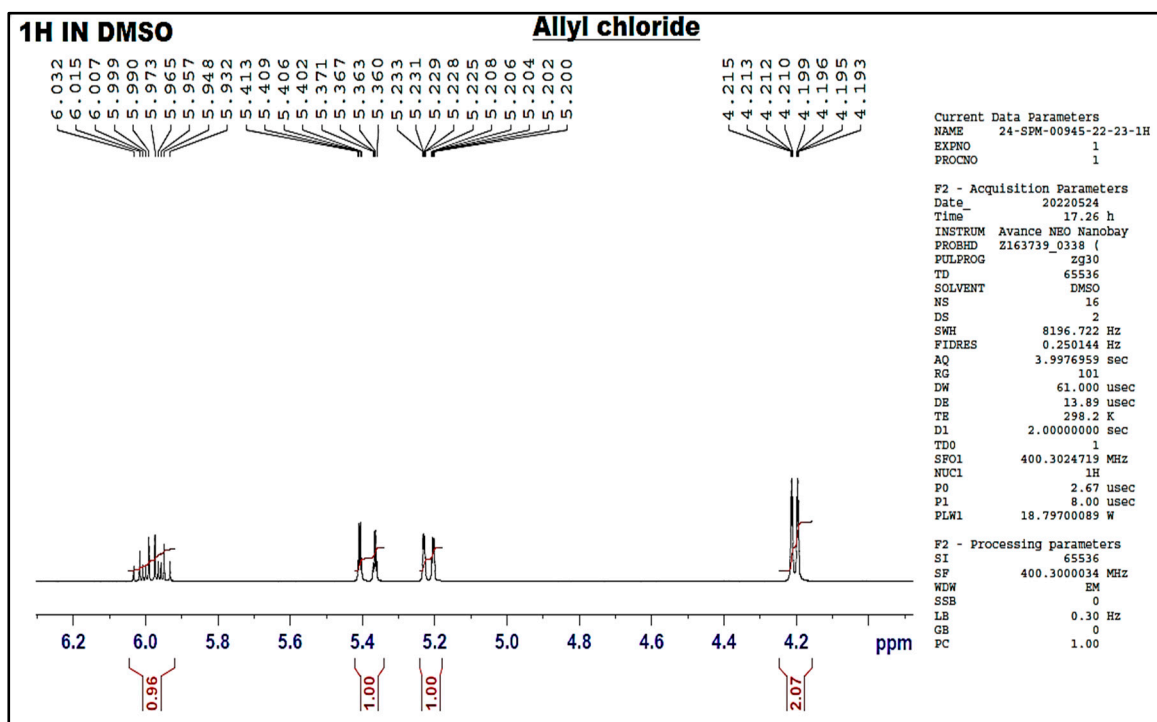


Figure S7. Allyl chloride standard ¹H-NMR data-4.

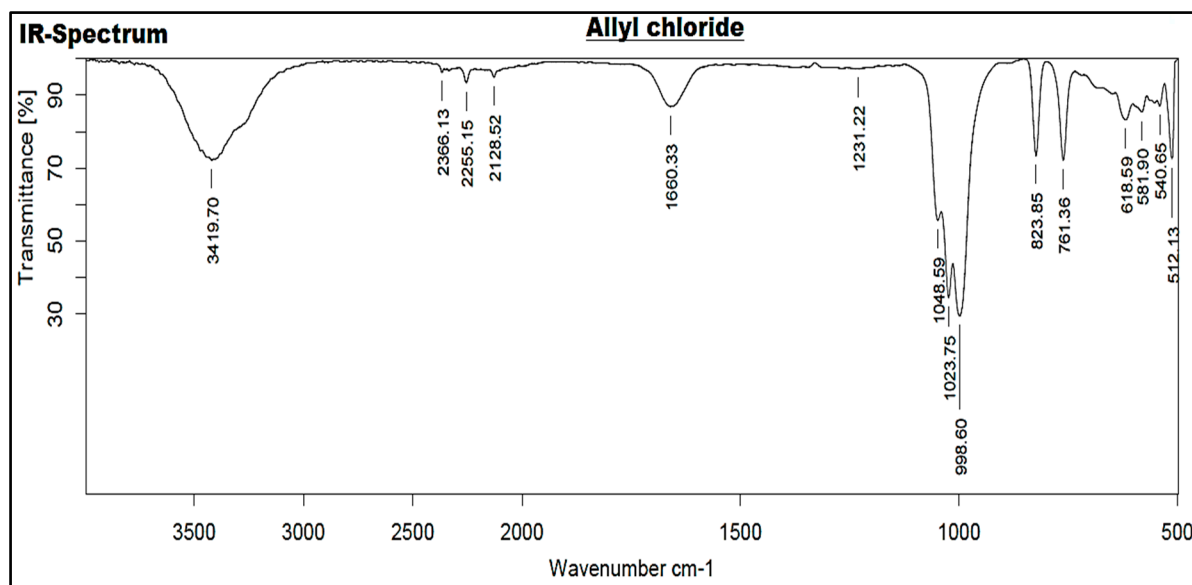


Figure S8. Allyl chloride standard IR-Spectrum.

Validation parameters:

1. System suitability and Specificity chromatograms:

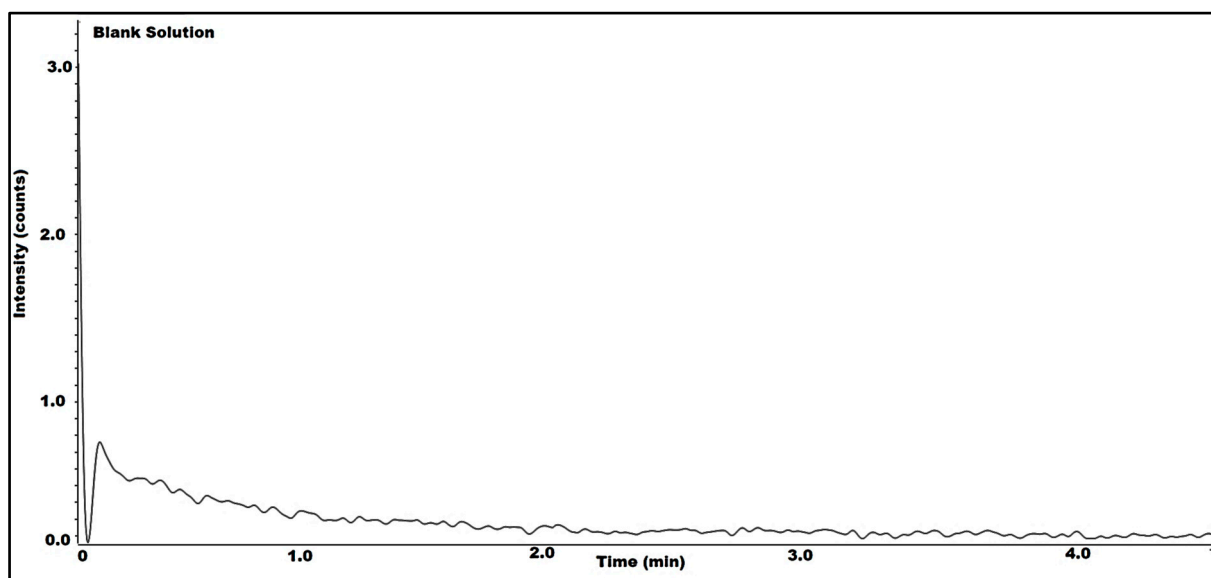


Figure S9. MS/MS chromatogram of Blank solution.

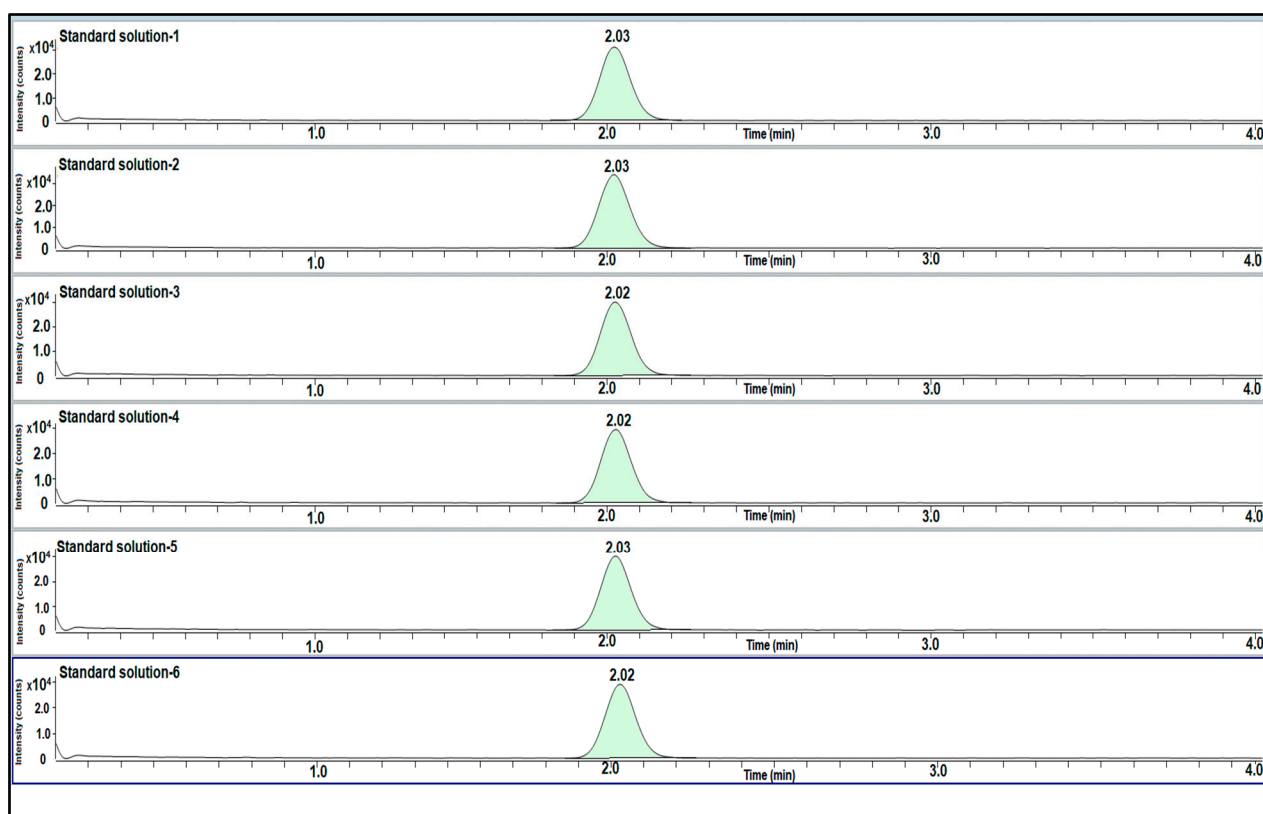


Figure S10. MS/MS chromatogram of System suitability standard solution.

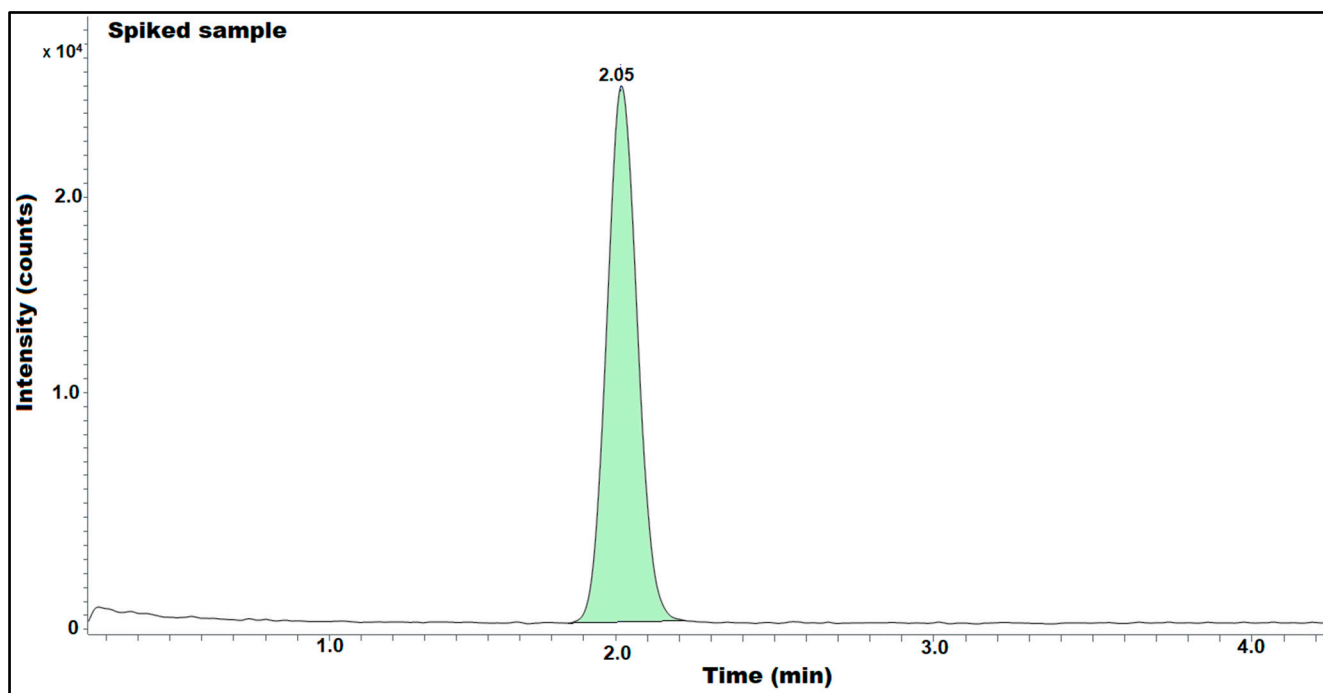


Figure S11. MS/MS chromatogram of spiked sample solution.

2. Method precision

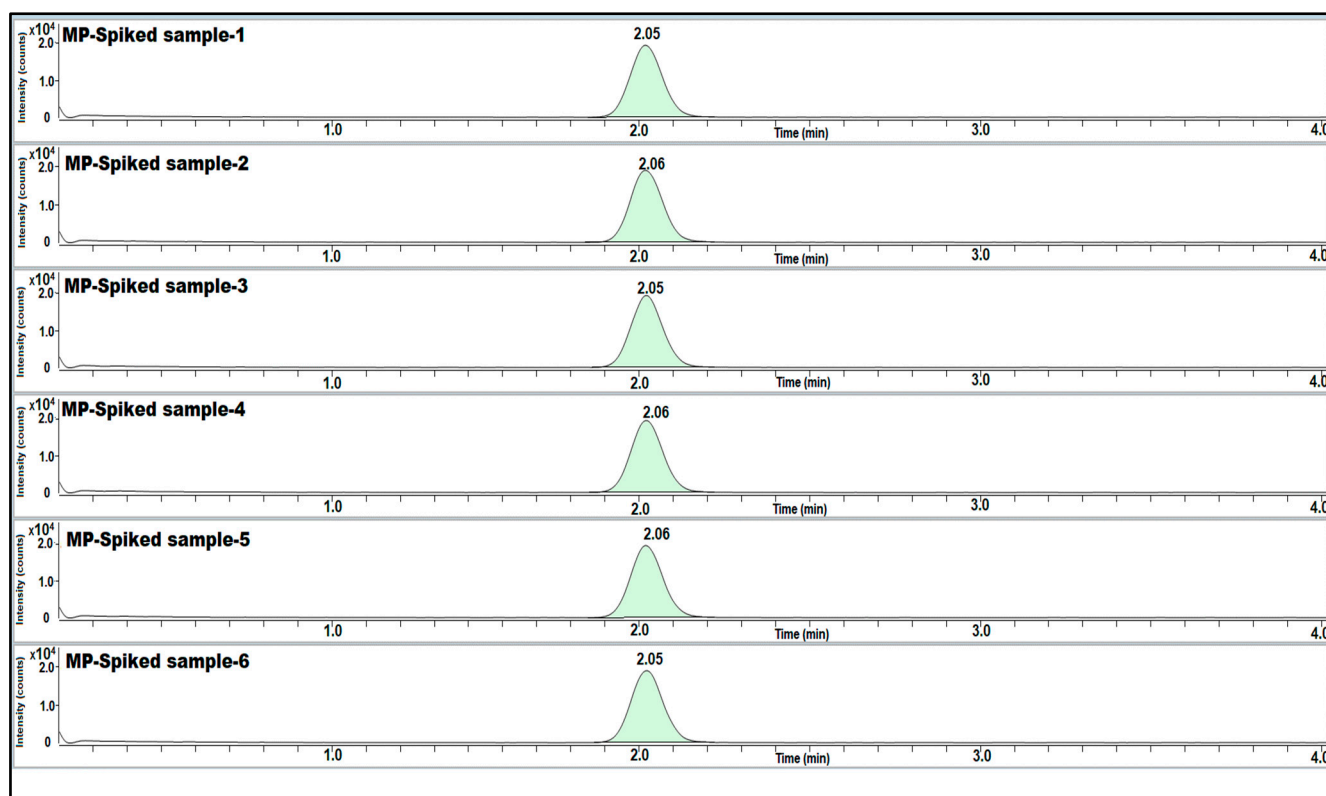


Figure S12. MS/MS chromatograms of Method precision.

3. Intermediate precision

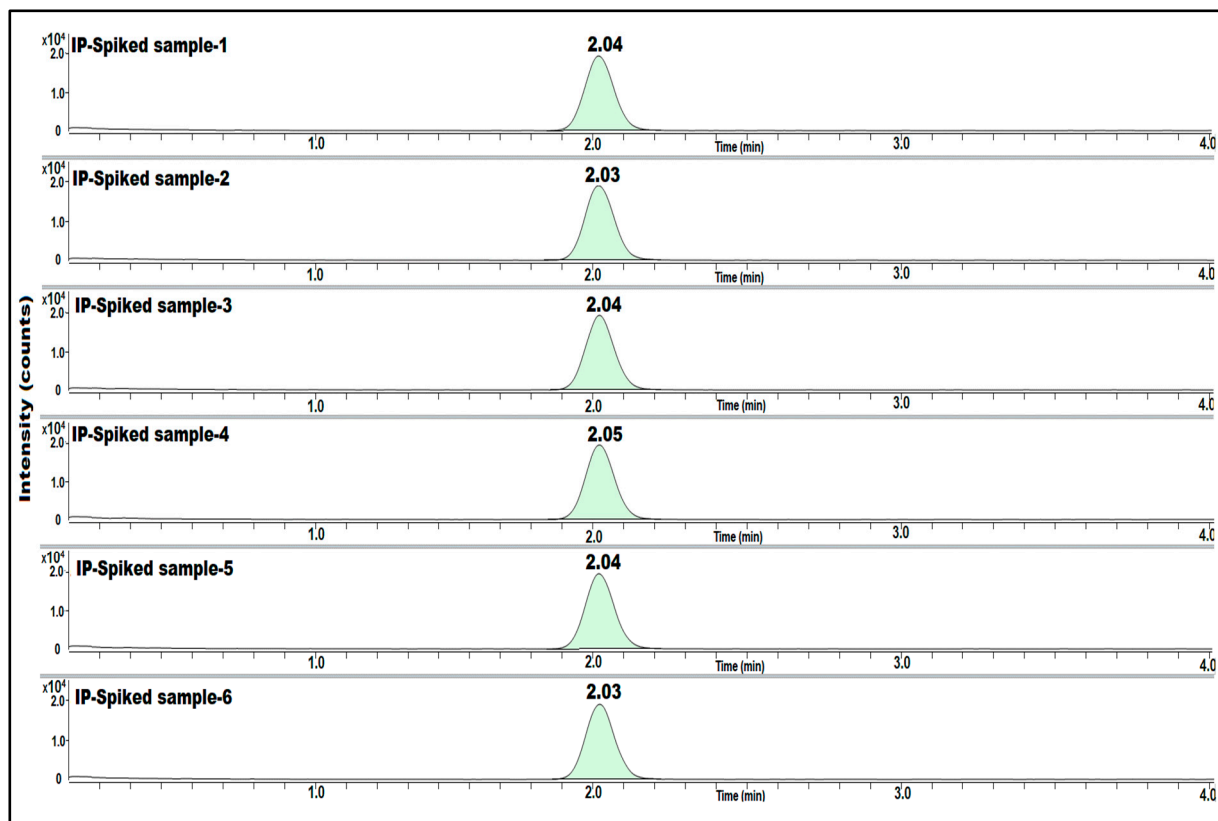


Figure S13. MS/MS chromatograms of Intermediate precision.

4. Accuracy

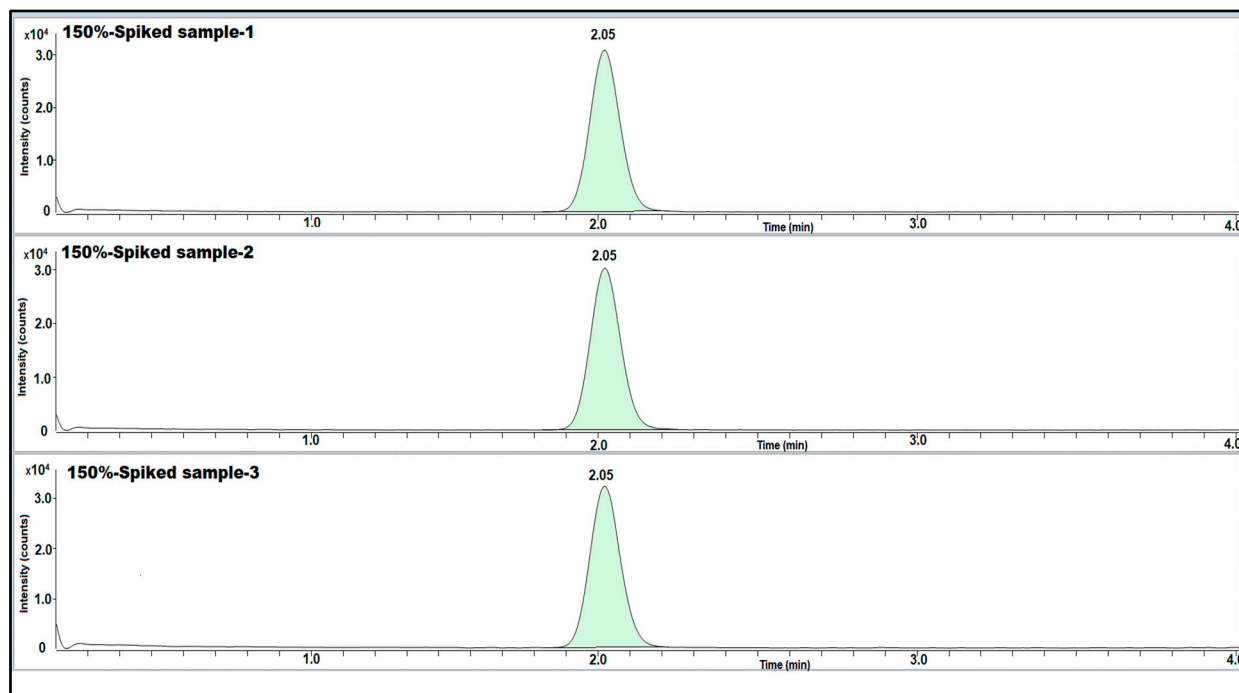


Figure S14. MS/MS chromatograms of 150% Accuracy.

5. Solution Stability

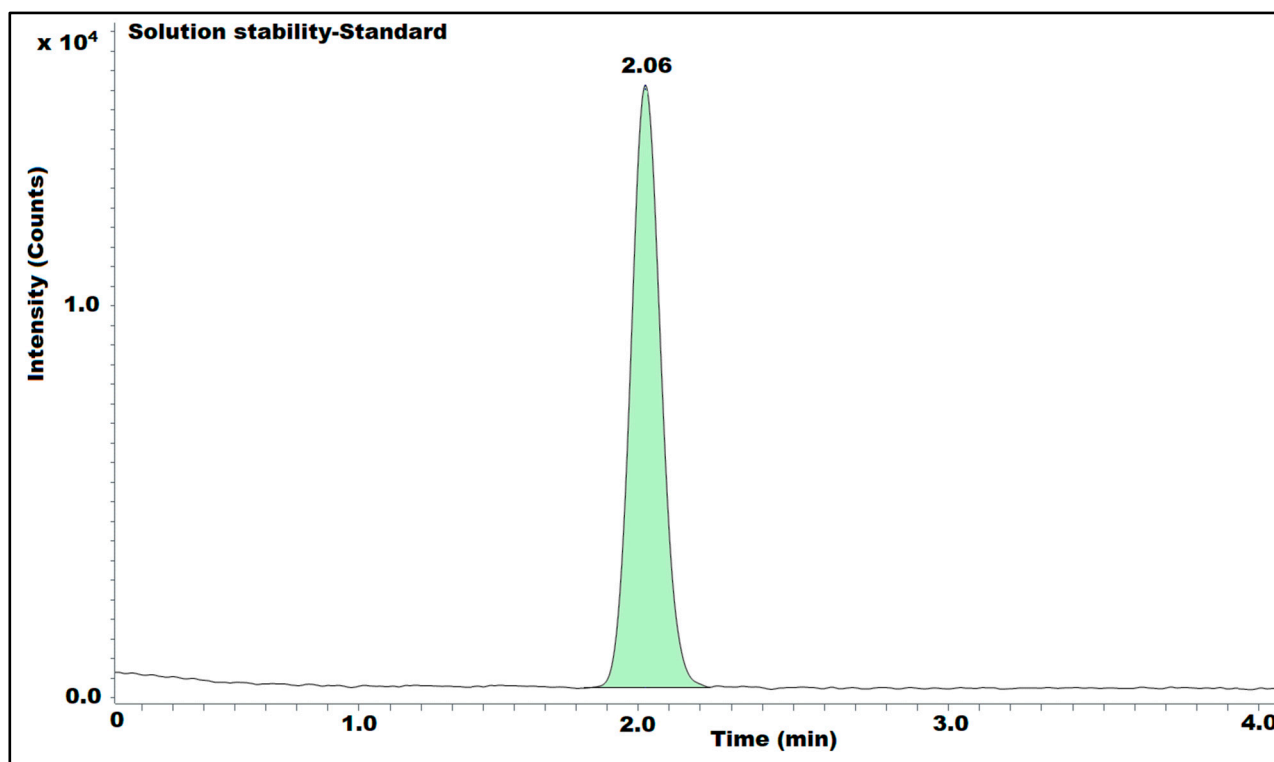


Figure 15: MS/MS chromatograms of Solution stability standard.

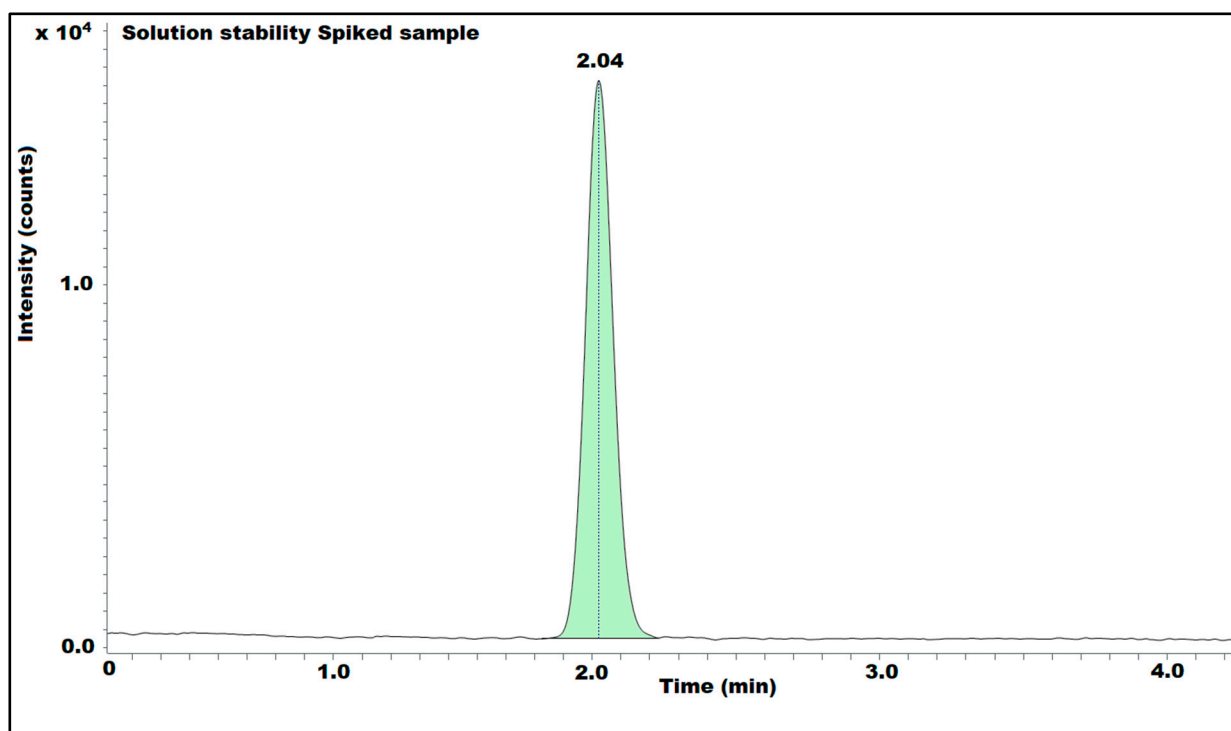


Figure S16. MS/MS chromatograms of Solution stability spiked sample.

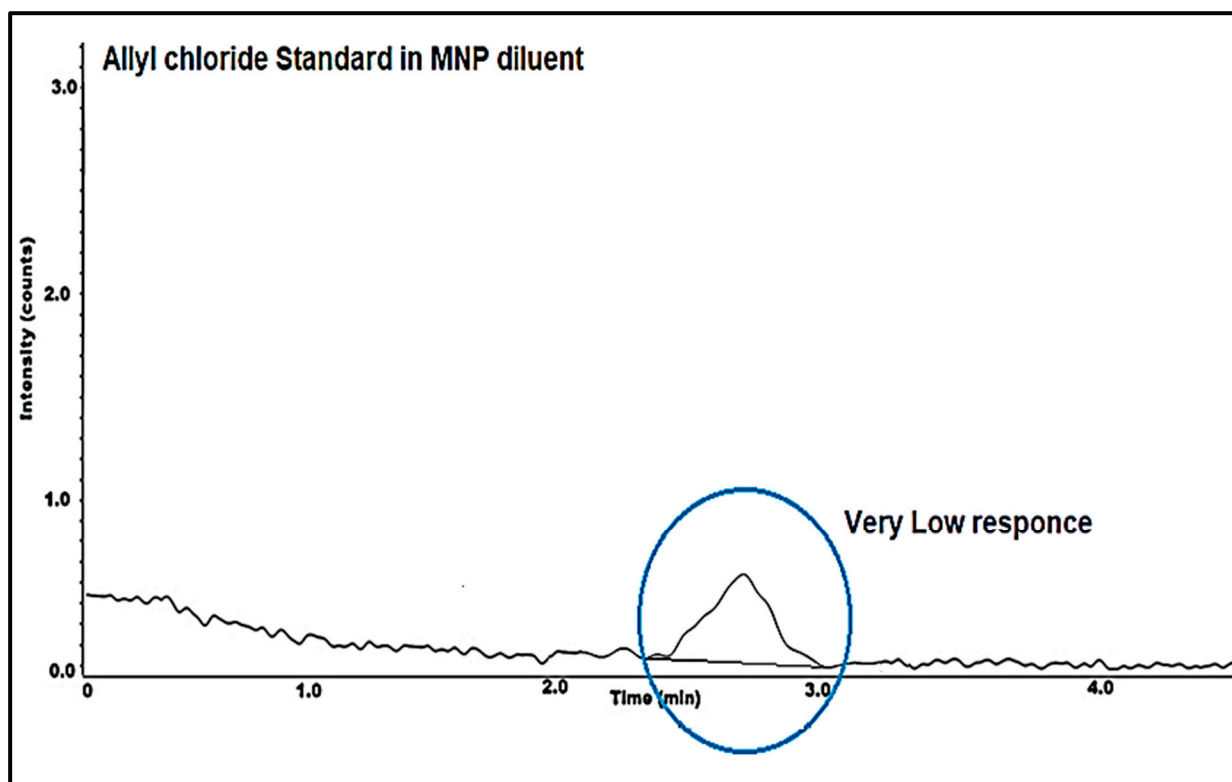


Figure S17. MS/MS chromatograms of Allyl chloride standard poor response and improper peak in Method optimization with different diluents study.