

Residual Solvents

General separation technologies, Inc.

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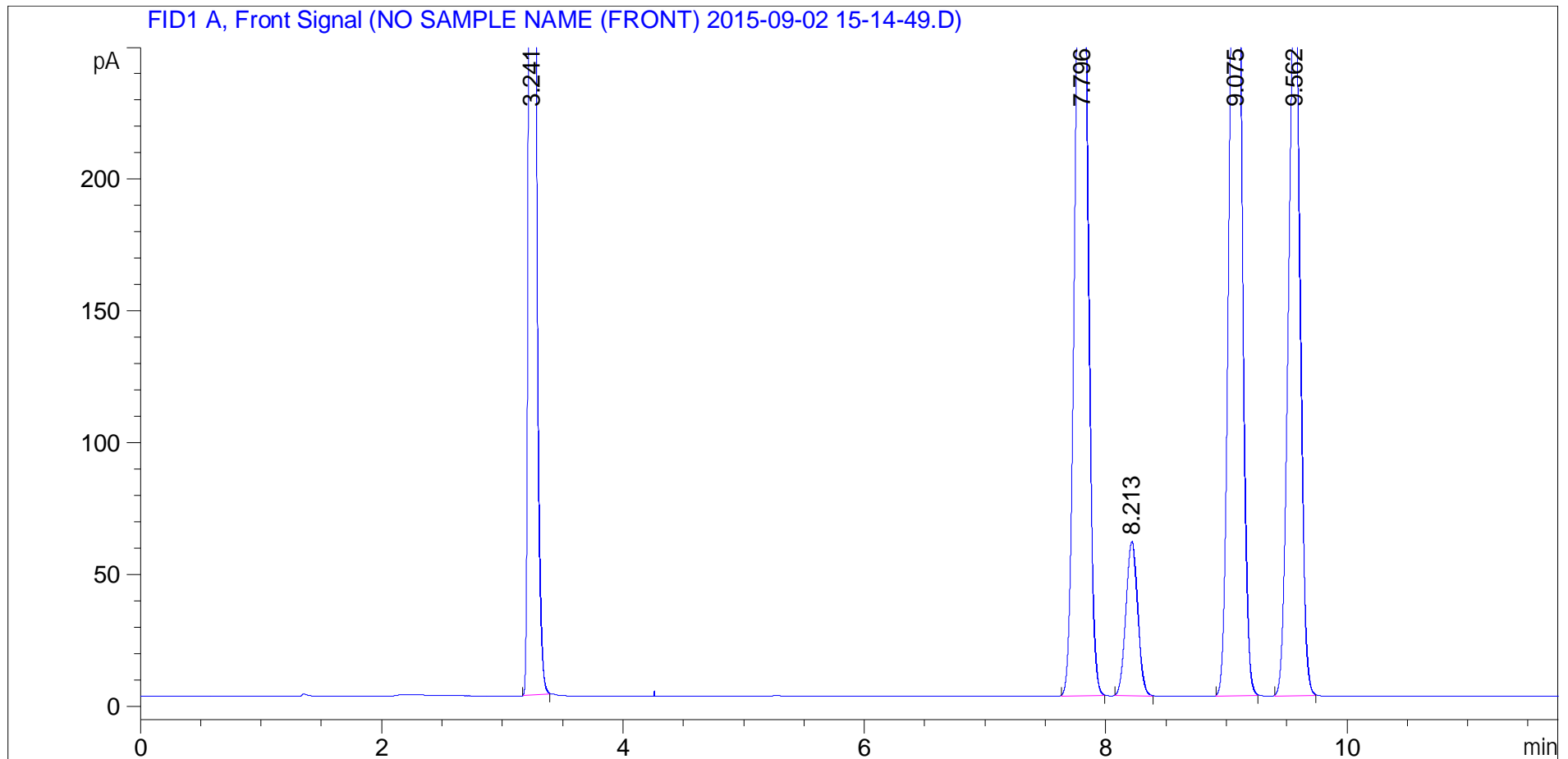
Mimy Phung

Instrumentation Conditions

- GC: Agilent 7890 w/ FID
- Cat no: 6232-3018 *30m x 0.32mm x 1.8um*
- Oven: 40°C 20min 10 °C /min 240 °C 20min
- Carrier: Hydrogen, flow 2.3ml/min
- Inlet: Split, 260 °C, split flow 60ml/min
- Detector: FID 280 °C
- Sample: residual solvent Class 1 and Class 2 sample

Chromatogram

Sample: USP class 1 residual solvent mixture

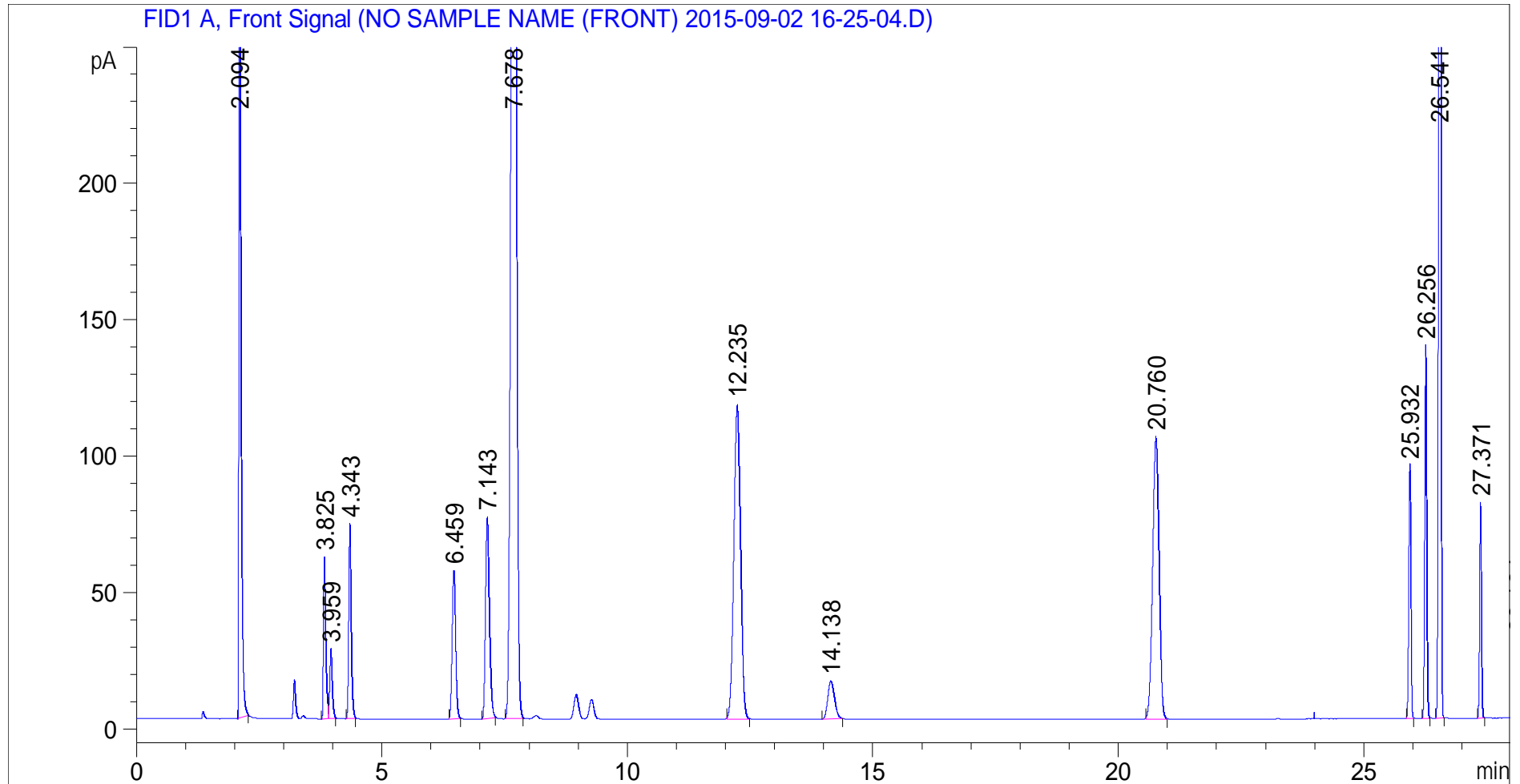


Peak Identifications

Peak#	Compound	Retention time (min)
1	1,1-Dichloroethene	3.241
2	1,1,1-Trichloroethane	7.796
3	Carbon Tetrachloride	8.213
4	Benzene	9.075
5	1,2-Dichloroethane	9.562

Chromatogram

Sample: USP class 2 residual solvent mixture A



Peak Identifications

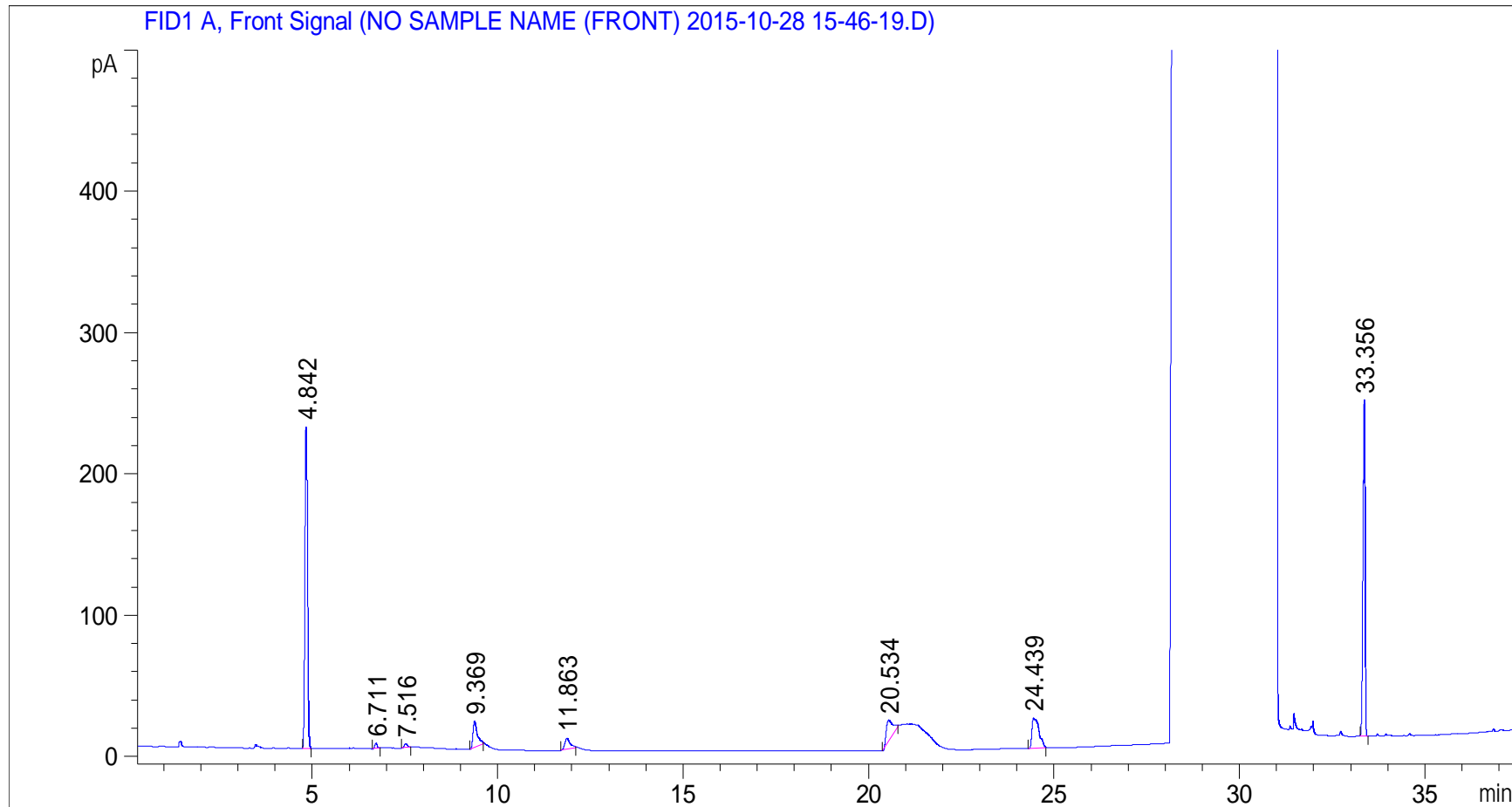
Peak#	Compound	Retention time (min)	Resolution
1	Methanol	2.094	
2	Acetonitrile	3.825	
3	Dichloromethane	3.959	2.55
4	trans-1,2-Dichloroethene	4.343	
5	cis-1,2-Dichloroethene	6.459	
6	Tetrahydrofuran	7.143	
7	Cyclohexane	7.678	5.65

Peak Identifications (continued)

Peak#	Compound	Retention time (min)	Resolution
8	Methylcyclohexane	12.235	
9	1,4-Dioxane	14.138	
10	Toluene	20.760	
11	Chlorobenzene	25.932	
12	Ethyl benzene	26.256	
13	m-Xylene / p-Xylene	26.541	
14	o-Xylene	27.371	

Chromatogram

Sample: USP class 2 residual solvent mixture B



Peak Identifications

Peak#	Compound	Retention time (min)
1	Hexane	4.842
2	Nitromethane	6.711
3	Chloroform	7.516
4	1,2-Dimethoxyethane	9.369
5	Trichloroethylene	11.863
6	Pyridine	20.534
7	2-Hexanone	24.439
8	Tetralin	33.356

Conclusion:

The 7890 GC system equipped with our GsBP-624 column provides an excellent method for separating, identifying, and quantifying residual solvents outlined by USP 467. Beyond the expected coelutions, the peaks in all three classes are well resolved from each other with good resolution and can be quantified repeatably. The resolution could be further improved by adjusting the program temperature and column flow.