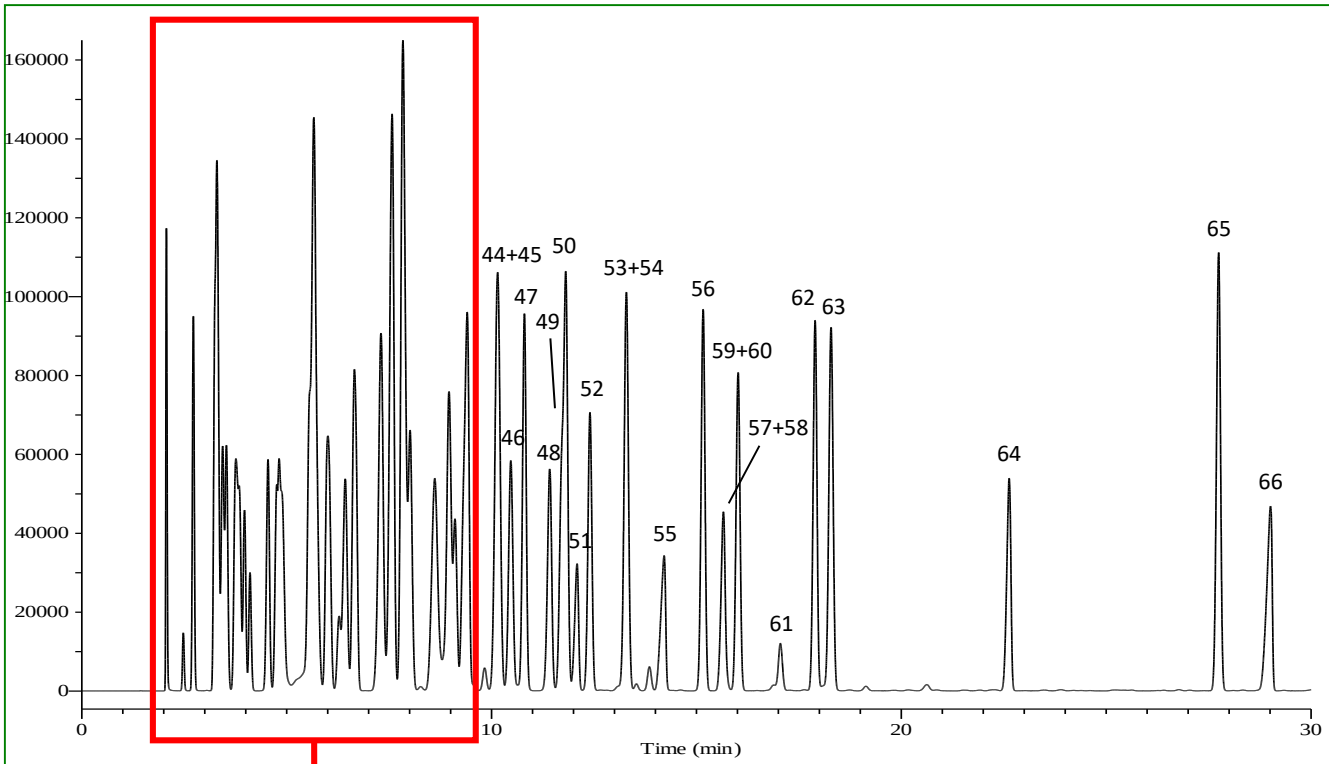
GT036

GL Sciences Inc.

Analysis of Residual Solvent Components in Pharmaceutical Products - Using InertCap 5

This application presents an example of the analysis of components subject to the Guideline for Residual Solvents in Pharmaceuticals.
According to the level of toxicity, this guideline classifies solvents as Class 1, Class 2, Class 3, and those for which no appropriate toxicity data is available. In this study, simultaneous analysis of components was made using GC/FID and performed with InertCap 5, a low-polarity column.

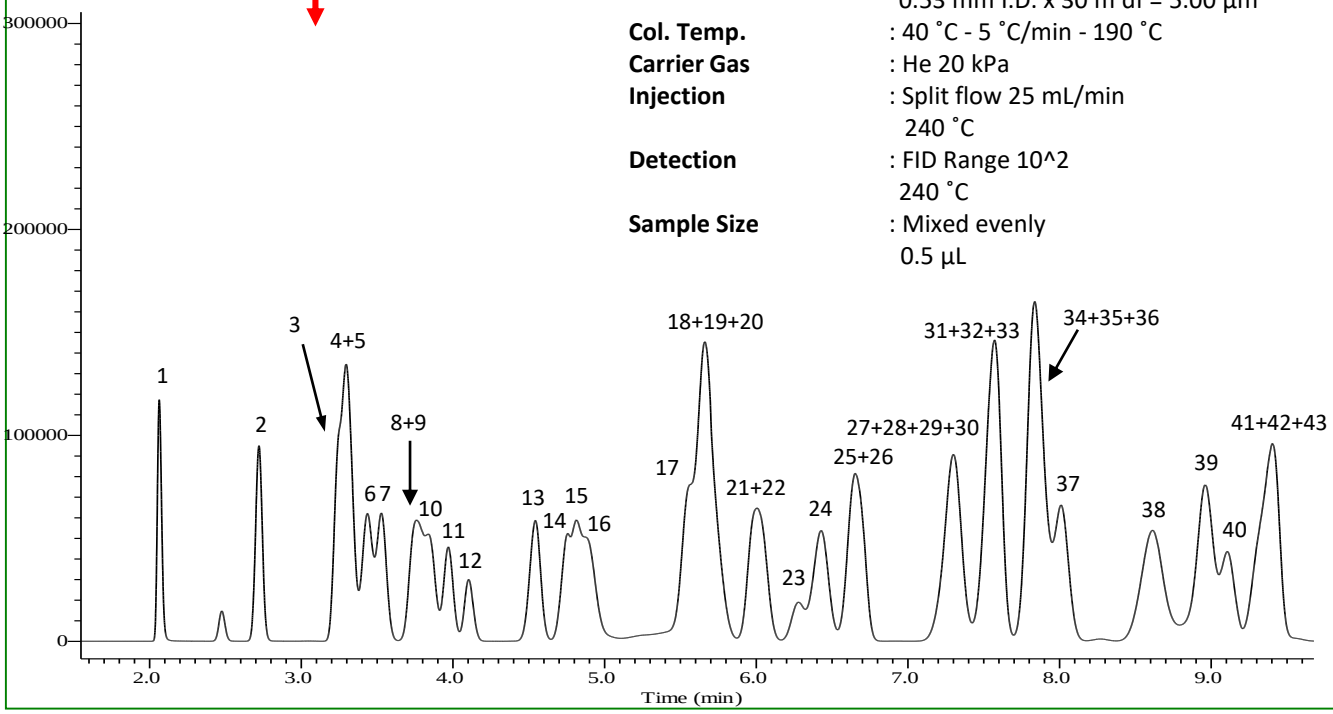
Example : Measurement of mixed sample



Enlarged view

Conditions

System	: GC - FID
Column	: InertCap 5 0.53 mm I.D. x 30 m df = 5.00 µm
Col. Temp.	: 40 ˚C - 5 ˚C/min - 190 ˚C
Carrier Gas	: He 20 kPa
Injection	: Split flow 25 mL/min 240 ˚C
Detection	: FID Range 10^2 240 ˚C
Sample Size	: Mixed evenly 0.5 µL



Sample name and retention index

Component	RI	Component	RI	Component	RI
1. Methanol	362	24. 2-Methyl-1-propanol (Isobutyl alcohol)	624	45. 3-Methyl-1-butanol (Isoamyl alcohol)	731
2. Ethanol	439				
3. Acetonitrile	486	25. Tetrahydrofuran	630	46. 4-Methyl-2-pentanone(MIBK)	739
4. Acetone	488	26. 2-Methoxyethanol (Methyl cellosolve)	630	47. Pyridine	748
5. 2-Propanol(Isopropyl alcohol)	488			48. 1-Pentanol(Amyl alcohol)	764
6. *n*-Pentane	500	27. 1,2-Dimethoxyethane	650	49. Isobutyl acetate	772
7. Diethyl ether	504	28. 1,1,1-Trichloroethane	650	50. Toluene	774
8. Ethyl formate	515	29. 1,2-Dichloroethane	650	51. N,N-Dimethylformamide	781
9. 1,1-Dimethoxymethane	515	30. 2,2-Dimethoxypropane	650	52. 2-Hexanone(MBK)	789
10. 1,1-Dichloroethylene	518	31. Methyl isopropyl ketone	658	53. Propionaldehyde diethyl acetal	811
11. Methyl acetate	524	32. Isopropyl acetate	658	54. n-Butyl acetate	811
12. Dichloromethane	530	33. 1-Butanol	658	55. Dimethyl sulfoxide(DMSO)	834
13. 1-Propanol	550	34. Benzene	666	56. Chlorobenzene	858
14. trans-1,2-Dichloroethylene	560	35. Carbon tetrachloride	666	57. N,N-Dimethylacetamide	870
15. tert-Butyl methyl ether	562	36. Cyclohexane	666	58. Ethylbenzene	870
16. Nitromethane	564	37. 2-Methyltetrahydrofura	672	59. *p*-Xylene	879
17. 2-Butanone(MEK)	597	38. 2,2,4-Trimethylpentane	690	60. *m*-Xylene	879
18. 2-Butanol	600	39. *n*-Heptane	700	61. *o*-Xylene	905
19. *n*-Hexane	600	40. Trichloroethylene	704	62. Anisole	926
20. Diisopropyl ether	600	41. 2-Ethoxyethanol	712	63. Cumene	936
21. *cis*-1,2-Dichloroethylene	611	42. *n*-Propyl acetate	712	64. *n*-methyl-2-pyrrolidone	1050
22. Ethyl acetate	611	43. 1,4-Dioxane	712	65. 1,2,3,4-Tetrahydronaphthalene	1194
23. Chloroform	619	44. Methylcyclohexane	731	66. Sulfolane	1232

Xylene used is a mixture of *m*-Xylene, *p*-Xylene, *o*-Xylene, and Ethylbenzene.

Retention indices are...

This value is based on the carbon number of straight-chain alkanes and is calculated using the retention time of each component and hydrocarbon.

In this application, a temperature-rise analysis was made . The formula is shown below.

Retention index

$$I = 100 \times \frac{TR - tR(Z)}{TR(Z+1) - tR(Z)} + 100 \times Z$$

TR = retention time of the target component
T R(Z) = retention time of straight-chain alkanes that precede the components of interest
TR(Z+1) = retention time of straight-chain alkanes emerging after the component of interest.
Z = number of carbon in the straight-chain alkane with retention time tR(Z)

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