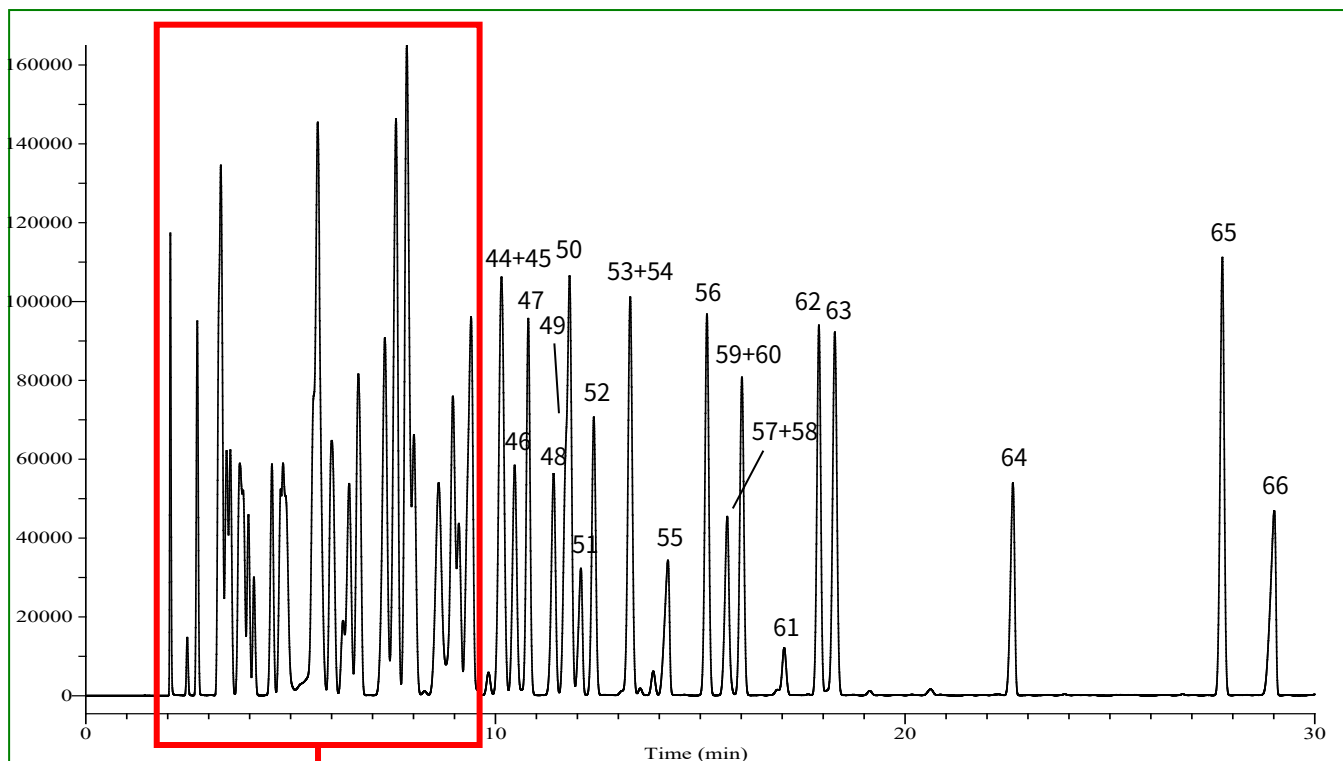


Analysis of Residual Solvent Components in Pharmaceutical Products - Using InertCap 5

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.

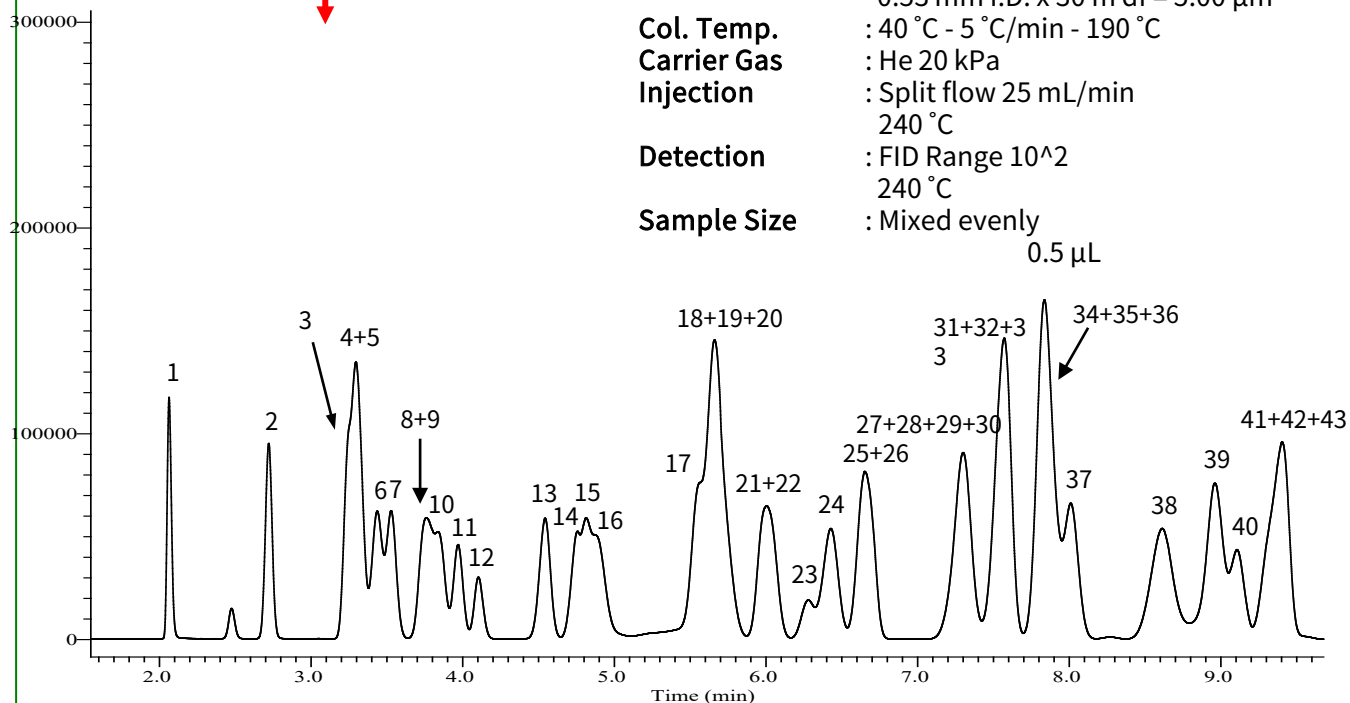
Example : Measurement of mixed sample



Enlarged
view

Conditions

System	: GC - FID
Column	: InertCap 5 0.53 mm I.D. x 30 m df = 5.00 μ m
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 μ L



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

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.

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

TR = retention time of the target component
 TR(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)

GL Sciences disclaims any and all responsibility for any injury or damage which may be caused by this data directly or indirectly. We reserve the right to amend this information or data at any time and without any prior announcement.

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