Analysis of Residual Solvent Components in Pharmaceutical Products – Using InertCap Pure-WAX

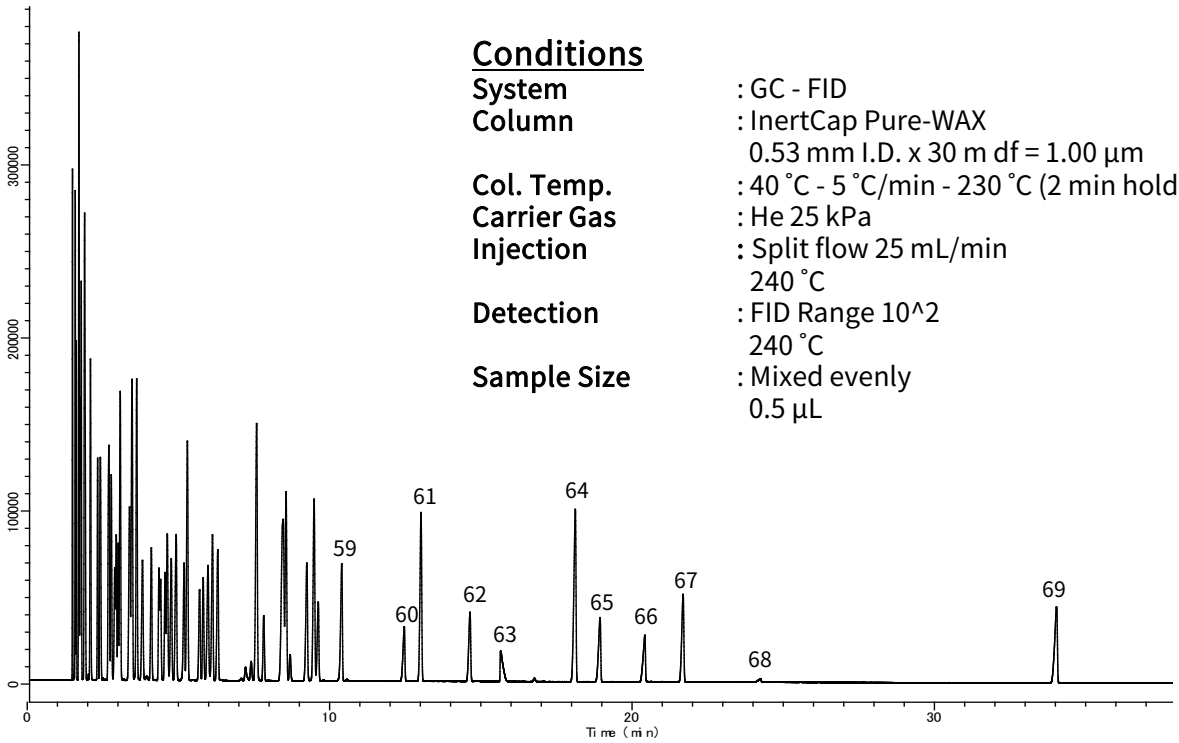
This application is an example of the analysis of components subject to the Guideline for Residual Solvents in Drugs.

Depending on the level of toxicity, this guideline classifies solvents as Class 1, Class 2, Class 3, and those for which no appropriate toxicity data are available. For these solvents, simultaneous analysis of the components was performed using GC/FID.

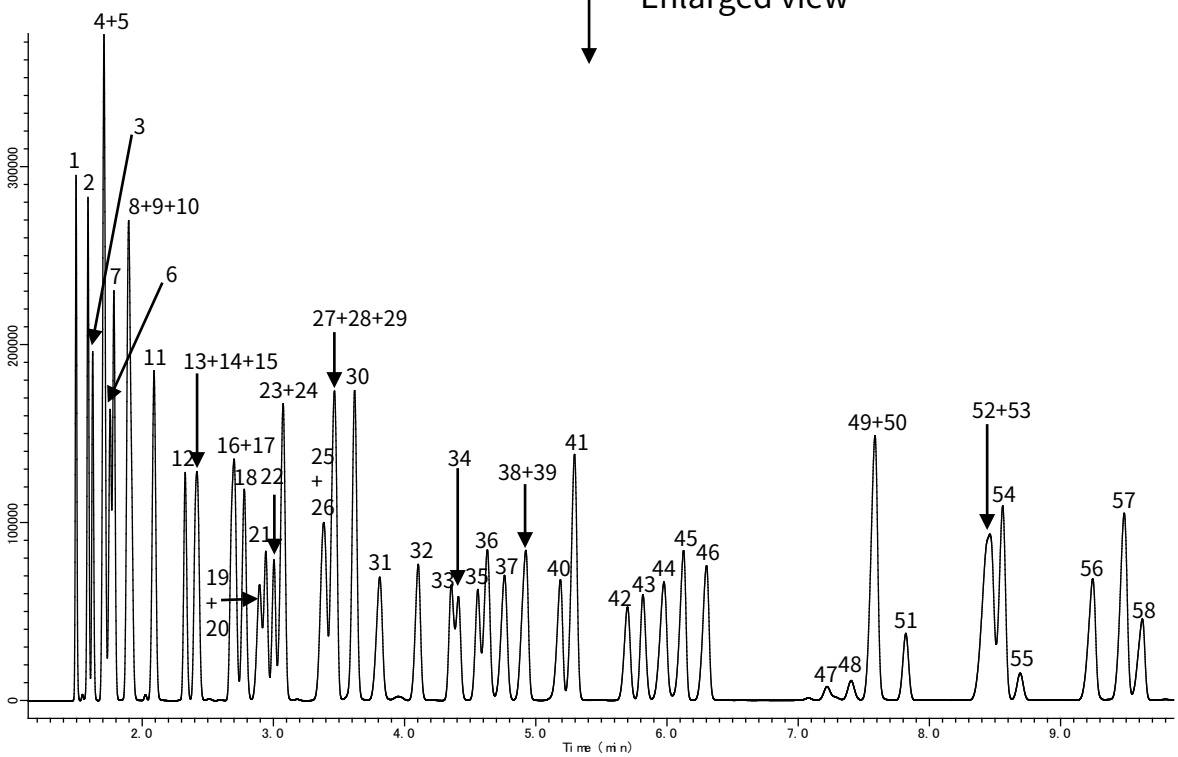
Example: measurement of mixed sample

Conditions

System	: GC - FID
Column	: InertCap Pure-WAX 0.53 mm I.D. x 30 m df = 1.00 µm
Col. Temp.	: 40 ˚C - 5 ˚C/min - 230 ˚C (2 min hold)
Carrier Gas	: He 25 kPa
Injection	: Split flow 25 mL/min 240 ˚C
Detection	: FID Range 10^2 240 ˚C
Sample Size	: Mixed evenly 0.5 µL



Enlarged view



Sample name and retention index

InertCap Pure WAX

Component	RI	Component	RI	Component	RI
1. *n*-Pentane	500	25. 1,2-Dimethoxyethane	931	48. p-Xylene	1143
2. *n*-Hexane	600	26. 2-Propanol(Isopropyl alcohol)	931	49. 1-Butanol	1151
3. Diethyl ether	632	27. Dichloromethane	937	50. *m*-Xylene	1151
4. 2,2,4-Trimethylpentane	670	28. Ethanol	937	51. Nitromethane	1160
5. Diisopropyl ether	670	29. Methyl isopropyl ketone	937	52. 2-Methoxyethanol (Methyl cellosolve)	1186
6. tert-Butyl methyl ether	691	30. Benzene	948		
7. *n*-Heptane	700	31. Propionaldehyde diethyl aceta	963	53. Cumene	1186
8. 1,1-Dimethoxymethane	729	32. *n*-Propyl acetate	984	54. Pyridine	1191
9. Cyclohexane	729	33. *cis*-1,2-Dichloroethylene	1001	55. *o*-Xylene	1195
10. 1,1-Dichloroethylene	729	34. Trichloroethylene	1004	56. 3-Methyl-1-butanol (Isoamyl alcohol)	1217
11. Methylcyclohexane	777	35. Acetonitrile	1012		
12. Acetone	819	36. 4-Methyl-2-pentanone(MIBK)	1016	57. Chlorobenzene	1225
13. 2,2-Dimethoxypropane	830	37. Isobutyl acetate	1022	58. 2-Ethoxyethanol	1231
14. Methyl acetate	830	38. Chloroform	1031	59. 1-Pentanol(Amyl alcohol)	1259
15. Ethyl formate	830	39. 2-Butanol	1031	60. N,N-Dimethylformamide	1335
16. Tetrahydrofuran	866	40. 1-Propanol	1044	61. Anisole	1354
17. trans-1,2-Dichloroethylene	866	41. Toluene	1049	62. N,N-Dimethylacetamide	1413
18. 2-Methyltetrahydrofuran	876	42. 1,4-Dioxane	1069	63. Acetic acid	1448
19. 1,1,1-Trichloroethane	891	43. 1,2-Dichloroethane	1074	64. 1,2,3,4-Tetrahydronaphthalene	1541
20. Carbon tetrachloride	891	44. *n*-Butyl acetate	1083	65. Dimethyl sulfoxide(DMSO)	1574
21. Ethyl acetate	897	45. 2-Hexanone(MBK)	1091	66. Ethylene glycol	1631
22. Methanol	903	46. 2-Methyl-1-propanol (Isobutyl alcohol)	1100	67. N-methyl-2-pyrrolidone	1681
23. 2-Butanone(MEK)	908			68. Formamide	1787

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

Retention indices are...

This value is based on the number of carbons in the straight-chain alkanes and is calculated using the retention time of each componentt.

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

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

TR = retention time of the target compound
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 carbons in the straight-chain alkane with hydrocarbon retention time tR(Z)

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