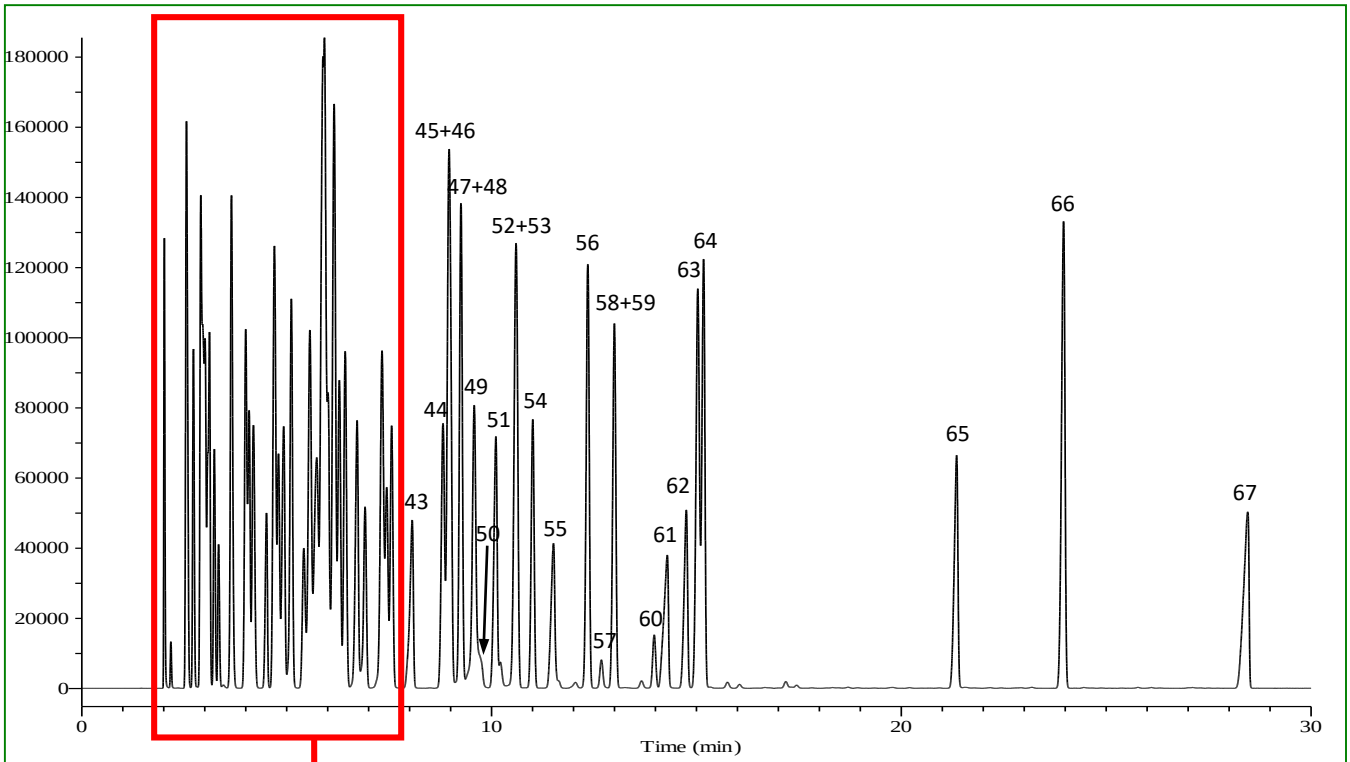
GT035

GL Sciences Inc.

Analysis of Residual Solvent Components in Drugs - Using InertCap 624

This application note is 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 analyses of components was made using GC/FID and performed with InertCap 624, a column for VOC analysis.

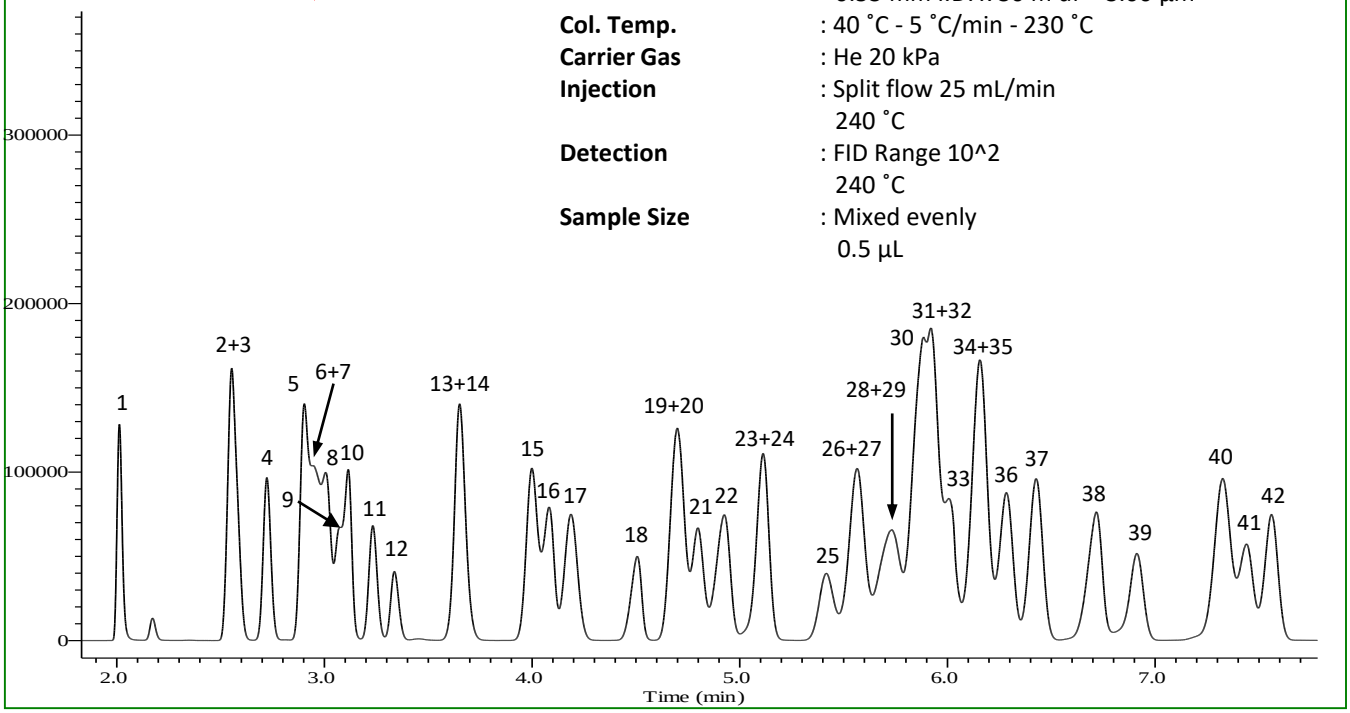
Example: Measurement of mixed sample



Enlarged view

Conditions

System	: GC - FID
Column	: InertCap 624 0.53 mm I.D. x 30 m df = 3.00 µm
Col. Temp.	: 40 ˚C - 5 ˚C/min - 230 ˚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

Sample	RI	Sample	RI	Sample	RI
1. Methanol	416	24. Chloroform	646	46. 3-Methyl-1-butanol (Isoamyl alcohol)	778
2. Ethanol	500	25. 1,1,1-Trichloroethane	659		
3. n-Pentane	500	26. Cyclohexane	665	47. Toluene	787
4. Diethyl ether	510	27. 2,2-Dimethoxypropane	665	48. Ethylene glycol	787
5. Acetone	523	28. Carbon tetrachloride	671	49. Isobutyl acetate	797
6. 1,1-Dichloroethylene	528	29. 2-Methyl-1-propanol (Isobutyl alcohol)	671	50. Formamide	799
7. 1,1-Dimethoxymethane	528			51. 1-Pentanol(Amyl alcohol)	812
8. 2-Propanol(Isopropyl alcoh	530	30. 1,2-Dimethoxyethane	677	52. Propionaldehyde diethyl ace	826
9. Ethyl formate	536	31. 1,2-Dichloroethane	680	53. 2-Hexanone(MBK)	826
10. Acetonitrile	538	32. Benzene	680	54. *n*-Butyl acetate	837
11. Methyl acetate	546	33. Isopropyl acetate	683	55. N,N-Dimethylformamide	850
12. Dichloromethane	554	34. 2,2,4-Trimethylpentane	689	56. Chlorobenzene	874
13. trans-1,2-Dichloroethylen	576	35. 2-Methyltetrahydrofuran	689	57. Ethylbenzene	883
14. tert-Butyl methyl ether	576	36. Methyl isopropyl ketone	694	58. *p*-Xylene	891
15. n-Hexane	600	37. n-Heptane	700	59. *m*-Xylene	891
16. 1-Propanol	603	38. 1-Butanol	709	60. *o*-Xylene	918
17. Diisopropyl ether	608	39. Trichloroethylene	715	61. Dimethyl sulfoxide(DMSO)	925
18. Nitromethane	621	40. Methylcyclohexane	728	62. N,N-Dimethylacetamide	939
19. 2-Butanone(MEK)	629	41. 1,4-Dioxane	731	63. Cumene	947
20. *cis*-1,2-Dichloroethylene	629	42. *n*-Propyl acetate	735	64. Anisole	951
21. Ethyl acetate	633	43. 2-Ethoxyethanol	750	65. N-methyl-2-pyrrolidone	1124
22. 2-Butanol	638	44. 4-Methyl-2-pentanone(MIBK	774	66. 1,2,3,4-Tetrahydronaphthale	1203
23. Tetrahydrofuran	646	45. Pyridine	778	67. Sulfolane	1244

Xylene 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 alkane 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
T R(Z+1) = retention time of straight-chain alkanes emerging after the components of interest
Z = number of carbons in the straight-chain alkane with retention time tR(Z)

GL Sciences, Inc. Japan
22-1 Nishishinjuku 6-Chome
Shinjuku-ku, Tokyo,
163-1130, Japan
Phone: +81-3-5323-6620
Fax: +81-3-5323-6621
Email: world@gls.co.jp
Web: www.glsciences.com

GL Sciences B.V.
De Sleutel 9
5652 AS Eindhoven
The Netherlands
Phone: +31 (0)40 254 95 31
Email: info@glsciences.eu
Web: www.glsciences.eu

GL Sciences, Inc. USA
4733 Torrance Blvd. Suite 255
Torrance, CA 90503
Phone: 310-265-4424
Fax: 310-265-4425
Email: info@glsciencesinc.com
Web: www.glsciencesinc.com

GL Sciences (ShangHai) Ltd.
Tower B, Room 2003,
Far East International Plaza,
NO,317 Xianxia Road,
Changning District.
Shanghai, China P.C. 200032
Phone: +86 (0)21-6278-2272
Email: contact@glsciences.com.cn
Web: www.glsciences.com.cn

International Distributors
Visit our Website at www.glsciences.com/distributors