chrozen

USP 467 Player

The Real
Plug & Play Solution

YOUNG IN Chromass

For pharmacopeial purposes, residual solvents in pharmaceuticals are defined as organic volatile chemicals that are used or produced in the manufacture of drug substances or excipients, or in the preparation of drug products. Because these solvents can be harmful to human body if they remain in the final products, it is required to regulate these compounds not to exceed the specific limits defined in certain regulations.
United Stated Pharmacopeia (USP) classifies the residual solvents into Class Ⅰ, Class Ⅱ and Class III depending on their risk to human health and USP 467 test method describes all the requirements for the analysis of residual solvents.

ChroZen GC coupling with ChroZen PAL Headspace is the optimized system for determination of residual solvents by fully complying with USP 467 and verifies the validity of analysis results for each analysis method.

Figure 1. ChroZen USP 467 Player

Summary of Test Method

Table 1. Headspace Condition

Static Headspace Conditions	
Incubation time	30min
Incubation Temperature	85°C
Agitator Speed	750rpm
Purge Time	5s
Syringe Temperature	100°C
Injection Flow Rate	60mL/min
Injection Volume	1mL

Table 2. GC/FID Condition

GC Conditions		FID Conditions	
Column	Rxi-624Sil MS (30m x 0.32 mm x 1.8 µm)	Temperature	250°C
Oven temperature program	40°C (20 min) → 10°C/min → 240°C (20min)	Air	300mL/min
Carrier gas	He (35cm/sec)	H2	30mL/min
Inlet	140°C / Capillary / Split(10:1)		

USP<467> - Class 1

As a result of the analysis of Class 1 residual solvent mixture, all compounds in Class 1 mixture had the S/N higher than 3 and 1,1,1-trichloroethane's S/N was higher than 5, which are satisfied with the requirements [Fig.2]. In particular, Carbon Tetrachloride, which has the lowest response in FID, had the S/N to 5.54 and this satisfies all requirement.

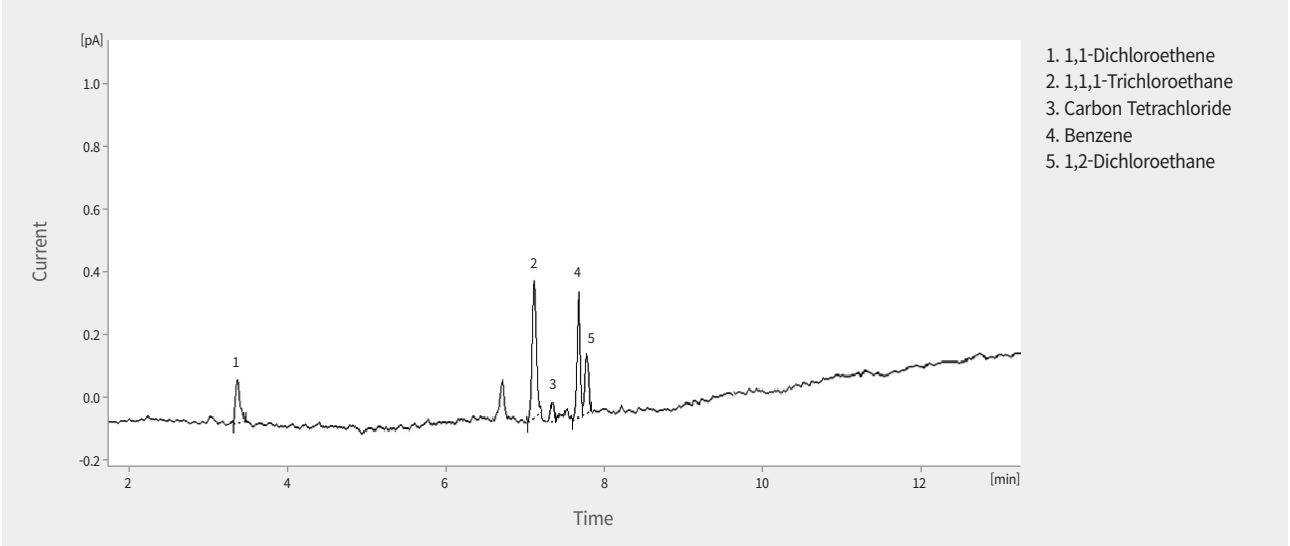

Fig 2. Chromatogram of Residual Solvents in Class 1

USP<467> - Class 2A, 2B

Class 2 is classified into 3 types. (2A, 2B, 2C) and USP 467 describes the methods for 2A and 2B only. [Fig 3] shows the analysis result for residual solvents in Class 2A and 2B. The resolution of Acetonitrile and Methylene chloride was 2.48, which sufficiently satisfies the requirement (not less than 1).

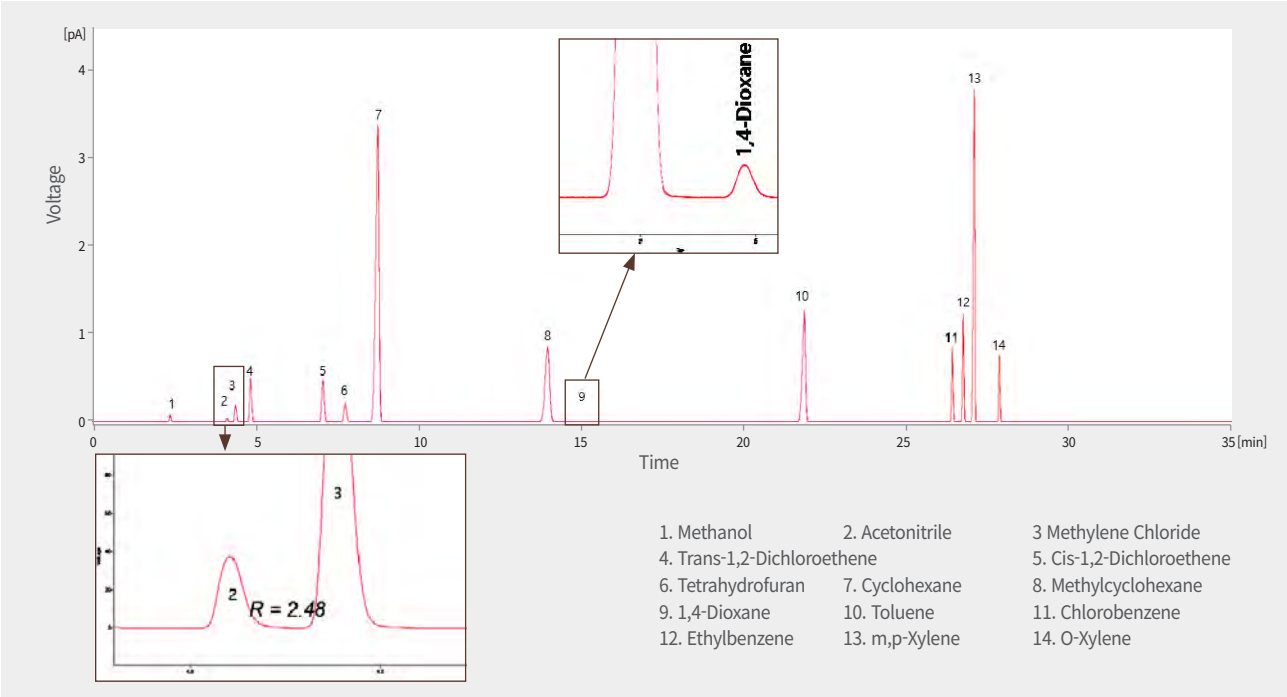

Fig 3. Chromatogram of Residual Solvents in Class 2A

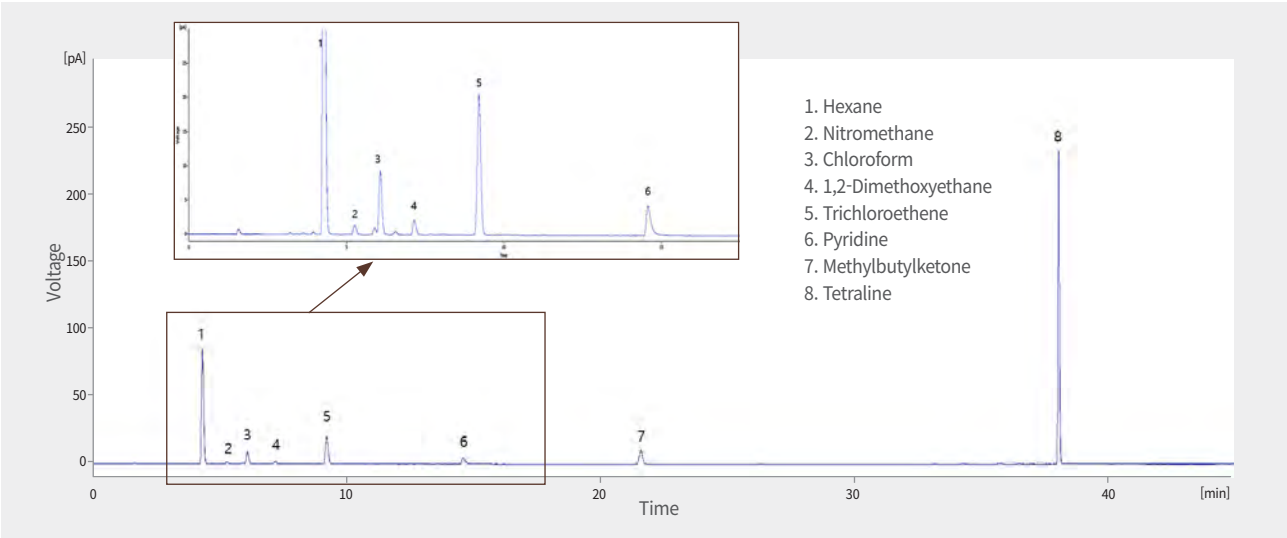

Fig 4. Chromatogram of Residual Solvents in Class 2B

The determination of residual solvents (Class 1 & 2) in pharmaceutical products by ChroZen GC with ChroZen PAL Headspace was conducted according to the method (Procedure A) specified in USP 467.
All of 5 compounds in Class 1 mixture had the S/N higher than 3 and 1,1,1-trichloroethane's S/N was higher than 5. Moreover, the resolution of acetonitrile and methylene chloride was 2.48, which proves all are satisfied with the requirements.
ChroZen GC with ChroZen PAL Headspace is the right system for analysis of residual solvents while providing the system suitability and reliability according to USP 467.

ChroZen USP 467 Player

Total Dream Solution includes:

1. Smart Hardware Platform (Based on ChroZen GC)
2. Smart ChroZen PAL 3 Series II
3. Smart Software Control (Chromatography Data System) with Method Setup
4. All Related Consumables and Accessories
5. The Real Plug & Play Solution
   - QC Report according to the specified application
   - Method Set-Up & File Embedded
   - Specified Easy Manual
6. Columns - 624MS Column : midpolarity Crossbond phase fused silica 30 m x 0.32 mm x 1.80 µm

Target Compounds Coverage

Class I	Class II	Class III
Benzene	Acetonitrile	Acetic acid
Carbon tetrachloride	Chlorobenzene	Acetone
1,2-Dichloroethane	Chloroform	Anisole
1,1-Dichloroethene	Cumene	1-Butanol
1,1,1-Trichloroethane	Cyclohexane 0	2-Butanol
1,2,4-Trimethylbenzene	1,2-Dichloroethene	Butyl acetate
	1,2-Dimethoxyethane	tert-Butylmethyl ether
	N,N-Dimethylacetamide	Dimethyl sulfoxide
	N,N-Dimethylformamide	Ethanol
	1,4-Dioxane	Ethyl acetate
	2-Ethoxyethanol	Ethyl ether
	Ethylene glycol	Ethyl formate
	Formamide	Formic acid
	Hexane	Heptane
	Methanol	Isobutyl acetate
	2-Methoxyethanol	Isopropyl acetate
	Methylbutylketone	Methyl acetate
	Methylcyclohexane	3-Methyl-1-butanol
	Methylene chloride	Methylethylketone
	N-Methylpyrrolidone	Methylisobutylketone
	Nitromethane	2-Methyl-1-propanol
	Pyridine	Pentane
	Sulfolane	1-Pentanol
	Tetrahydrofuran	1-Propanol
	Tetralin	2-Propanol
	Toluene	Propyl acetate
	Trichloroethylene	
	Xylene	

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