



Residual Solvent Analyzer

Volume 1

# Residual Solvent Analyzer

Enhanced User Convenience | Excellent Reproducibility



- Young Lin Residual Solvent Analyzer delivers you reliable data with convenient use.

Residual solvents in pharmaceuticals are organic volatile impurities (OVIs) that are either used or produced during the manufacture of active pharmaceutical ingredients, excipients and drug products. Although these solvents are critical to the synthesis process, they have no therapeutic benefit. Thus, all residual solvents should be carefully selected.

USP(United States Pharmacopoeia) <467> restricts the concentration of toxic solvents contained in medicine. Since the residual solvents on the food packing material may cause the low safety, **Korea Foods Industry Association** set the self-regulation standard as follows.

- The revised regulation for residual solvent of food packing material  
Residual Solvent < 6mg/m<sup>2</sup>                      Toluene < 2mg/m<sup>2</sup>

General guidelines by ICH (International Conference on Harmonization) divide solvents into three classes.

- Classification of Residual Solvents by Risk Assessment

**Class 1 solvents : Solvents to be avoided-**

Known human carcinogens, strongly suspected human carcinogens, and environmental hazards.

**Class 2 solvents : Solvents to be limited-**

Solvents suspected of other significant but reversible toxicities.

**Class 3 solvents : Solvents with low toxic potential-**

Solvents with low toxic potential to man; no health-based exposure limit is needed. Class 3 solvents have PDE's(Permitted Daily Exposure)of 50 milligrams (mg) or more per day.

Widely, **headspace method** is used for the analysis of residual solvents.

In the headspace, once the sample in the sealed vial is heated up to a state of equilibrium, volatile components diffuse into the gas phase. The sample is then taken from the headspace. In this measurement, only a sample of the gas in the headspace is injected into a GC system, so it reduces contamination of the injector, column and detector for long-time use of the instrument.

The Young Lin Residual Solvent Analyzer is organized for **accurate results** and for **your convenient analysis** of residual materials only.



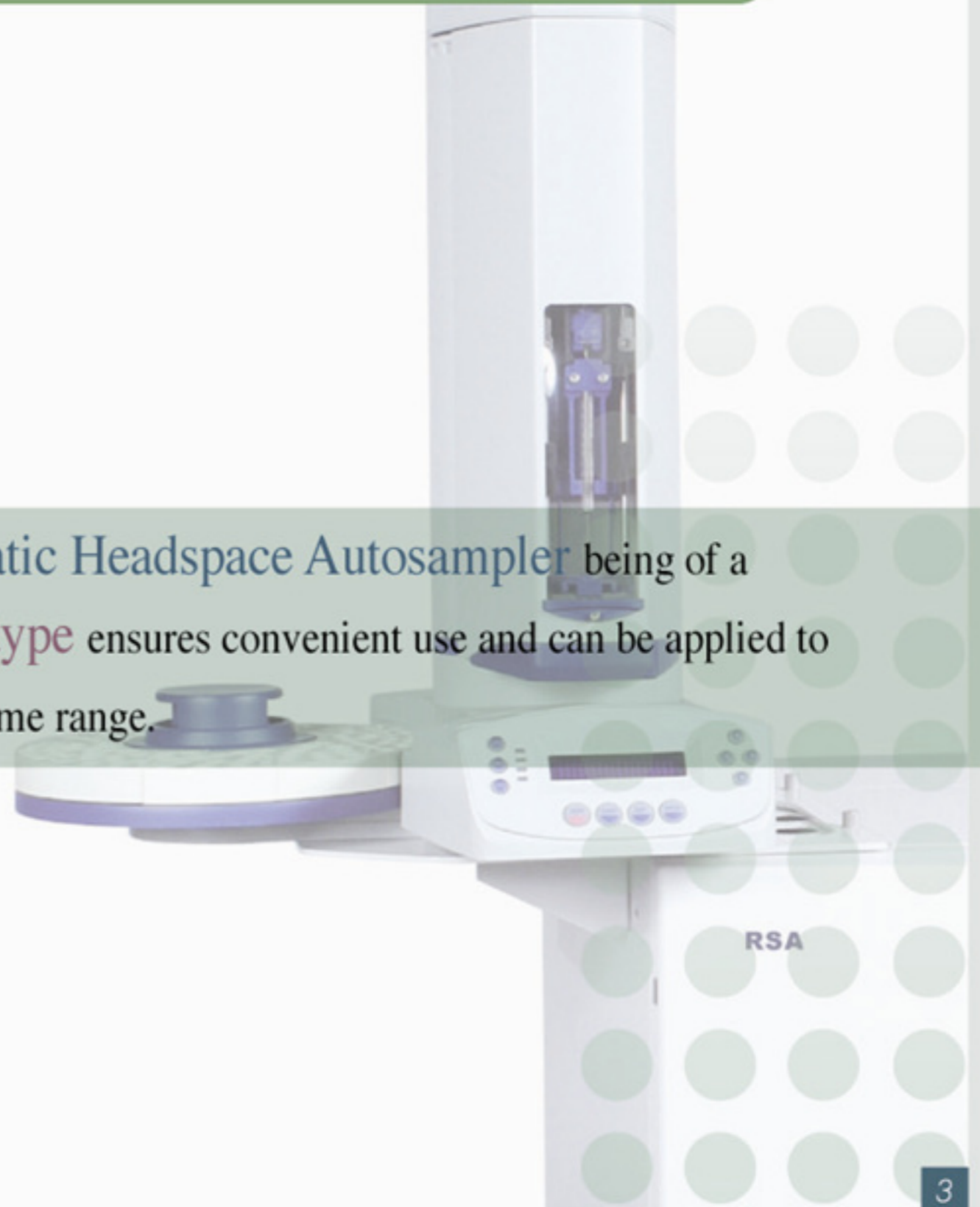
## ❖ Key Features of Residual Solvent Analyzer

- Easy sample preparation with Headspace Autosampler
- No need for extra heater (Oven installed inside.)
- This system delivers reproducible data minimizing analysis error in use with ISTD (Internal Standard measuring)
- Monitoring various residual materials at one time.
- One Young Lin Residual Solvent Analyzer includes all accessories and preparation system you need for analysis of residual material analysis

## ❖ Application

- Analysis of residuals on food packing material
- Analysis of residuals on the drugs analysis of residual materials on the extracted pigments from food

The Young Lin Static Headspace Autosampler being of a **Gas-tight syringe type** ensures convenient use and can be applied to samples in a wide volume range.

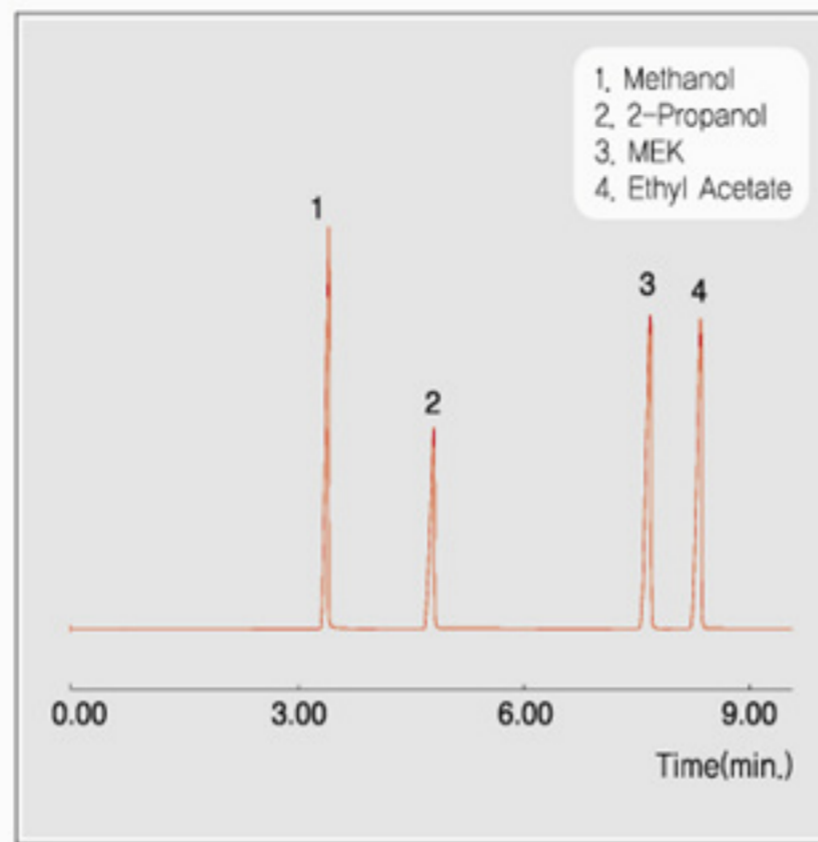


## Residual Solvent Analysis

- Analysis of General Residuals I
- Analysis of General Residuals II
- Analysis of Residual Solvents on Class 1
- Analysis of Residual Solvents on Class 2

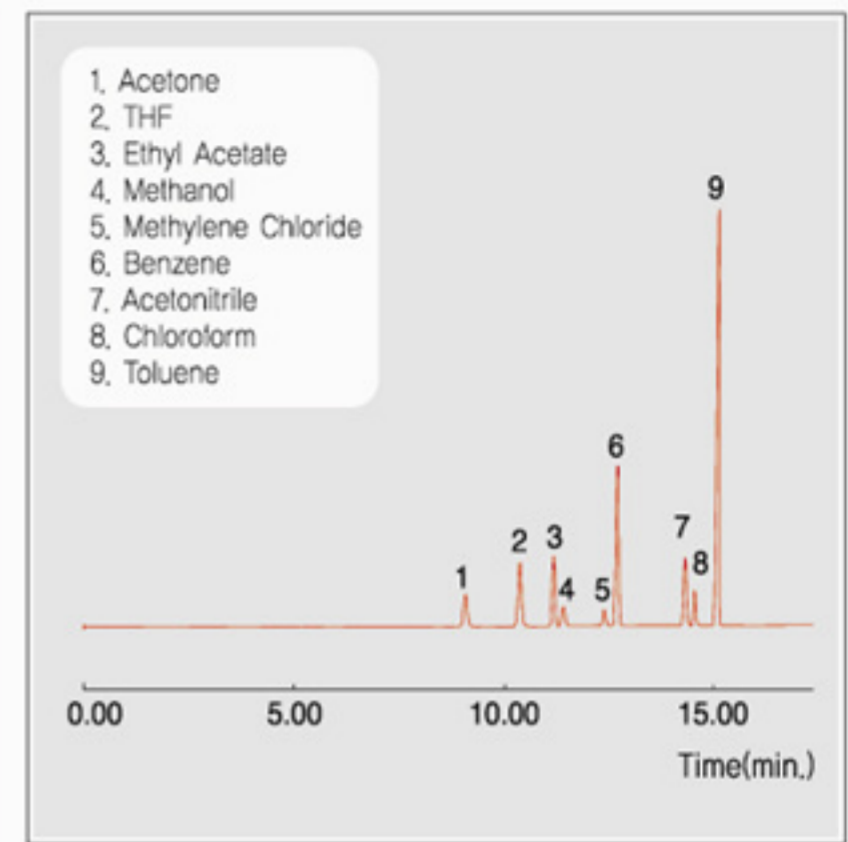
Headspace Autosampler

### Analysis of General Residuals I



Oven : 35°C(5min) – 5°C/min – 150°C(5min)  
Column : HP – 5 (30m\*0.32mm\*1.0um)  
Carrier gas : He, 1.0ml/min (Split ratio 50:1)  
Injector : Capillary 230°C  
Detector : FID 250°C

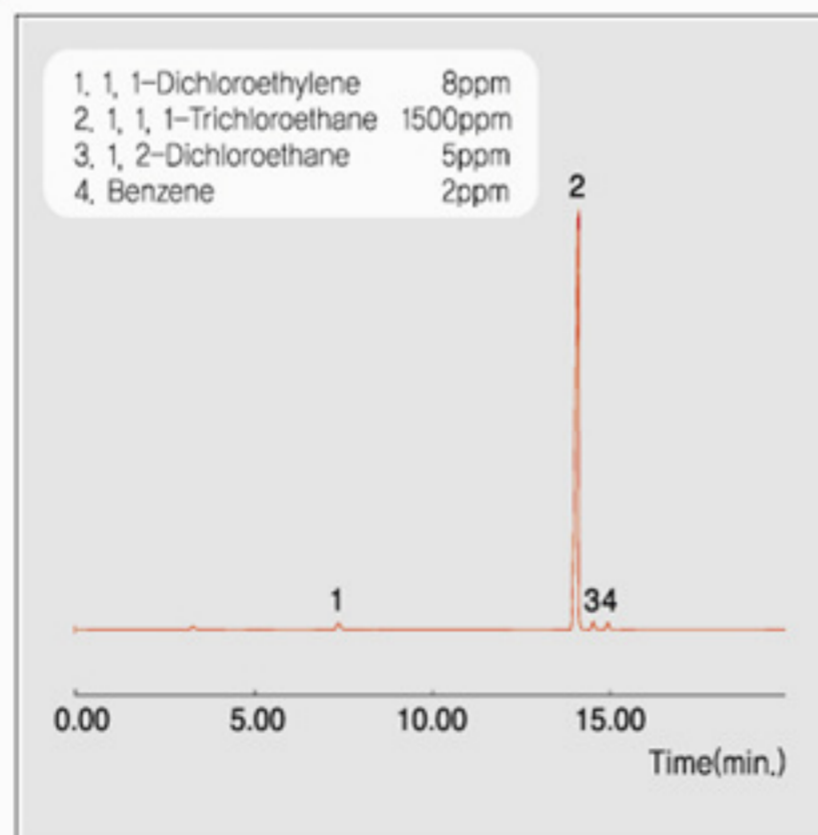
### Analysis of General Residuals II



Oven : 35°C(8min) – 10°C/min – 150°C(5min)  
Column : HP – INNOWax (30m\*0.32mm\*0.5um)  
Carrier gas : He, 1.0ml/min (Split ratio 50:1)  
Injector : Capillary 230°C  
Detector : FID 250°C

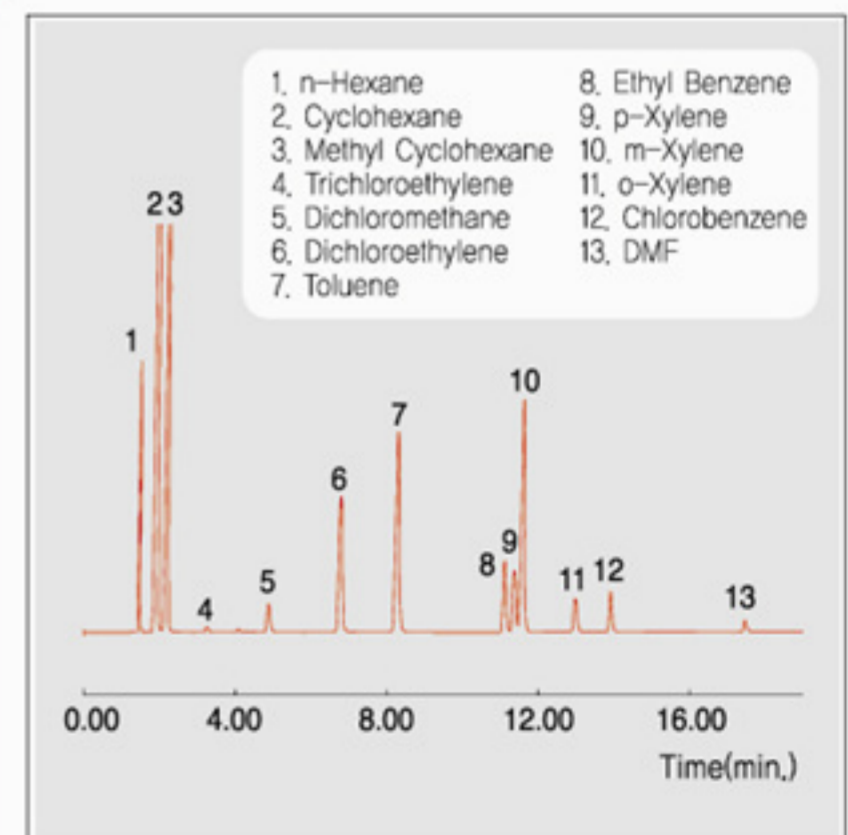
### Analysis of Residual Solvents on Class 1

(This is the limited concentration in accordance with the law)



Oven : 40°C(7min) – 10°C/min – 150°C(5min)  
Column : HP – VOC (60m\*0.32mm\*1.8um)  
Carrier gas : He, 3.0ml/min (Split ratio 5:1)  
Injector : Capillary 230°C  
Detector : FID 250°C  
Headspace : 80°C, 60min Heating

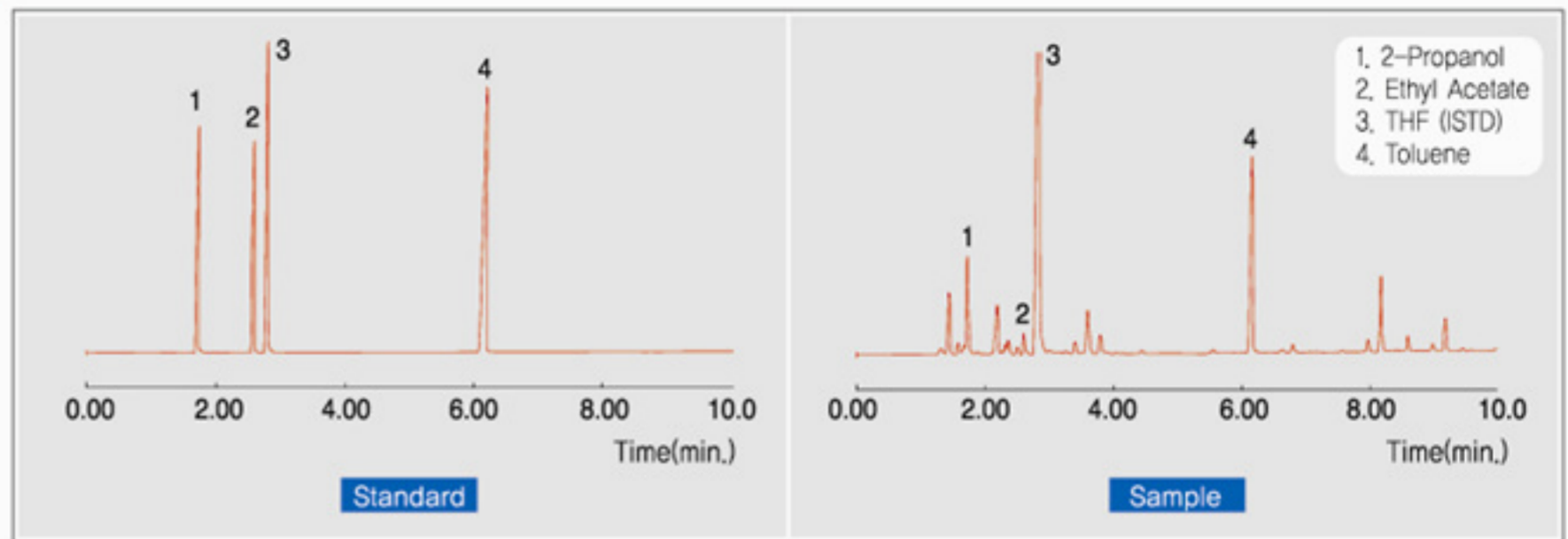
### Analysis of Residual Solvents on Class 2



Oven : 35°C(5min) – 5°C/min – 100°C(0.1min) – 13°C/min – 200°C(5min)  
Column : HP – INNOWax (30m\*0.53mm\*1.0um)  
Carrier gas : He, 6.0ml/min (Split ratio 5:1)  
Injector : Capillary 230°C  
Detector : FID 250°C  
Headspace : 80°C, 60min Heating



## •• Analysis of Residuals on the Food Packing Material



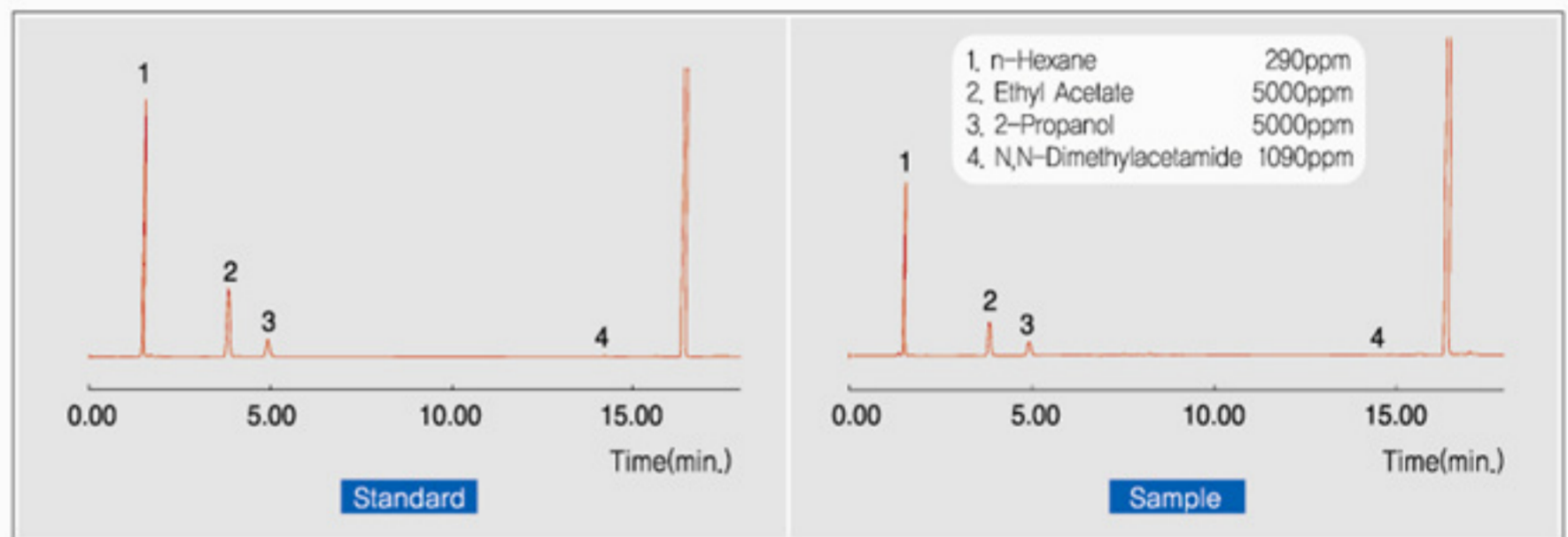
Oven : 35°C(5min) – 10°C/min – 150°C(5min)  
 Column : AN – 1 (30m\*0,32mm\*0,5um)  
 Carrier gas : He, 3,0ml/min (Split ratio 10:1)

Injector : Capillary 230°C  
 Detector : FID 250°C  
 Headspace : 80°C, 30min Heating

## •• Analysis of Residual Solvents in Pharmaceutical Ingredients

(n-Hexane, Ethyl Acetate, 2-Propanol, N, N-Dimethylacetamide)

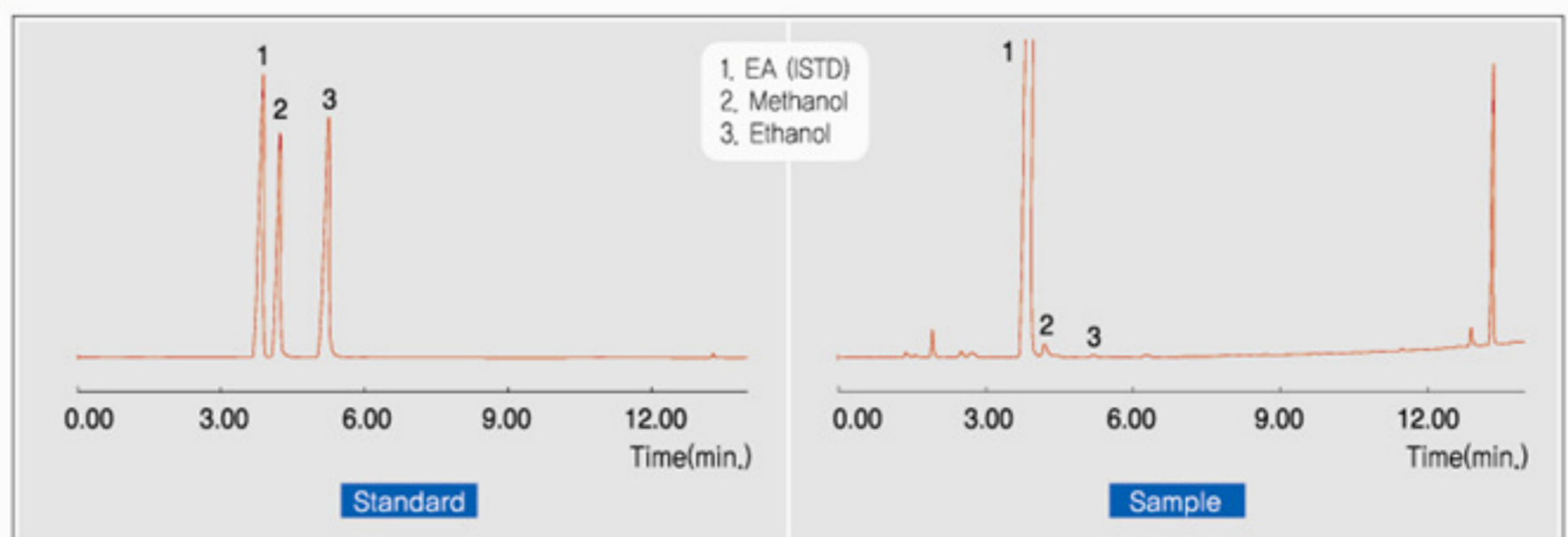
(This is the limited concentration in accordance with the law)



Oven : 35°C(5min) – 10°C/min – 200°C(5min)  
 Column : HP – INNOWax (30m\*0,53mm\*1,0um)  
 Carrier gas : He, 6,0ml/min (Split ratio 5:1)

Injector : Capillary 230°C  
 Detector : FID 250°C  
 Headspace : 80°C, 60min Heating

## •• Analysis of Methanol & Ethanol in Extraction from Chinese Medicine



Oven : 35°C(5min) – 10°C/min – 150°C(5min)  
 Column : HP – INNOWax (30m\*0,53mm\*1,0um)  
 Carrier gas : He, 6,0ml/min (Split ratio 5:1)

Injector : Capillary 230°C  
 Detector : FID 250°C  
 Headspace : 80°C, 30min Heating



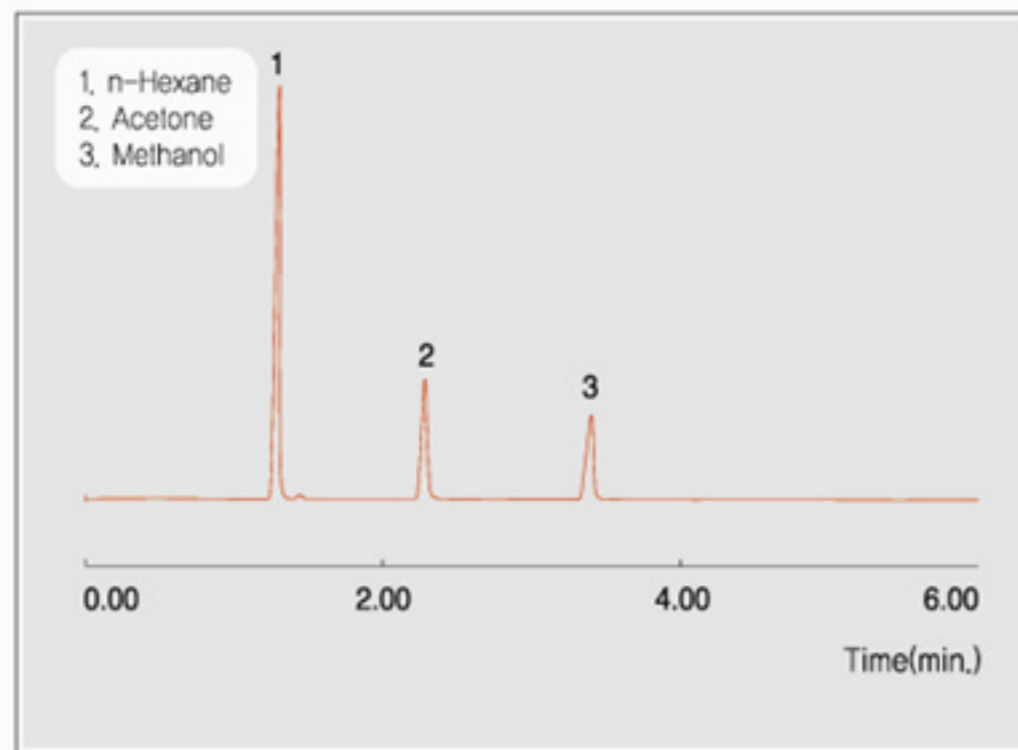
### Residual Solvent Analysis

- Analysis of Residuals on the food packing material
- Analysis of residual solvents in pharmaceutical ingredients
- Analysis of Methanol & Ethanol in extraction from Chinese medicine

## Residual Solvent Analysis

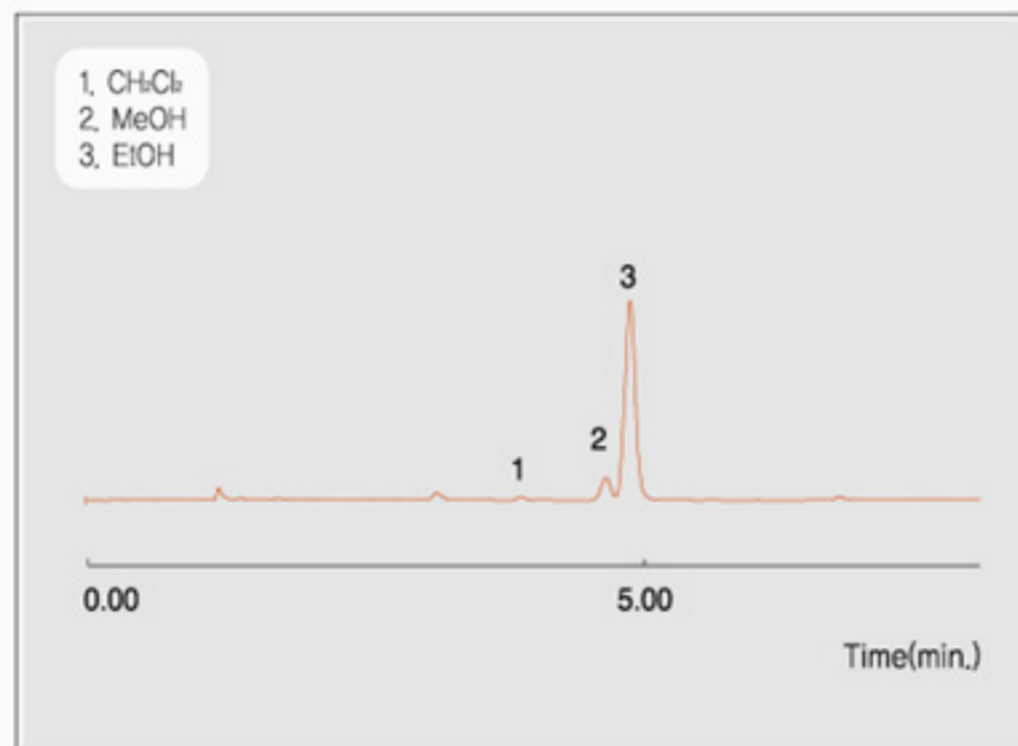
- Analysis of Residual solvents among the extracted pigments from food.
- Analysis of residual solvents in medicine
- Analysis of residual solvents in medicine
- Analysis of residuals in drugs (Direct injection)
- Analysis of residual solvents in pharmaceutical ingredients
- Analysis of residual solvents in pharmaceutical ingredients

### ●● Analysis of Residual Solvents Among the Extracted Pigments from Food.



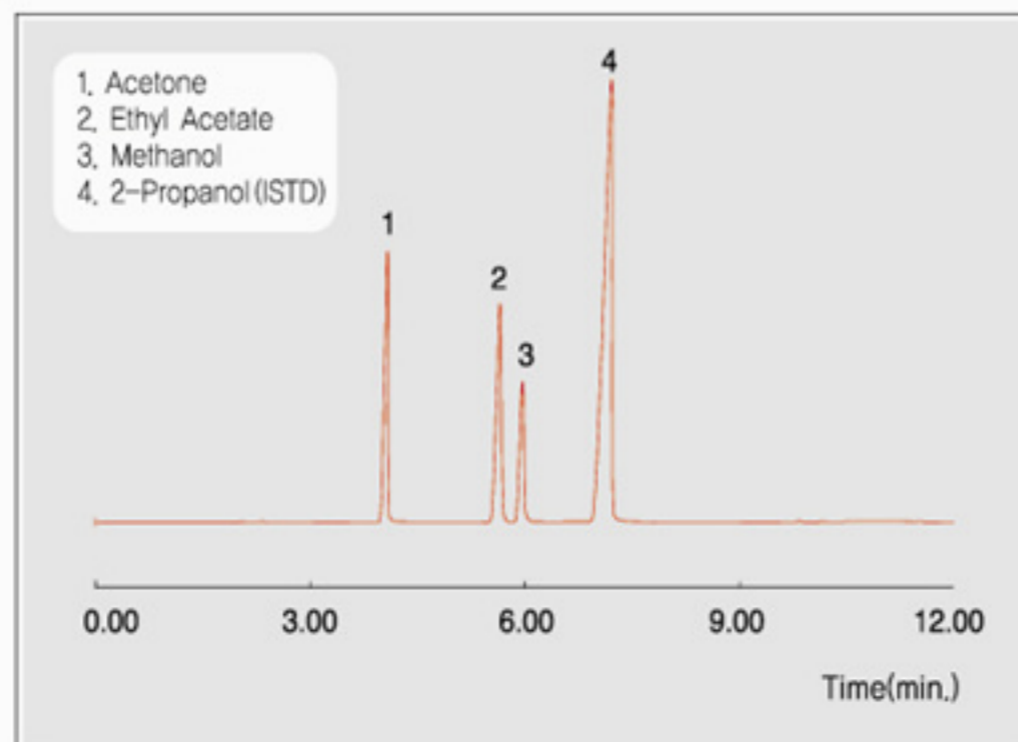
Oven : 35°C(8min) – 5°C/min – 150°C(5min)  
Column : HP – INNOWax (30m\*0.32mm\*0.5um)  
Carrier gas : He, 3.0ml/min (Split ratio 10:1)  
Injector : Capillary 230°C  
Detector : FID 250°C  
Headspace : 80°C, 30min Heating

### ●● Analysis of Residual Solvents in Medicine (Dichloromethane, Methanol, Ethanol)



Oven : 35°C(5min) – 10°C/min – 200°C(10min)  
Column : HP – INNOWax (30m\*0.53mm\*1.0um)  
Carrier gas : He, 5.0ml/min (Split ratio 5:1)  
Injector : Capillary 250°C  
Detector : FID 250°C  
Headspace : 80°C, 60min Heating

### ●● Analysis of Residual Solvents in Medicine (Acetone, Ethyl Acetate, Methanol)

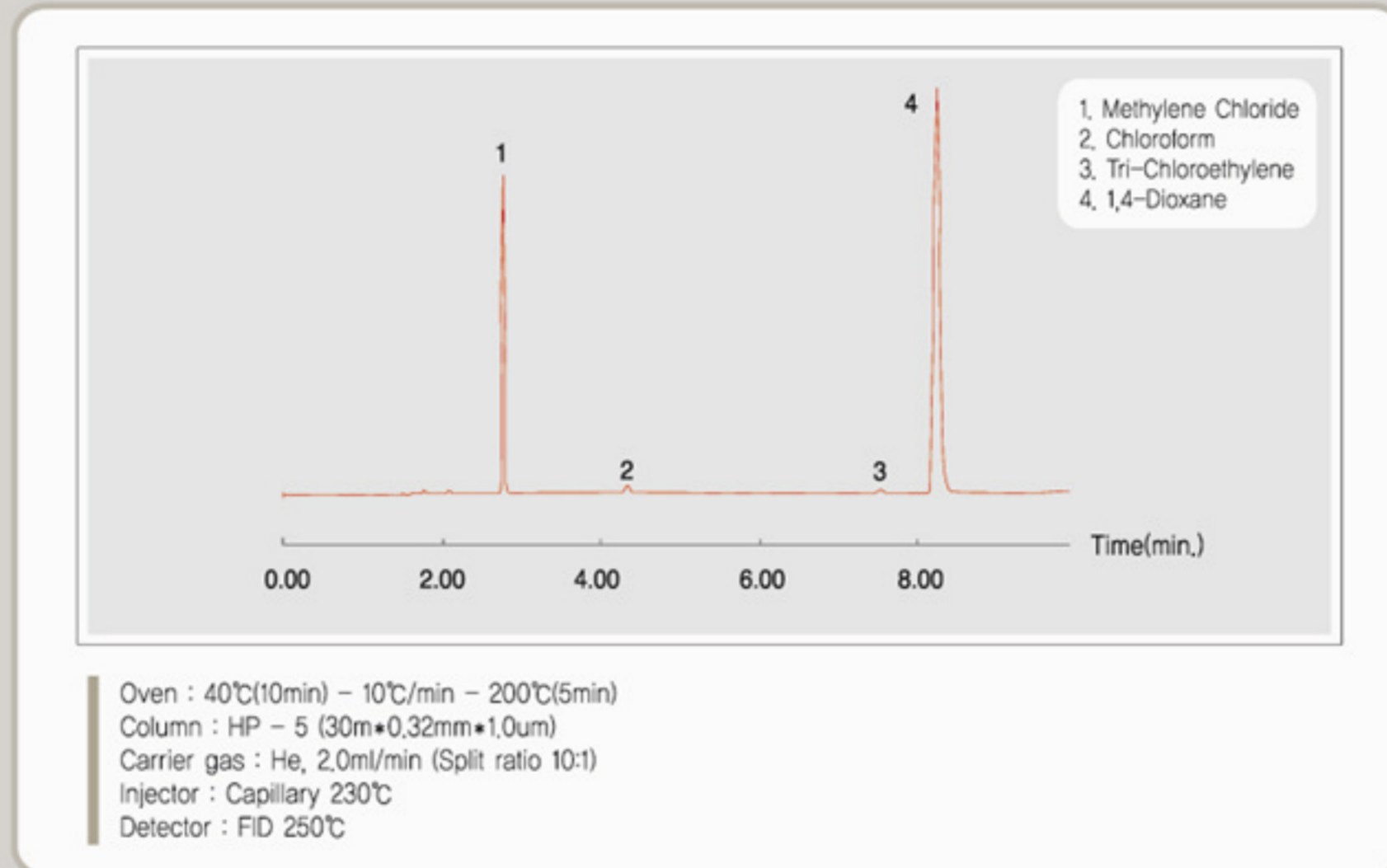


Oven : 35°C(8min) – 20°C/min – 150°C(5min)  
Column : HP – INNOWax (30m\*0.32mm\*0.5um)  
Carrier gas : He, 1.0ml/min (Split ratio 30:1)  
Injector : Capillary 230°C  
Detector : FID 250°C  
Headspace : 80°C, 60min Heating

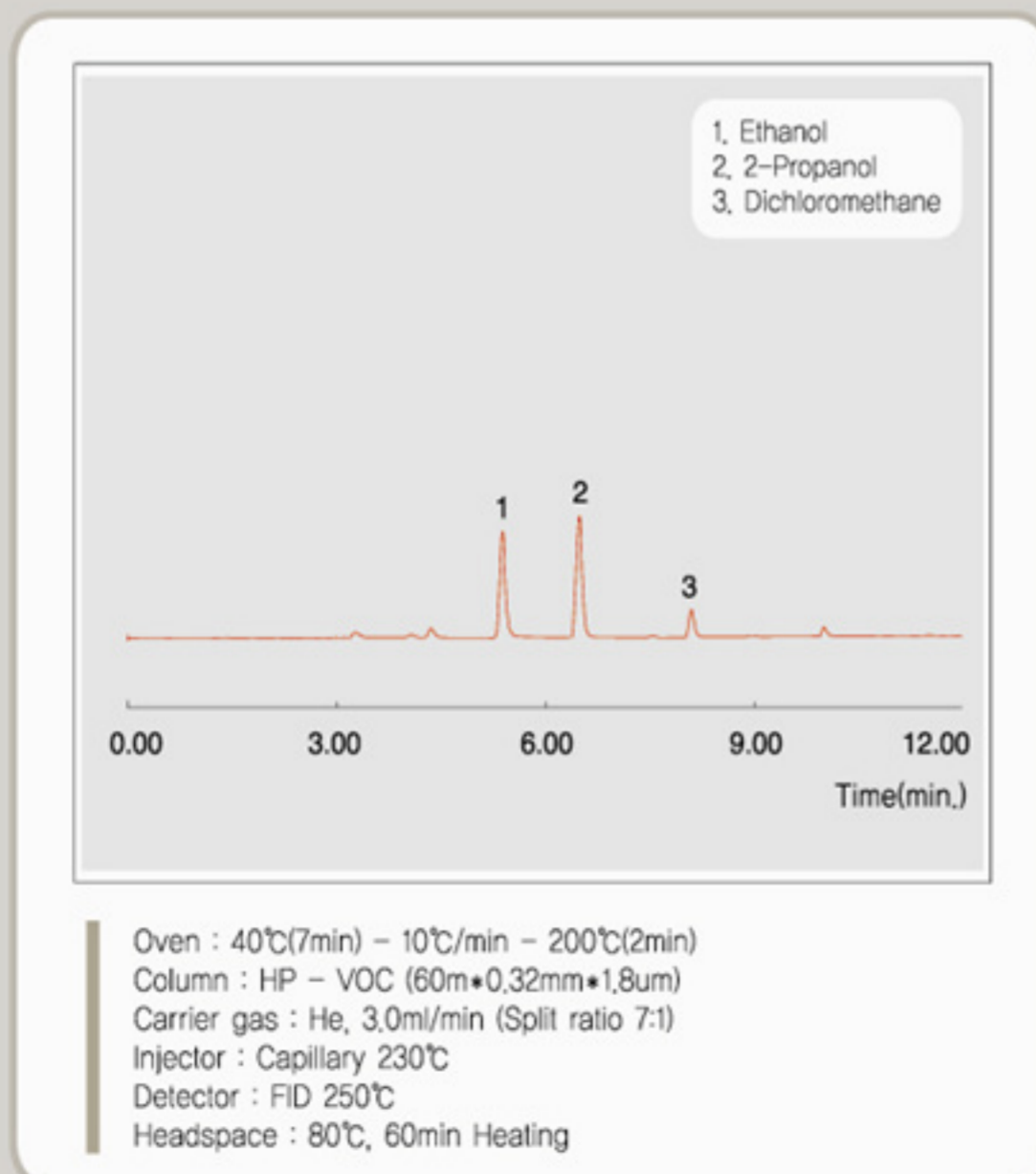
Autospace  
Headspace



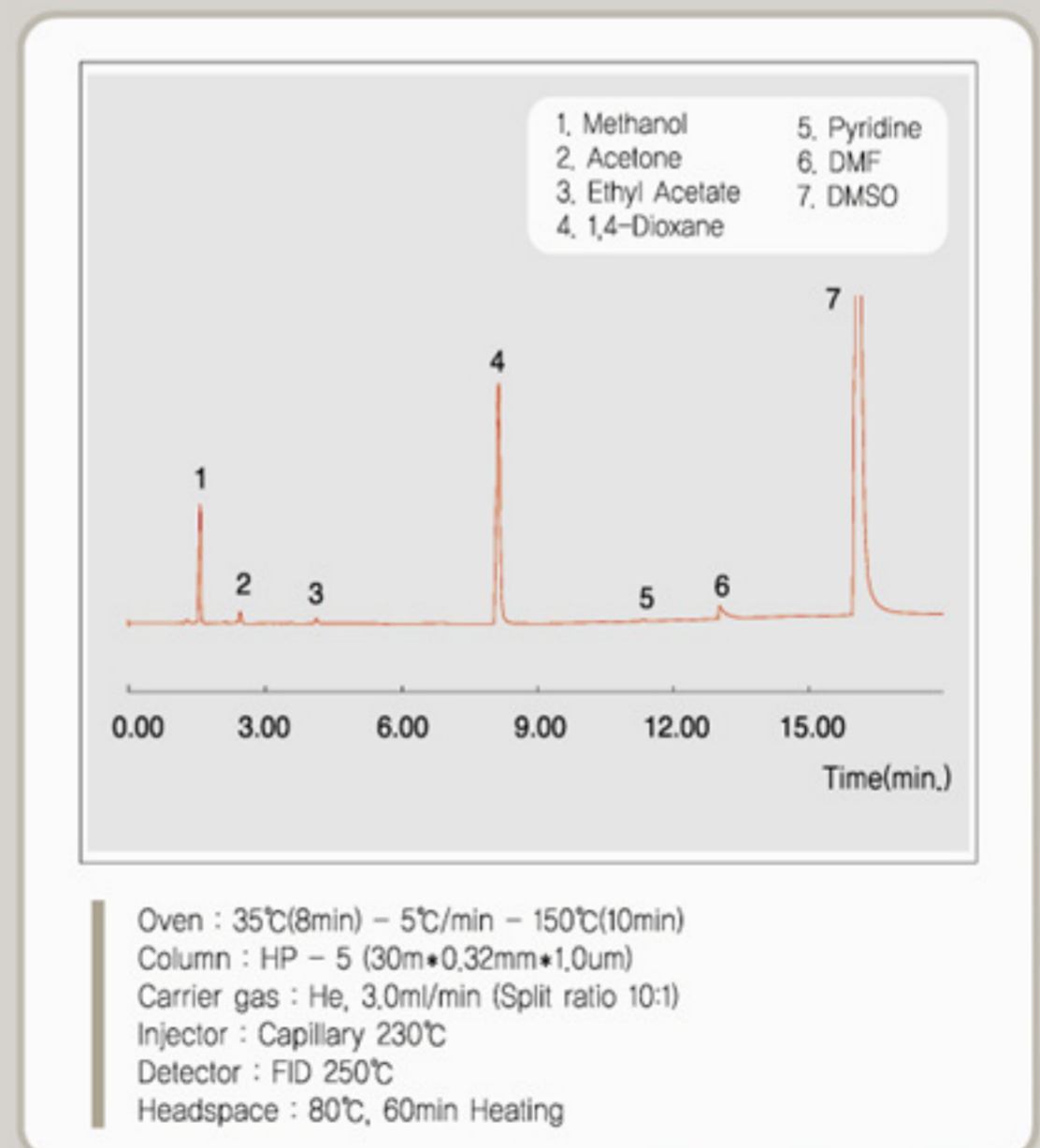
## Analysis of Residuals in Drugs (Direct Injection)



## Analysis of Residual Solvents in Pharmaceutical Ingredients (Ethanol, 2-Propanol, Dichloromethane)



## Analysis of Residual Solvents in Pharmaceutical Ingredients





These products are manufactured in the Young Lin  
ISO 9001 - certified facility that is periodically  
audited by the registering body to ensure compliance



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