

CoreFocus Report

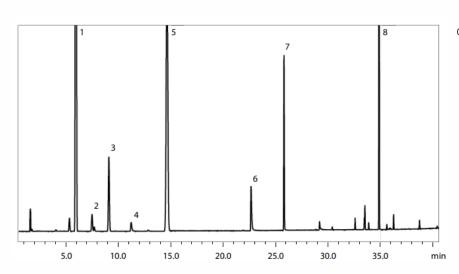
No.308

GC **FID SH Series** HS

SH-I-624Sil MS

Analysis of Residual Solvents in drug products

Keywords: USP <467>, Residual Solvents, Procedure A



Class 2B

- 1. Hexane
- Nitromethane
- Chloroform
- 1,2-Dimethoxyethane
- Trichloroethene
- Pvridine
- Methylbutylketone
- 8. Tetraline

GC Method for USP 467 Procedure A

: Nexis™ GC-2030 Model Detector : FID-2030 Headspace Sampler : HS-20

: SH-I-624Sil MS (30 m x 0.32 mm I.D. df = 1.8 μ m), Column

P/N: 227-36077-01

: 40 °C(20 min) – 10 °C/min - 240 °C (20 min) Total 60 min Column Temperature

Injection Mode : Split 1:5

Carrier Gas Controller : Constant Linear Velocity (He)

Linear Velocity : 35 cm/s **Detector Temperature** : 250 °C Injection Volume : 1 mL

HS-20 Method for USP 467 Procedure A

Oven Temperature	: 80 °C
Sample Line Temperature	: 110 °C
Transfer Line Temperature	: 120 °C
Vial Stirring	: OFF
Vial Volume	: 20 mL
Vial Heat-retention Time	: 60 min
Vial Pressurization Time	: 1 min
Vial Pressure	: 75 kPa
Loading Time	: 1 min
Needle Flush Time	: 5 min

Source: Application News G290 (JP, ENG)

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