

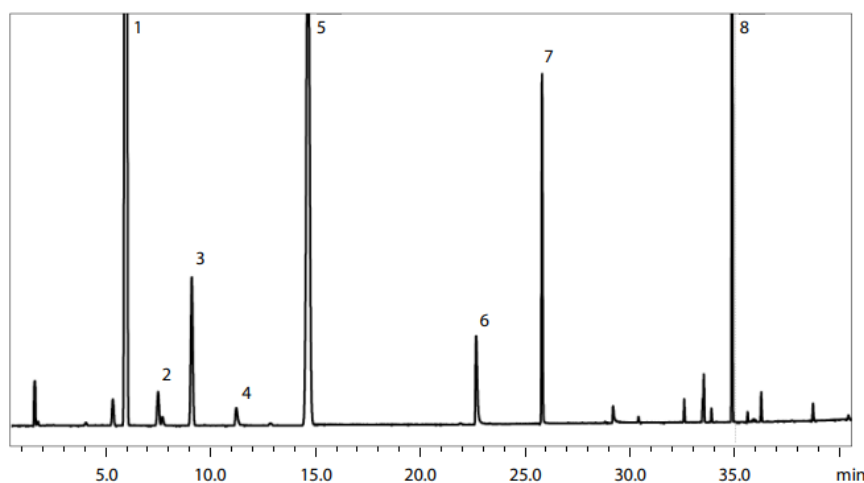
CoreFocus
Report
No.308

GC FID HS SH Series

SH-I-624Sil MS

Analysis of Residual Solvents in drug products

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



- Class 2B
1. Hexane
 2. Nitromethane
 3. Chloroform
 4. 1,2-Dimethoxyethane
 5. Trichloroethene
 6. Pyridine
 7. Methylbutylketone
 8. Tetraline

GC Method for USP 467 Procedure A

Model	: Nexis™ GC-2030
Detector	: FID-2030
Headspace Sampler	: HS-20
Column	: SH-I-624Sil MS (30 m x 0.32 mm I.D. df = 1.8 μm), P/N: 227-36077-01
Column Temperature	: 40 °C(20 min) – 10 °C/min - 240 °C (20 min) Total 60 min
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

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