



Integra-Guard™ Takes the Frustration Out of Analyzing Residual Solvents

The United States Pharmacopeia (USP) has published several methods for the analysis of residual solvents in pharmaceutical products. USP 467 outlines five methods for Organic Volatile Impurities (OVI) that utilize several different sample introduction techniques and analytical columns. Methods I and V have become the most popular because of the simplified sample introduction technique. Both of these methods involve the direct dissolution of the pharmaceutical product in water followed by direct aqueous injection. Since many pharmaceutical products contain inorganic additives and non-volatile components, the USP methods recommend the use of a 5 meter guard column to protect the analyti-

cal column. Although the use of a guard column can greatly increase the life expectancy of your analytical column, making a consistent leak-free connection has been difficult.

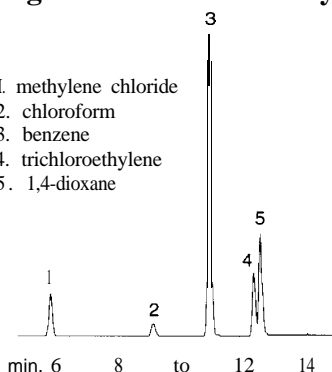
To eliminate the headache of making those difficult connections between the guard column and the analytical column, the Wizards at Restek have developed Integra-Guard™ (capillary columns with integrated guard columns). These columns are available with the two most common stationary phases used for OVI analysis. Figure 1 shows the analysis of common solvents on a 30 meter, 0.53mm ID, 5.0um Rtx™-G27 Integra-Guard™ column (5% phenyl/95%

methyl polysiloxane). Figure 2 shows the same analysis on a 30meter, 0.53mm ID, 3.0um Rtx™-G43 Integra-Guard™ column (6% cyanopropylphenyl polysiloxane). Both columns are manufactured with high purity, bonded stationary phases for low bleed and unsurpassed inertness. Each column is tested to meet stringent requirements to insure reproducible analysis.

Save time and money and improve your analysis by using Rtx™-G27 and Rtx™-G43 Integra-Guard™ columns to analyze residual solvent impurities in pharmaceutical products. In addition, Restek offers several high quality calibration standards for USP 467 methods. Data packages with complete quality assurance information are available for all Restek standards.

Figure 1 - USP 467 analysis on a 30m, 0.53mm ID, 5.0um Rtx™-G27 Integra-Guard™ column

1. methylene chloride
2. chloroform
3. benzene
4. trichloroethylene
5. 1,4-dioxane



1.0ul direct injection of USP 467 Mix #1 (cat.# 36001).
Oven temp.: 35°C (hold 5 min.) to 175°C @ 8C/min. to 260C @ 35C/min.
Inj. / det. temp.: 200°C / 240°C
Carrier gas: helium
Linear velocity: 30cm/sec. set @ 35°C
FID sensitivity: 1 x 10-11 AFS

Columns

30m, 0.53mm ID, 5.0um
 Rtx™-G27 Integra-Guard™
 cat.# 10279-126

30m, 0.53mm ID, 3.0um
 Rtx™-G43 Integra-Guard™
 cat.# 16085-126

Standards

USP 467 Mix #1 (in DMSO)
 cat.# 36001, ea.
 cat.# 36101, 10-pk.

USP 467 Mix #2 (in methanol)
 cat.# 36002, ea.
 cat.# 36102, 10-pk.

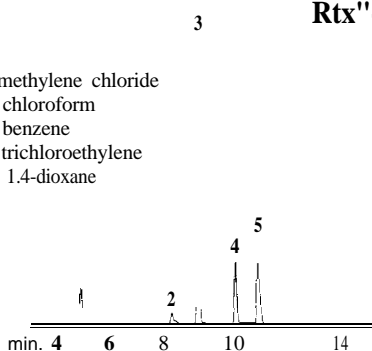
USP 467 Mix #3 (in DMSO)
 cat.# 36004, ea.
 cat.# 36104, 10-pk.

International USP 467 Mix (in methanol)
 cat.# 36003, ea.
 cat.# 36103, 10-pk.

See Resteks Product Guide for more information on USP 467 standard mixes.

Figure 2 - USP 467 analysis on a 30m, 0.53mm ID, 3.0um Rtx™-G43 Integra-Guard™ column

1. methylene chloride
2. chloroform
3. benzene
4. trichloroethylene
5. 1,4-dioxane



1.0ul direct injection of USP 467 Mix #1 (cat.# 36001).
Oven temp.: 35°C (hold 5 min.) to 175°C @ 8C/min. to 260C @ 35C/min.
Inj. / det. temp.: 200°C / 240°C
Carrier gas: helium
Linear velocity: 34cm/sec. set @ 35°C
FID sensitivity: 1 x 10-11 AFS

- Integrated guard column eliminates leaks.
- Meets all requirements of USP 467 methods.
- Bonded phase columns for low bleed & excellent inertness.