

VALIDATION PROCEDURE

Agilent 8890 GC System – Serial # US2233A040

Agilent 5977B GC/MSD – Serial # US2227M017

Alma

Instrument Setup

The initial instrument setup and check-out procedure was performed by Agilent technical representative Ron Boruff (ron.boruff@agilent.com). All electrical requirements and performance gases (helium, hydrogen and air) were in place as specified prior to installation.

Maintenance

Throughout the validation procedure, regular inlet maintenance, autotunes, and analysis of the GC/MS Calibration Standard Mix will be performed. Note: this will not necessarily be performed on a weekly basis but in conjunction with time devoted to the development, testing and establishment of the methods.

Establishing Method Parameters

Utilizing the ChemStation software, method construction begins with loading the system's default.m method and referencing established TBI FCU GC/MS methods to first construct MSDRUGS100. From the MSDRUGS100 method, all parameters of the remaining methods will be constructed, named and saved respective to MS, ASMS, GC or ASGC designations.

Analytical Standards Analysis – The GC/MS Calibration Standard Mix of pethidine, cocaine and hydrocodone will be analyzed on all methods constructed.

Low Temperature Initial Set Points – The GC/IR Test Solution will be analyzed on all 60 and 100°C methods.

Higher Temperature Set Points – Buprenorphine, LSD, Testosterone Acetate and Testosterone Benzoate will be analyzed on all 200° C methods.

INSTRUMENT AND COMPONENT SPECIFICATIONS

Agilent 8890 GC System – Serial # US2233A040

Agilent 5977B GC/MSD – Serial # US2227M017

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GAS CHROMATOGRAPH

Agilent 8890 GC System (G3540A)

Serial #US2233A040

MASS SPECTROMETER

Agilent 5977B GC/MSD (G7077B)

Serial #US2227M017

AUTOSAMPLER TRAY

Agilent G4514A

Serial #R022297009

AUTOSAMPLER TOWERS

MS: Agilent 4513A

Serial #R022335016

GC: Agilent 4513A

Serial #R022335025

COLUMNS

GC: Agilent J&W HP-1MS

Part #19091S-913, 15 meters, 0.320 mm diameter, 0.25 μ film thickness

MS: Agilent J&W HP-1MS

Part #19091S-602, 12.5 meters, 0.200 mm diameter, 0.33 μ film thickness