Instructions for Using the General Quantitation Worksheet

1 There are four sheets. Two are for use if the purity will be calculated as the base drug, and the other two are for when the purity will be calculated as the salt form.

2 All of the formula cells have been protected. Data entry cells are not protected and should be filled in as indicated below.

3 Fill in your FS Lab #, Name, Analyte and Internal Standard information at the top of each sheet used.

4 On the Standards tab, enter the weights and correction factor for the calibration standard and check standard. Enter the volumes for the calibration standard and check standard. For the "calc. as base" option, enter the molecular weight (MW) of both the base drug and the specific standard used.

5 On the Quant sheet, edit your Item numbers.

6 Enter the Peak Areas from the GC Integration for each of the three runs for your standard, check standard and each of the six samples.

7 Enter the volume (mL) used to make each item.

8 Enter the weight (mg) used to make each item.

9 After entering all of the data, check the quality control information at the bottom. The precision must be below 3% and the accuracy must be below 5%. If the values are higher, the samples must be rerun and/or remade.

FS Lab #:		**Analyte:**	
Chemist:		**Internal Std:**	

Internal Standard Concentration (mg/mL)

Standards Preparation	Calibration Standard	Check Standard
Weight (mg)	0.00	0.00
Volume (mL)		
MW of base drug (g/mol)		
MW of std (including salt, waters of hydration, etc.) (g/mol)		
If the standard is monobasic, enter 1. If the standard is dibasic, enter 2.		
Theoretical Concentration (mg/mL)	#DIV/0!	#DIV/0!
Correction to base (MW base/MW std)	#DIV/0!	#DIV/0!
Corrected Concentration (mg/mL)	#DIV/0!	#DIV/0!

Calibration Standard Purity Correction:	
Weight of Standard (mg)	
Percent Purity (decimal)	
Corrected Weight (mg)	0.0000

Check Standard Purity Correction:	
Weight of Standard (mg)	
Percent Purity (decimal)	
Corrected Weight (mg)	0.0000

FS Lab #-Item#: | **Analyte:**

Chemist: | **Internal Std:**

****RESULTS CALCULATED AS THE BASE**

	[CAL. STD]	Ratio (R_2)	Ratio (R_1)	Volume (V)	Weight (W)	Calculated Concentration (mg/mL)
Check Std.	#DIV/0!	#DIV/0!	#DIV/0!	0.0	0.00	#DIV/0!
Sample 1	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 2	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 3	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 4	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 5	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 6	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!

% Purity Calculation:
% Drug ={([STD] * R_2 * V) / (R_1 * W)} * 100

[STD] = Concentration of Standard in mg/mL
R_2= Peak Area of Sample / Peak Area of Internal Standard
R_1= Peak Area of Standard / Peak Area of Internal Standard
V= Volume of Internal Standard used in mL
W= Sample Weight in mg

Quality Control

	Run #1		Run #2		Run #3		
	Peak Area (Analyte)	Peak Area (Internal Std)	Peak Area (Analyte)	Peak Area (Internal Std)	Peak Area (Analyte)	Peak Area (Internal Std)	Average Ratio
Cal. Std.							#DIV/0!
Check Std.							#DIV/0!

	Calc. Conc. 1	Calc. Conc. 2	Calc. Conc. 3	Std Deviation	Precision (%)	Accuracy (%)	Purity (%)
Check Std	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

Corrected Theoretical Concentration #DIV/0!

FS Lab #-Item#:	**0**	**Analyte:**	**0**
Chemist:	**0**	**Internal Std:**	**0**

****RESULTS CALCULATED AS THE BASE**

Data Table

	Peak Area (Analyte)	Peak Area (Internal Std)	Ratio	% Purity (Analyte)*	*Values are to be reported as "calculated as the base"
Sample 1			#DIV/0!	#DIV/0!	
Sample 2			#DIV/0!	#DIV/0!	
Sample 3			#DIV/0!	#DIV/0!	
Sample 4			#DIV/0!	#DIV/0!	
Sample 5			#DIV/0!	#DIV/0!	
Sample 6			#DIV/0!	#DIV/0!	
			Mean	#DIV/0!	
			Standard Deviation	#DIV/0!	
			Relative Standard Deviation	#DIV/0!	

Uncertainty of Measurement

Acceptance Criteria for QC Purity Solutions: ±5 %Relative

The acceptance criteria for QC purity is considered a rectangular distribution in which a=5.0

$u=(5/\sqrt{3}) = 2.89\%_{Relative}$

Calculation of Combined Uncertainty

Check Std Purity Tolerance	2.89
Replicate Relative Std. Deviation	#DIV/0!
Combined Uncertainty	#DIV/0!

Calcuation of Expanded Uncertainty

95% Confidence Level	#DIV/0!
95% Confidence Level %purity	#DIV/0!

Reported Results	95% Confidence Level	#DIV/0!	± #DIV/0!

FS Lab #-Item#:		**Analyte:**	
Chemist:		**Internal Std:**	

****RESULTS CALCULATED AS THE SALT**

	[CAL. STD]	Ratio (R_2)	Ratio (R_1)	Volume (V)	Weight (W)	Calculated Concentration (mg/mL)
Check Std.	#DIV/0!	#DIV/0!	#DIV/0!	0.0	0.00	#DIV/0!
Sample 1	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 2	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 3	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 4	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 5	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!
Sample 6	#DIV/0!	#DIV/0!	#DIV/0!			#DIV/0!

% Purity Calculation:
% Drug ={([STD] * R_2 * V) / (R_1 * W)} * 100

[STD] = Concentration of Standard in mg/mL
R_2= Peak Area of Sample / Peak Area of Internal Standard
R_1= Peak Area of Standard / Peak Area of Internal Standard
V= Volume of Internal Standard used in mL
W= Sample Weight in mg

Quality Control

	Run #1		Run #2		Run #3		
	Peak Area (Analyte)	Peak Area (Internal Std)	Peak Area (Analyte)	Peak Area (Internal Std)	Peak Area (Analyte)	Peak Area (Internal Std)	Average Ratio
Cal. Std.							#DIV/0!
Check Std.							#DIV/0!

	Calc. Conc. 1	Calc. Conc. 2	Calc. Conc. 3	Std Deviation	Precision (%)	Accuracy (%)	Purity (%)
Check Std	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

Corrected Theoretical Concentration #DIV/0!

FS Lab #-Item#:		**Analyte:**	
Chemist:		**Internal Std:**	

****RESULTS CALCULATED AS THE SALT**

Data Table

	Peak Area (Analyte)	Peak Area (Internal Std)	Ratio	% Purity (Analyte)*	*Salt form will be reported with the % purity
Sample 1			#DIV/0!	#DIV/0!	
Sample 2			#DIV/0!	#DIV/0!	
Sample 3			#DIV/0!	#DIV/0!	
Sample 4			#DIV/0!	#DIV/0!	
Sample 5			#DIV/0!	#DIV/0!	
Sample 6			#DIV/0!	#DIV/0!	
			Mean	#DIV/0!	
			Standard Deviation	#DIV/0!	
			Relative Standard Deviation	#DIV/0!	

Uncertainty of Measurement

Acceptance Criteria for QC Purity Solutions: ±5 %Relative

The acceptance criteria for QC purity is considered a rectangular distribution in which a=5.0

$u=(5/\sqrt{3}) = 2.89\ \%_{Relative}$

Calculation of Combined Uncertainty

Check Std Purity Tolerance	2.89
Replicate Relative Std. Deviation	#DIV/0!
Combined Uncertainty	#DIV/0!

Calcuation of Expanded Uncertainty

95% Confidence Level	#DIV/0!
95% Confidence Level %purity	#DIV/0!

Reported Results	95% Confidence Level	#DIV/0!	± #DIV/0!