

Feature Note: Setting SamplerSight-Pharma to Report Contiguous Sample Statistics

General

Since the USP requires averages over multiple series in some situations, in Version 2.1 Service Pack 2, we added a “Report Statistics Data” report which gives statistics for all the samples displayed in the report. This report also gives PASS/FAIL status for the individual series data as well as for sample data.

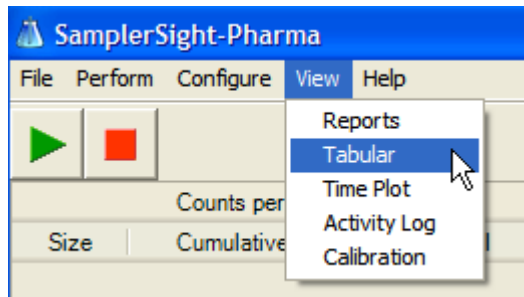
The below steps will walk you through how to retrieve multiple series of samples in this new report.

Steps to Report Contiguous Sample Statistics


Take the three samples. In my example I took two two-samples from each of three separate containers.

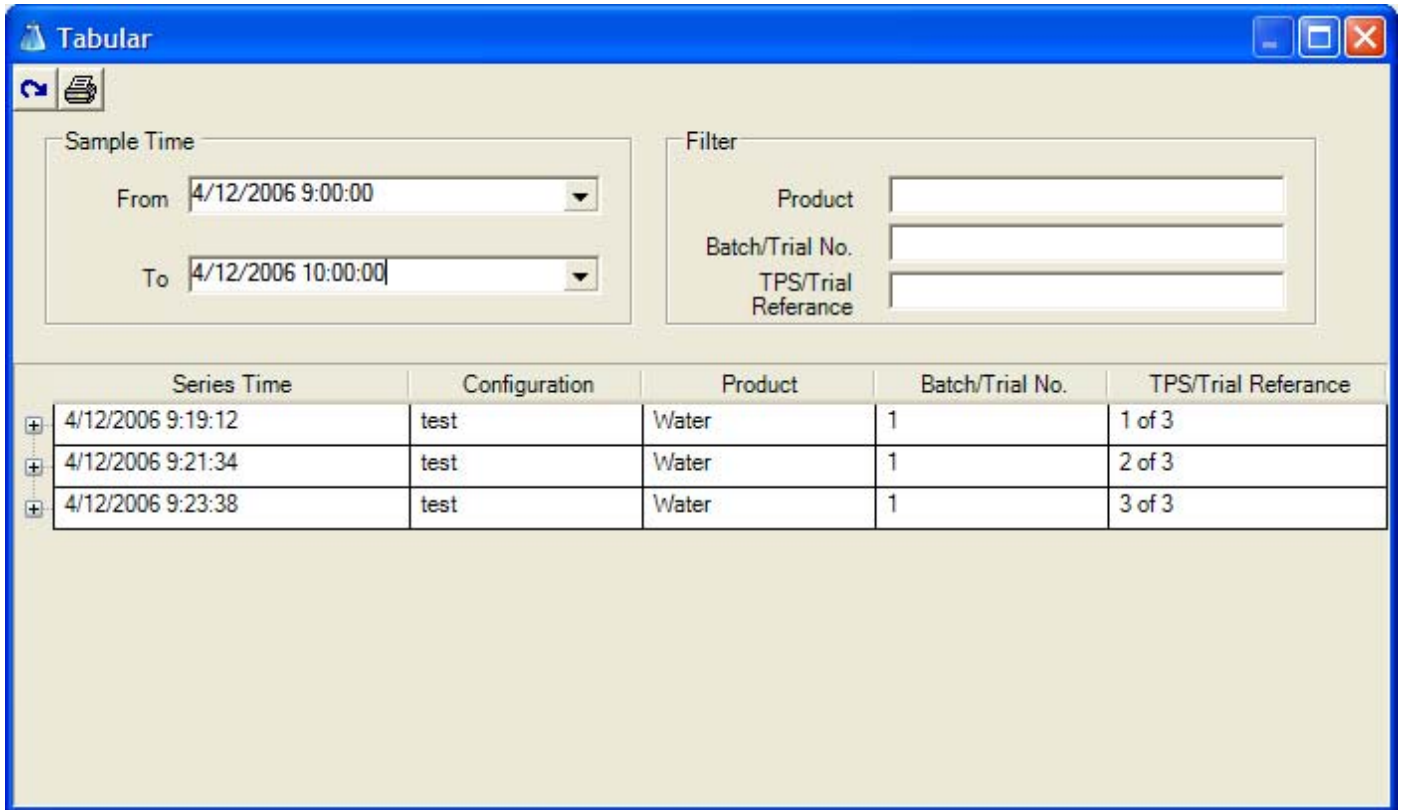
Note: There are rules: container volume and sample volume must be the same.

Select the View → Tabular function.



In the tabular configuration set the time and date to span the three sets of samples taken (i.e. Time frame: From 09:00:00 To 10:00:00). See print screen example below.

Click on the retrieve arrow  (top left corner) to retrieve data from the time frame you entered.



The screenshot shows a software window titled "Tabular". At the top left, there is a refresh icon. Below it, there are two main sections: "Sample Time" and "Filter".

Sample Time: Contains two dropdown menus. The "From" dropdown is set to "4/12/2006 9:00:00" and the "To" dropdown is set to "4/12/2006 10:00:00".

Filter: Contains three input fields labeled "Product", "Batch/Trial No.", and "TPS/Trial Reference", all of which are currently empty.

Below the filters is a table with the following data:

| | Series Time | Configuration | Product | Batch/Trial No. | TPS/Trial Reference |
|---|-------------------|---------------|---------|-----------------|---------------------|
| + | 4/12/2006 9:19:12 | test | Water | 1 | 1 of 3 |
| + | 4/12/2006 9:21:34 | test | Water | 1 | 2 of 3 |
| + | 4/12/2006 9:23:38 | test | Water | 1 | 3 of 3 |

In the Tabular View, select the print reports button  to access Reports.

In the Reports screen, click on the down arrow for the list of Report Selections

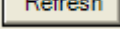
The screenshot shows a software window titled 'Report'. At the top, there is a 'Report Selection' dropdown menu set to 'Histogram Data' and a 'Report Title' text box containing 'Histogram Data Report'. A 'Refresh' button is located to the right of the report title. Below these are navigation icons including back, forward, and search. The main content area displays the report title 'Histogram Data Report' and the subtitle 'Counts per container'. The report content is organized into several sections:

| <u>Series Date & Time</u> | <u>Configuration</u> | <u>Product</u> | <u>Batch/Trial No.</u> | <u>TPS/Trial Reference</u> |
|-------------------------------|-------------------------|----------------|------------------------|----------------------------|
| 4/12/2006 9:19:12 | test | Water | 1 | 1 of 3 |
| <u>Containers Pooled</u> | <u>Container Volume</u> | | | |
| 1 | 10.0 | | | |


| <u>Sample #</u> | <u>Sample Date & Time</u> | <u>Interval</u> | seconds | <u>Fill Time</u> | seconds | <u>DC Li</u> |
|------------------|-------------------------------|-----------------|---------|------------------|---------|--------------|
| 2 | 4/12/2006 9:20:19 | 15.0 | | | | 5.4 |
| <u>Flow Rate</u> | <u>Volume</u> | | | | | |
| 20.0 | 5.0 | | | | | |

At the bottom of the report content, there are four tabs: 'Channel Size', 'Cumulative Data', 'Differential Data', and 'Status'. The 'Channel Size' tab is currently selected. The status bar at the bottom of the window shows 'Current Page No: 1', 'Total Page No: 4', and 'Zoom Factor: 100%'.

The report selected is the “Report Statistics Data” – this will give data for the last 3 sets of results and the final page will give the statistical analysis of that data. If a different report

template is default select “Report Statistics Data” and click Refresh button  to update the report format.

Note:

The list icon  has been activated to see the file tree.

The file tree shows 3 samples taken at different times.

The following report is generated (print screen examples of report to follow).

Pages 1-3 show each sample data including pass/fail, page 4 shows statistics.

Report Selection | Report Statistics Data | Report Title | Report Statistics Data | Refresh

4/12/2006 9:19:12 MainReport
 4/12/2006 9:21:34
 4/12/2006 9:23:38

Report Statistics Data

Counts per container 4/12/2006 14:40:06

| | | |
|--|------------------------------|-----------------------------|
| <u>Series Date & Time</u> 4/12/2006 9:19:12 | <u>Configuration</u> test | <u>User</u> Default User |
|--|------------------------------|-----------------------------|

| | | |
|----------------------------|------------------------------|-----------------------------------|
| <u>Product</u> Water | <u>Batch/Trial No.</u> 1 | <u>TPS/Trial Reference</u> 1 of 3 |
| <u>Containers Pooled</u> 1 | <u>Container Volume</u> 10.0 | milliliter |

| <u>Sample #</u> | <u>Sample Date & Time</u> | <u>Interval</u> seconds | <u>Volume</u> milliliter | <u>Flow Rate</u> vol/minute |
|-----------------|-------------------------------|-------------------------|--------------------------|-----------------------------|
| 2 | 4/12/2006 9:20:19 | 15.0 | 5.0 | 20.0 |
| | | <u>Sample Value</u> | <u>DC Light</u> volts | <u>Fill Time</u> seconds |
| | | 200.4 | 5.4 | |

| <u>Channel Size</u> | <u>Cumulative Data</u> | <u>Differential Data</u> | <u>Status</u> |
|---------------------|------------------------|--------------------------|---------------|
| 2.0 | 2,004.0 | 590.0 | Fail |
| 5.0 | 1,414.0 | 512.0 | Fail |
| 10.0 | 902.0 | 516.0 | Pass |
| 15.0 | 386.0 | 248.0 | Pass |
| 25.0 | 138.0 | 138.0 | Pass |

| <u>Sample #</u> | <u>Sample Date & Time</u> | <u>Interval</u> seconds | <u>Volume</u> milliliter | <u>Flow Rate</u> vol/minute |
|-----------------|-------------------------------|-------------------------|--------------------------|-----------------------------|
| 3 | 4/12/2006 9:20:53 | 15.0 | 5.0 | 20.0 |
| | | <u>Sample Value</u> | <u>DC Light</u> volts | <u>Fill Time</u> seconds |
| | | 216.8 | 5.7 | |

| <u>Channel Size</u> | <u>Cumulative Data</u> | <u>Differential Data</u> | <u>Status</u> |
|---------------------|------------------------|--------------------------|---------------|
| 2.0 | 2,168.0 | 680.0 | Fail |
| 5.0 | 1,488.0 | 592.0 | Fail |
| 10.0 | 896.0 | 498.0 | Pass |
| 15.0 | 398.0 | 236.0 | Pass |

Current Page No: 1 | Total Page No: 4 | Zoom Factor: 100%

Report Selection: Report Statistics Data Report Title: Report Statistics Data Refresh

4/12/2006 9:19:12 MainReport
 4/12/2006 9:21:34
 4/12/2006 9:23:38

Counts per container 4/13/2006 10:31:25

Report Statistics **Samples Processed** 6

Includes all displayed values in the report

| Cumulative Data | 2.00 | 5.00 | 10.00 | 15.00 | 25.00 |
|------------------------|-------------|------------|------------|------------|----------|
| Minimum | 2,004.0000 | 1,374.0000 | 790.0000 | 376.0000 | 100.0000 |
| Maximum | 2,286.0000 | 1,546.0000 | 1,026.0000 | 480.0000 | 168.0000 |
| Average | 2,159.3333 | 1,471.0000 | 893.6667 | 425.6667 | 143.0000 |
| Std Deviation | 93.0777 | 64.0219 | 87.5846 | 44.3155 | 24.1578 |
| Total | 12,956.0000 | 8,826.0000 | 5,362.0000 | 2,554.0000 | 858.0000 |

| Differential Data | 2.00 | 5.00 | 10.00 | 15.00 | 25.00 |
|--------------------------|------------|------------|------------|------------|----------|
| Minimum | 590.0000 | 512.0000 | 342.0000 | 236.0000 | 100.0000 |
| Maximum | 810.0000 | 696.0000 | 546.0000 | 340.0000 | 168.0000 |
| Average | 688.3333 | 577.3333 | 468.0000 | 282.6667 | 143.0000 |
| Std Deviation | 79.8540 | 66.6293 | 75.7047 | 37.9192 | 24.1578 |
| Total | 4,130.0000 | 3,464.0000 | 2,808.0000 | 1,696.0000 | 858.0000 |

Current Page No: 4 Total Page No: 4 Zoom Factor: 100%