QC Advances in the Pharma ICP Laboratory

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21CFR Part 11 Compliant

- That all experimental protocols are clearly documented and identified.
- That the system has been validated to operate correctly.
## Control of Parameters in ICP-OES

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wavelength:</td>
<td>0.001-0.002nm</td>
</tr>
<tr>
<td>Forward RF power:</td>
<td>1-2 watts</td>
</tr>
<tr>
<td>Gas flows:</td>
<td>0.01%</td>
</tr>
<tr>
<td>Detector temp:</td>
<td>0.1 degree Celsius</td>
</tr>
<tr>
<td>Spray chamber temp:</td>
<td>??????</td>
</tr>
<tr>
<td>Sample uptake:</td>
<td>??????</td>
</tr>
</tbody>
</table>
Intensity vs. Chamber Temperature
PE 2100DV (1.0ml/min uptake)
Temperature Plots on PE 2100DV

Transport Efficiency

AVG INTENSITY

normalized intensity

IsoMist Temperature

10C 15C 20C 25C 30C 35C

0.8 0.9 1 1.1 1.2 1.3 1.4 1.5 1.6 1.7 1.8
Effect of Temperature on Intensity
20ul/min uptake rate

133% increase from 21 to 40°C or 7% per degree C
IsoMist™ Programmable Temperature Spray Chamber (PTSC)
IsoMist on Optima 2100DV

Customization
• Position of SC
• Torch interface
• Mounting bracket
IsoMist Characteristics

• Programmable from -10 to 60°C in 1 degree increments
• Maintains temperature to within 0.1 degree
• Built-in Peltier device
• No external plumbing
• Temperature measured near the chamber surface
• Permanent electronic record of temp. vs. time
PC Screen showing IsoMist Software

IsoMist Temperature °C

-5 °C

Fan Speed

4,687

Power

59%

Internal Temp

27.8 °C
Constant temperature benefits
(1ml/min sample uptake)

- Higher accuracy
- Higher productivity
- Greater reproducibility
- Better experiments
Current record of sample flow rate

• ID of peristaltic pump tubing used
• Speed of pump
• Make and model of ICP

Flow rate is estimated from above parameters
Effect of sample flow rate on signal

- Ag_328
- As_188
- Ba_233
- Be_313
- Cd_214
- Co_228
- Cr_267
- Cu_3249
- Mn_257
- Ni_232
- Pb_220
- Se_196
- Tl_190
- V_292
- Zn_213
- Zn_202
What can affect Sample Uptake?

• Clogged nebulizer
• Worn pump tubing
• Kinked sample capillary
• Worn pump rollers
• Incorrect pressure of pump tubing clamp
• Faulty peri pump
TruFlo Sample Uptake Monitor

- Adjustable damping
- Settable alarm limits
- Digital display
- Recordable graph
- Range: 0 to 4ml/min
How it works
Thermal Flow Measurement

Flow Rate is related to $(\text{Temp}_A - \text{Temp}_B)$
Features of TruFlo

- Adjustable damping
- Settable alarm limits
- Digital display
- Recordable graph
- Range: 0.05 to 4ml/min
Adjustable damping
Effect of Clamp Position
Validation for TruFlo

TruFlo Accuracy Verification Procedure

1. Overview & Scope

The following procedure is used to verify the accuracy of the TruFlo's
accuracy. Please note that this procedure is a guideline only and is not
necessarily applicable to all flow meters. In order to obtain accurate measurements, you will require
appropriate test equipment and calibration measurement tools, and stable testing conditions.

2. Test Plan Requirements

The following conditions are required to achieve accurate and reproducible
verification results:

- A temperature-controlled environment is required to perform the test.
- The procedure must be conducted at 25°C.
- The equipment used should be calibrated to a specified tolerance.
- The equipment should be used in accordance with the manufacturer’s instructions.
- The equipment should be properly maintained and calibrated.
- The equipment should be used in a clean and controlled environment.
- The equipment should be used in a controlled environment at 25°C.
- The equipment should be used in a controlled environment at 25°C, with a deviation of ±1°C.
- The equipment should be used in a controlled environment at 25°C, with a deviation of ±1°C, and the calibration certificate should be included.
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Certificate of calibration

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product Name</th>
<th>Test Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td>TruFlo</td>
<td>2023-01-15</td>
</tr>
</tbody>
</table>

Calibration Temperature: 25°C ±1°C

Signatory: [Signature]

Date: [Date]

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Applications of TruFlo

- ICP-OES
- ICP-MS

Potential Applications of TruFlo
- HPLC
- UV-Vis
- FTIR
- Any technique where sample flow rate is important