**Flame Sealing Temperature Test:  
Ampulmatic**®**-10 Sealer**

**Background**

Case Study

One of the largest international pharmaceutical companies is packaging a product in glass ampules, to be kept at a temperature between 2° C and 8° C.

The purpose of this project was to measure the rise in temperature of the liquid after being flame sealed by the Ampulmatic-10 Ampule Sealer.

**Procedure**

We filled 1 mL Wheaton ampules with 1 mL of water and 5 mL Wheaton ampules with 5 mL of water. Everything was cooled to 5° C or less and placed inside a cooler with ice packs.

The Ampulmatic-10 Sealer was used to flame seal each ampule. The Ampulmatic-10 System utilizes the tip seal method for sealing glass ampules. The flame melts the glass at the top of the ampule while the Sealer spins the ampule, creating a strong hemispherical seal.

Each ampule was placed in the carousel one space before the flame sealing position. Immediately after sealing, we broke open the ampule, placed it in a refrigerated environment, and used a digital thermometer to measure the temperature of the liquid. The thermometer probe was kept at ~4° C between measurements to minimize equilibration time.

**Results**

In the 1 mL ampules, temperature rise ranged from 3.0° C to 3.7° C.

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| --- | --- | --- |
| **1 mL ampule Temperature Sealing Test 7/25/18** | | |
|  | | |
| Starting Temperature (°C) | Temperature After Sealing (°C) | Temperature Rise (°C) |
| 1.7 | 5.4 | 3.7 |
| 2.6 | 6.9 | 4.3 |
| 4.0 | 7.0 | 3.0 |

In the 5 mL ampules, temperature rise ranged from 1.8° C to 2.1° C.

|  |  |  |
| --- | --- | --- |
| **5 mL ampule Temperature Sealing Test 7/26/18** | | |
|  |  |  |
| Starting Temperature (°C) | Temperature After Sealing (°C) | Temperature Rise (°C) |
| 3.5 | 5.4 | 1.9 |
| 2.5 | 4.3 | 1.8 |
| 1.9 | 4.0 | 2.1 |
| 1.9 | 4.0 | 2.1 |

**Recommendations**

* Ampules should be pre-filled and kept refrigerated until ready to seal.
* The pre-filled ampules should be kept at the lowest possible temperate before sealing.
* The operator should use Kevlar insulated gloves (Bioscience PCN 270 114) to reduce heat transfer.
* Immediately after sealing, the ampule should be returned to refrigerated conditions.
* It’s our opinion that the smaller ampules will have the greatest variability in temperature, so care should be taken to keep the liquid chilled during the sealing process.