

Baxa Corporation

ShrinkSafe[®] Paralytic ID Bands

Technical Paper

The effects of temperature increase on vial contents
during the band application process



Baxa Corporation
14445 Grasslands Drive
Englewood, CO 80112

tel: 303-690-4204
fax: 303-690-4804
www.baxa.com

Introduction

The ShrinkSafe Paralytic ID Band is a plastic heat-shrink sleeve specific to high-alert medications. It was designed to prevent adverse medication events associated with the administration of paralytic agents and to prevent the inadvertent administration of a paralytic agent to a non-intubated patient.

Paralytic agents are used in the Operating Room (OR) and the Intensive Care Unit (ICU) to:

- 1) eliminate spontaneous breathing / promote mechanical ventilation
- 2) cause pharmacologic restraint to prevent patients from harming themselves
- 3) decrease oxygen consumption

ShrinkSafe ID Bands are applied to 10 mL vials using a heat tunnel. This paper details the testing performed to measure the effect of the application of heat to vials and their contents.

Testing

Testing comprised two parts. The first established the temperature/time profile range to program a heat tunnel to satisfactorily apply a ShrinkSafe ID Band. The second part demonstrated the temperature increase experienced by the contents of a glass 10 mL vial when exposed to this established temperature/time profile.

Testing was performed to replicate the different temperatures experienced for drug storage. The first series of tests started with the internal vial temperature equal to room temperature, which is consistent with drugs stored in a controlled room environment. The second started with an internal vial temperature at 38 – 44° F (3.33 – 6.67° C). This is the temperature range associated with refrigerated drugs.

Acceptance Criteria for Satisfactorily Applied ShrinkSafe ID Band

The following criteria determined whether a ShrinkSafe ID Band was considered “satisfactorily applied”:

- Legible vial labeling and drug name
- Legible ShrinkSafe Band labeling
- ShrinkSafe Band sealed completely around the vial and did not rotate or allow for up-and-down movement
- No excessive wrinkling of the band
- ShrinkSafe Band prevented unintentional removal of vial cap
- To access vial contents, integrity of ShrinkSafe must be compromised

Test Equipment

Description	Baxa ID	Last Calibration	Calibration Due
Stop Watch	3063	9/02	9/04
Fluke Thermometer	3041	7/7/04	7/7/05
Fluke Thermometer	3035	7/7/04	7/7/05
Shrink Tunnel #2	2213	3/30/04	3/31/05
Tachometer	3135	3/26/04	3/26/05

Data

Table 1: Initial internal vial temperature at 73° F (22.8° C) – room temperature

Heat Tunnel Temperature (Deg. F)	Time (sec.)	ShrinkSafe Pass / Fail	Highest Avg. internal vial temp.(Deg. F)	Standard Deviation	Comments
315	5	P	74.7	0.35	
	6	P	75.2	0.36	Required 2 passes
	7	P	75.6	0.57	
320	5	P	74.7	0.19	
	6	P	74.6	0.42	
	7	P	76.4	2.4	

Notes: 1) Temperature/time profiles generating unsatisfactorily applied bands are excluded from this table.
 2) The term "required 2 passes" refers to the number of times the vials were passed through the tunnel to generate a satisfactory seal.

Table 2: Initial internal vial temperature range of 38 - 44° F – refrigerated

Heat Tunnel Temperature (Deg. F)	Time (sec.)	ShrinkSafe Pass / Fail	Highest Avg. Internal Vial Temp.(Deg. F)	Standard Deviation	Comments
315	5	P	44.2	2.2	Required 2 passes
	6	P	42.9	2.2	
	7	P	43.4	0.6	
320	5	P	44.0	2.9	
	6	P	42.9	3.8	Required 2 passes
	7	P	39.8	1.4	

Analysis

The testing data indicates the temperatures and associated time profiles programmed in to a heat tunnel required to generate a satisfactory band application. It also indicates the resultant internal vial temperatures generated to achieve satisfactory band application.

Conclusion

The temperature increases of the 10 mL glass vial contents attained during the process of applying the ShrinkSafe Paralytic ID Band during the testing are relatively low. The data should be considered when making decisions regarding appropriate drug storage guidelines for specific drugs. This data is intended to facilitate appropriate decision-making, but does not replace the professional judgment of a pharmacist.