

Bouncer measures silicone layer thickness and distribution for prefilled syringes

Introduction

Silicone oil is commonly sprayed or baked on to the inner surface of syringes to provide lubrication, allowing the plunger to move smoothly. Once coated, the orientation the syringe is stored in can cause redistribution of the silicone. Understanding the distribution of the silicone layer following long term storage is crucial to optimizing siliconization procedures and storage conditions.

Bouncer measures silicone thickness along the length of the syringe barrel and radially around the syringe to provide a 3D representation of silicone thickness and distribution (Figure 1). In this application note, Bouncer was used to measure the thickness and distribution of silicone in a prefilled syringe (PFS) that was stored horizontally to show the impact of storage orientation on the silicone layer.

Methods

A 1 mL PFS was stored horizontally for 4 weeks. Following storage the thickness and distribution of silicone in the PFS was analyzed with Bouncer.



Figure 1: Bouncer measures silicone thickness, distribution and mass for silicone coated devices.

Bouncer automatically captured 50 data points along 50 mm lines down the length of the syringe, starting from the flange and ending at the tip. The PFS was automatically rotated in 60° increments to capture 6 lines from the single syringe. In total, 50 measurements were collected from each of six 50 mm long lines totaling 300 measurements in 5

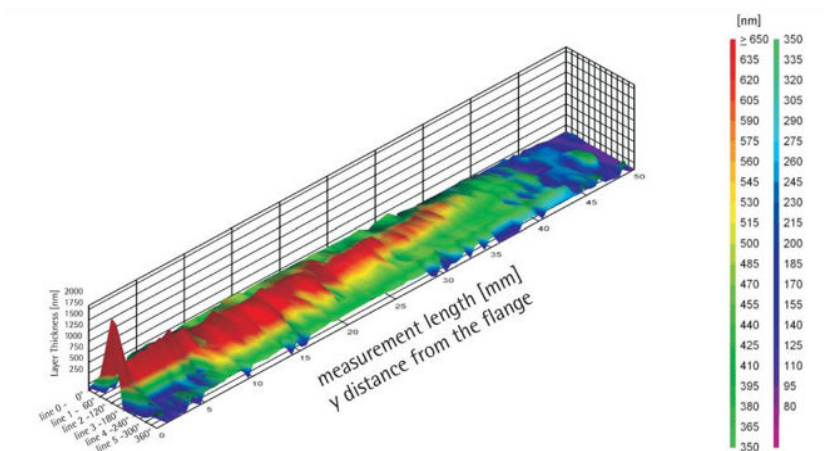


Figure 2: The 3D map of silicone oil distribution in a prefilled syringe that was stored horizontally for 4 weeks at room temperature.

minutes. From the thickness and distribution data, total silicone mass was calculated.

Results

Figure 2 shows a 3D map of the silicone oil distribution in the barrel of the PFS after horizontal storage. The down facing side of the PFS barrel has a silicone layer more than 10 times as thick as the upper portion of the barrel. In total 397 μg of silicone coated this PFS, although the distribution of this silicone is uneven.

Summary

For optimal lubrication and usability, the silicone layer in a syringe should be thin and homogeneous. Total silicone content and distribution data from Bouncer can be useful in optimizing the amount of silicone initially sprayed into the syringe to minimize redistribution during storage.

Bouncer also provides insight into the impact storage conditions have on the thickness and distribution of the silicone layer within drug delivery devices like prefilled syringes.



Unchained Labs
6870 Koll Center Parkway
Pleasanton, CA 94566
Phone: 1.925.587.9800
Toll-free: 1.800.815.6384
Email: info@unchainedlabs.com

© 2018 Unchained Labs. All rights reserved. The Unchained Labs logo, The Bouncer logo is a trademark and/or registered trademarks of Unchained Labs. All other brands or product names mentioned are trademarks owned by their respective organizations.

Rev A