

RESIDUAL VOLUME CERTIFICATE

TICKER[®]

TRANSDERMAL DISPENSER



CERTIFICATE OF CONFORMANCE ● CERTIFICADO DE ANÁLISE ● ANALYSENZERTIFIKAT ● BOLETÍN DE ANÁLISIS

biosrx

Product: **TICKER® CLASSIC**
SKU: **T37-TEAL-40**
LOT: **05082017**

Quantity: 40 Units
Manufacture Date: 05/08/2017
Package Date: 05/12/2017

Product Description:
Semi-clear container with accompanying colored base and caps.
Other info: Sold as a single carton

CONTROL OF PARAMETERS

Average Weight (per unit): 28.7g
Total Height: 93 mm
Diameter: 43.8 mm
Chamber Capacity: 36.8 mL
Click: Pass
Rotation: Pass
Sealing: Pass
Visual control: Pass
Parts fitting: Pass

PARTS WEIGHT (GRAMS)

Body/Housing: Min: 15.13g Max: 15.17g Net: 15.15g
Dispenser lid: Min: 1.84g Max: 1.86g Net: 1.85g
Safety cap: Min: 2.20g Max: 2.24g Net: 2.22g
Base: Min: 5.89g Max: 5.99g Net: 5.94g
Screw: Min: 2.02g Max: 2.04g Net: 2.03g
Piston: Min: 1.74g Max: 1.78g Net: 1.76g

MATERIAL(S)

Body/Housing: Clarified Copoly 3435E Formolene
Dispenser Lid: Clarified Copoly 3435E Formolene
Safety cap: Clarified Copoly 3435E Formolene
Base: Clarified Copoly 3435E Formolene
Screw: Clarified Copoly 3435E Formolene
Piston: Clarified Copoly 3435E Formolene

Results: COMPLIANT

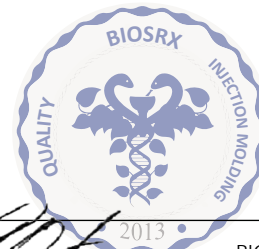
RESIDUAL CREAM IN DISPENSER

For the 37mL TICKER, the residual volume inside the dispenser and therefore not available for dispensation is 2.5mL. Note, no additional amount of cream/gel/flowable preparation can be further dispensed with the turn of the dial. Therefore, compounding facilities need to take into account the residual volume in order to package the proper amount of medication the patient is to receive, as indicated. This volumetric amount may vary depending on the density of the base being used. The residual volume in a study using Lipoderm® base from PCCA was examined in a study, and the data is displayed below. Factors that may influence these values include, but are not limited to altitude, air pressure, and the methodology used to prepare compounded preparations.

Lipoderm®

N= 20	Ave. Vol. 2.52g Median 2.48g SD 0.13g
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BIOSRX, INC., California—USA, manufacturing facility fulfills the requirements of ISO 9001:2008 scope registration custom injection molding decorative and assembly. Systematic procedures for new product development and production implementation are strictly adhered to. BIOSRX certifies that the items manufactured are in full conformance to all purchase orders and drawings requirements. Materials used are U.S. FDA compliant. Product used in fabrication of all applicator components are made in the USA.



Physical/Chemical characteristics of the raw materials used for manufacturing these products as mentioned above comply by the USP set standards.

BIOSRX, INC. USA
Frank Ortiz; Quality Assurance Director

Certificate Expiry: 08/19/2018

RESIDUAL VOLUME CERTIFICATE

Ticker mini®



CERTIFICATE OF CONFORMANCE ● CERTIFICADO DE ANÁLISE ● ANALYSENZERTIFIKAT ● BOLETÍN DE ANÁLISIS

biosrx

Product: **TICKERMINI**
SKU: **T20-TEAL-40**

Quantity: 40 Units
Manufacture Date: 01/05/2017
Package Date: 01/12/2017

Product Description:
Amber semi-clear container with accompanying colored base and caps.
Other info: Sold as a single carton

CONTROL OF PARAMETERS

Weight (per unit; gram): 24.8g
Total Height: 69 mm
Diameter: 43.8 mm
Chamber Capacity: 20-22 mL
Click: Pass
Rotation: Pass
Sealing: Pass
Visual control: Pass
Parts fitting: Pass

PARTS WEIGHT (GRAMS)

Body/Housing: Min: 10.79g Max: 10.87g Net: 10.83g
Dispenser lid: Min: 1.81g Max: 1.80g Net: 1.80g
Safety cap: Min: 2.04g Max: 2.51g Net: 2.27g
Base: Min: 5.72g Max: 5.95g Net: 5.84g
Screw: Min: 1.54g Max: 1.56g Net: 1.55g
Piston: Min: 2.33g Max: 2.39g Net: 2.36g

MATERIAL(S)

Body/Housing: Clarified Copoly 3435E Formolene
Dispenser Lid: Clarified Copoly 3435E Formolene
Safety cap: Clarified Copoly 3435E Formolene
Base: Clarified Copoly 3435E Formolene
Screw: Clarified Copoly 3435E Formolene
Piston: Clarified Copoly 3435E Formolene

Results: COMPLIANT

RESIDUAL CREAM IN DISPENSER

The residual volume inside the dispenser and therefore, not available for dispensation is **1.8mL**. Note, no additional amount of cream/gel/flowable preparation can be further dispensed with the turn of the dial. Therefore, compounding facilities need to take into account the residual volume in order to package the proper amount of medication the patient is to receive, as indicated. Residual values for TRANSDERMA® Trans D from XENEX Laboratories and Lipoderm® from PCCA were also examined in a study and displayed below. Factors that may influence these values include, but are not limited to altitude, air pressure, and the methodology used to prepare compounded preparations.

	Lipoderm®		Transderma® Trans D
N = 10	Ave. Vol. 1.76g Median 1.75g SD 0.12g	N = 10	Ave. Weight 1.72g Median 1.76g SD 0.17g

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