TICKER TRANSDERMAL DISPENSER

Ticker mini®

gentledose VAGINAL APPLICATOR

**CERTIFICATE OF CONFORMANCE • CERTIFICADO DE ANÁLISE • ANALYSENZERTIFIKAT • BOLETÍN DE ANÁLISIS**

Product: **TICKERMINI**
SKU: **T40AMBERWHITEMINI**
LOT: **010517**

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®

N = 10

Ave. Vol. 1.76g
Median 1.75g
SD 0.12g

Transderma® Trans D

N = 10

Ave. Weight 1.72g
Median 1.76g
SD 0.17g

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.

BIOSRX QUALITY INJECTION MOLDING 2013

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