TICKER
TRANSDERMAL DISPENSER

Ticker mini®

gentledose
VAGINAL APPLICATOR

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

Product: **CLASSIC TICKER**
SKU: **T37TEAL**
LOT: **05082017**

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

Product Description:
Amber 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

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