



MEDISCA[®]
YOUR TRUSTED PARTNER IN COMPOUNDING

Product No.: 7334



Syringe, PreciseDose Dispenser™, Amber, 35mL, w/Tip cap

DESCRIPTION: The PreciseDose Dispenser™, MEDISCA's line of branded syringes, is an FDA-registered medical device manufactured in an ISO 13485 facility. These oral and topical syringes are designed uniquely for the compounding industry. With quality in mind, these syringes were tested against graduated capacity and leak-resistance using BS/EN ISO 7886-1 – the standard used for the sterile hypodermic syringes. MEDISCA has taken a classic design and enhanced it to adhere to modern day oral and topical applications.

FEATURES:

- ✔ For oral and topical use
- ✔ FDA-Registered Medical Device as per ISO 13485
- ✔ FDA approved materials
- ✔ Leak-Resistance and Graduated Capacity tested against BS/EN ISO 7886-1
- ✔ Passed Testing for Ink Smudging
- ✔ Easy-to-read scale markings on both amber and clear syringes
- ✔ Amber syringes meet USP requirements for light sensitive drugs
- ✔ Clear tip caps included with syringe purchase
- ✔ Compatible with MEDISCA Adapter Caps and other bottle adapters
- ✔ Tip caps available in 10 different colors for easy medication identification
- ✔ Available in sizes: 0.5, 1, 3, 5, 10, 20, 35, 60mL
- ✔ PVC, BPA & Latex Free

LIST OF COMPONENTS & MATERIALS:

All materials listed are FDA approved.

| Part | Material |
|-----------|----------------------------------|
| Barrel | Polypropylene (PP) |
| Plunger | Polypropylene (PP) |
| Seal | Silicone |
| Tip Cap | High density polyethylene (HDPE) |
| Lubricant | Polydimethylsiloxane |

ADDITIONAL INFORMATION:

Automated Non-Sterile Liquid Filling Process:

- 7275: Syringe Stand Any MEDISCA PreciseDose Dispenser™
- 7395: Tubing (IV Spike Inlet to Luer Lock Outlet)
- 7396: PharmAssist Fluid Transfer Pump
- 9903: Luer Lock to Luer Slip Connector – Allows PreciseDose Dispenser™ to attach to tubing

Semi-Automated Non-Sterile Cream Filling Process:

- 6012: Modified 1L Samix Jar – Any sized Samix jar will also work
- 6664: Pink Nozzle – For front-filling PreciseDose Dispensers™
- 6668: Samix Applicator, Long – For back-filling PreciseDose Dispensers™
- 6682: Eazy-Fill™ Topical Transfer Gun
- 7778: Topi-Click Filling Nozzles – For back-filling PreciseDose Dispensers™
- 7947: Topi-Click Filling Station
- Any MEDISCA PreciseDose Dispenser™

Accuracy Validation:

Tolerance on Graduated Capacity*

The test that we perform for the tolerance on graduated capacity is demonstrative of the syringe's ability to give an accurate dose of any volume. It establishes the accuracy limits for a specific interval volume that is tested along the length of the barrel.

Table 1: Accuracy Limits of Target Intervals for Validation of Tolerance on Graduated Capacity for PreciseDose Dispensers™

| Nominal Capacity | Target Interval Tested [mL] | Greater than or Equal to Half Nominal Capacity | | Below Half Nominal Capacity | |
|------------------|-----------------------------|--|------------------|-----------------------------|------------------|
| | | Lower Limit [mL] | Upper Limit [mL] | Lower Limit [mL] | Upper Limit [mL] |
| 0.5 mL | 0.1 | 0.0950 | 0.1050 | 0.0905 | 0.1095 |
| 1 mL | 0.1 | 0.0950 | 0.1050 | 0.0830 | 0.1170 |
| 3 mL | 0.5 | 0.525 | 0.525 | 0.445 | 0.555 |
| 5 mL | 1.0 | 1.040 | 1.040 | 0.915 | 1.085 |
| 10 mL | 2.0 | 2.080 | 2.080 | 1.830 | 2.170 |
| 20 mL | 5.0 | 5.200 | 5.200 | 4.650 | 5.350 |
| 35 mL | 5.0 | 5.200 | 5.200 | 4.425 | 5.575 |
| 60 mL | 10.0 | 10.400 | 10.400 | 9.000 | 11.000 |

* Derived from the criteria according to ISO BS/EN ISO 7886-1