



MEDISCA[®]
YOUR TRUSTED PARTNER IN COMPOUNDING

PRODUCT NO.: 8143-01

















PRECISEDOSSE DISPENSER™ SAMPLE PACK

0.5 (Amber Only), 1, 3, 5, 10, 20mL Sizes Included, Clear & Amber w/Tip Caps and MEDISCA Adapter Caps [Green, Red, Blue, B (20–400)]

pk/11

DESCRIPTION: Welcome to the Accurate, Effective and Easy system for quality compounding! The PreciseDose Dispensers are accurate devices for measuring and dispensing oral or topical medication. In recognizing the importance of precision when dealing with medicated dosage forms, MEDISCA has taken a classic design and enhanced it to adhere to modern day oral and topical applications. The PreciseDose Dispenser™, MEDISCA's first line of branded syringes, is an FDA-registered medical device manufactured in an ISO 13485 facility. These high quality syringes are compatible with various new accessories, such as colored Adapter Caps and tip caps, allowing for easy product identification!

FEATURES:

-  Removes particles & Eliminates air
-  For oral and topical use
-  Available in: 0.5, 1, 3, 5, 10, 20 (35, 60mL sizes now available)
-  FDA-registered medical device manufactured in an ISO 13485 facility
-  ISO 7886-1:1997 compliant – validated tolerance on graduated capacity and leak resistance
-  Meets USP requirements:
 -  Made of medical-grade polypropylene
 -  For light-sensitive drugs (amber color)
-  Clear tip cap included for proper seal
-  Designed for easy back-filling
-  Compatible with MEDISCA Adapter Caps
-  PVC-free
-  Latex-free
-  BPA-free

ADDITIONAL INFORMATION:

List of Components & Materials:

All materials listed are of pharmaceutical grade according to USP and FDA standards.

Part	Material
Barrel	Polypropylene (PP)
Plunger	Polypropylene (PP)
Seal	Silicone
Tip Cap	High density polyethylene (HDPE)
Lubricant	Polydimethylsiloxane, medical grade

Accuracy Validation

Tolerance on Graduated Capacity

The test that we perform for the tolerance on graduated capacity is demonstrative of the syringes 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	0.1170	0.0830
3 mL	0.5	0.475	0.525	0.555	0.445
5 mL	1.0	0.960	1.040	0.915	1.085
10 mL	2.0	1.920	2.080	1.830	2.170
20 mL	5.0	4.800	5.200	4.650	5.350
35 mL	5.0	4.800	5.200	4.425	5.575
60 mL	10.0	9.600	10.400	9.000	11.000

*derived from the criteria according to ISO BS EN ISO 7886-1:1997: Sterile hypodermic syringes for single use.

Standard Deviation with respect to Nominal Capacity

The following standard deviation (SD) values represent the possible variation that can occur when dispensing at nominal capacity. The 95% confidence intervals for the SD show the probability ranges of the derived SD and signify the reliability of the results.

Table 2 – Standard Deviation with respect to Nominal Capacity of PreciseDose Dispensers™

	Syringe Nominal Capacity							
	0.5 mL	1 mL	3 mL	5 mL	10 mL	20 mL	35 mL	60 mL
Standard Deviation, SD [mL]	0.013	0.005	0.008	0.023	0.033	0.096	0.103	0.260
95% Confidence Interval for SD [mL]	0.00989 to 0.01899	0.00380 to 0.00730	0.00608 to 0.01168	0.01749 to 0.03359	0.02510 to 0.04820	0.07301 to 0.14021	0.07833 to 0.15044	0.19773 to 0.37975

With reference to the highlighted in Table 2, dispensing at nominal capacity from a 60mL syringe, the ejected volume should not deviate more than 0.260 mL. Furthermore, this estimated deviation should fall between 0.19773 mL and 0.37975 mL 95% of the time.