

# SMART Metered Dose Applicator - Accuracy Study



## Accuracy and Reproducibility Study

For this study, flowable transdermal composition<sup>1</sup> was transferred to the Ticker™ applicator, packaged and labeled, then allowed to settle overnight in order to eliminate air pockets. On the day of the study, each applicator unit was tapped for 30 seconds to further remove air pockets, and a visual test was conducted to confirm removal.

- ◆ Priming: 4g of composition expelled, (80 CLICKS).
- ◆ All applicator units were filled with composition to the max; ~37g
- ◆ Data Collection: November 12-17, 2012
- ◆ Calibrated Balance Used: OHAUS® Adventurer Pro
- ◆ Volumetric Output Measured in weight as grams (g)

(18 Degrees rotation)

**1-CLICK**

<sup>a</sup>

Average	0.049	g
Median	0.048	
SD	0.004	
(N)	240	

**0.05g**

(90 Degrees rotation)

**5-CLICKS**

<sup>b</sup>

Average	0.25	g
Median	0.25	
SD	0.007	
(N)	240	

**0.25g**

(360 Degrees rotation)

**20-CLICKS**

<sup>c</sup>

Average	1.011	g
Median	1.013	
SD	0.018	
(N)	240	

**1.0g**

<sup>a</sup> One applicator unit chosen at random for each study arm, (A1, A2, A3, A4). <sup>b</sup> One applicator unit chosen at random for each study arm, (B1, B2, B3, B4) <sup>c</sup> Two applicator units chosen at random for each study arm (C1, C2, C3, C4)

<sup>1</sup> Medisca HRT Base was used for this study.

Please visit [www.biosrx.com](http://www.biosrx.com) to download the actual study raw data



## Accuracy and Precision Study

For this study, flowable transdermal composition<sup>1</sup> was transferred to the HRTicker™ applicator, packaged and labeled, then allowed to settle overnight in order to eliminate air pockets. On the day of the study, each applicator unit was tapped for 30 seconds to further remove air pockets, and a visual test was conducted to confirm removal.

- ◆ Priming: 4g of composition expelled, (80 CLICKS).
- ◆ All applicator units were filled with composition to the max; ~37g
- ◆ Data Collection: August 22-26, 2014
- ◆ Calibrated Balance Used: OHAUS® Adventurer Pro
- ◆ Volumetric Output Measured in weight as grams (g)
- ◆ Base Examined: Humco HRT Base (Heavy)

(90 Degrees rotation)

### 5-CLICKS

	A (g)	B (g)	C (g)	D(g)
1	0.23	0.226	0.238	0.234
2	0.235	0.234	0.236	0.25
3	0.244	0.269	0.246	0.247
4	0.248	0.245	0.24	0.245
5	0.241	0.25	0.239	0.249
6	0.243	0.25	0.25	0.245
7	0.255	0.241	0.226	0.248
8	0.262	0.237	0.24	0.256
9	0.248	0.248	0.232	0.227
10	0.237	0.25	0.24	0.249
11	0.239	0.248	0.245	0.228
12	0.244	0.254	0.251	0.248
13	0.262	0.249	0.239	0.251
14	0.243	0.274	0.245	0.251
15	0.253	0.24	0.24	0.243
16	0.248	0.25	0.229	0.22
17	0.253	0.252	0.245	0.243
18	0.244	0.242	0.251	0.246
19	0.274	0.255	0.257	0.245
20	0.243	0.227	0.238	0.238
21	0.256	0.243	0.247	0.253
22	0.249	0.24	0.253	0.241
23	0.254	0.289	0.25	0.254
24	0.256	0.257	0.253	0.253
25	0.251	0.257	0.244	0.24
26	0.242	0.247	0.251	0.25
27	0.253	0.257	0.257	0.253
28	0.253	0.248	0.245	0.247
29	0.259	0.243	0.239	0.241
30	0.235	0.25	0.247	0.254
31	0.258	0.257	0.252	0.255
32	0.253	0.235	0.251	0.254
33	0.257	0.245	0.234	0.239
34	0.241	0.253	0.255	0.241
35	0.253	0.25	0.249	0.249
36	0.257	0.248	0.248	0.255
37	0.255	0.242	0.232	0.246
38	0.241	0.247	0.253	0.248
39	0.264	0.252	0.254	0.255
40	0.252	0.253	0.244	0.249
41	0.258	0.245	0.259	0.245
42	0.245	0.285	0.24	0.25
43	0.257	0.218	0.241	0.25
44	0.254	0.243	0.24	0.248
45	0.262	0.249	0.262	0.242
46	0.242	0.241	0.249	0.253
47	0.258	0.242	0.252	0.252
48	0.252	0.259	0.253	0.249
49	0.256	0.256	0.256	0.249
50	0.248	0.247	0.249	0.252
51	0.254	0.26	0.253	0.248
52	0.255	0.246	0.245	0.25
53	0.258	0.254	0.255	0.246
54	0.245	0.243	0.242	0.259
55	0.261	0.257	0.257	0.253
56	0.259	0.251	0.243	0.242
57	0.245	0.247	0.251	0.251
58	0.247	0.249	0.241	0.253
59	0.26	0.255	0.252	0.242
60	0.26	0.246	0.257	0.247

Average	0.249
Median	0.249
SD	0.008
(N)	240



### HRT HEAVY PROPERTIES

pH	7.5
Specific Gravity	1.04 g/ml
Viscosity	165,000 cps
Physical Format	Cream
Color	White
Transdermal Penetration	50%
API Compatibility	Lipophilic – 20%
Typical Applications	Male & Female Hormone Replacement





## Accuracy and Precision Study

For this study, flowable transdermal composition<sup>1</sup> was transferred to the HRTicker™ applicator, packaged and labeled, then allowed to settle overnight in order to eliminate air pockets. On the day of the study, each applicator unit was tapped for 30 seconds to further remove air pockets, and a visual test was conducted to confirm removal.

- ♦ Priming: 4g of composition expelled, (80 CLICKS).
- ♦ All applicator units were filled with composition to the max; ~37g
- ♦ Data Collection: June 24-26, 2015
- ♦ Calibrated Balance Used: OHAUS® Adventurer Pro
- ♦ Volumetric Output Measured in weight as grams (g)
- ♦ Base Examined: PCCA Lipoderm Base

(18 Degrees rotation)

### 1-CLICK

	A (g)	B (g)	C (g)	D(g)
1	0.048	0.04	0.037	0.035
2	0.05	0.049	0.044	0.037
3	0.041	0.045	0.037	0.052
4	0.045	0.05	0.039	0.046
5	0.044	0.044	0.047	0.045
6	0.053	0.053	0.052	0.053
7	0.044	0.032	0.048	0.035
8	0.057	0.037	0.044	0.054
9	0.047	0.046	0.045	0.042
10	0.05	0.04	0.042	0.052
11	0.054	0.049	0.046	0.048
12	0.044	0.043	0.051	0.038
13	0.06	0.046	0.045	0.054
14	0.047	0.048	0.05	0.047
15	0.049	0.054	0.048	0.045
16	0.054	0.043	0.048	0.042
17	0.041	0.044	0.045	0.044
18	0.045	0.053	0.042	0.049
19	0.042	0.048	0.046	0.052
20	0.04	0.042	0.042	0.046
21	0.043	0.048	0.047	0.048
22	0.048	0.049	0.039	0.049
23	0.048	0.048	0.047	0.053
24	0.04	0.037	0.046	0.045
25	0.044	0.055	0.048	0.05
26	0.05	0.046	0.034	0.04
27	0.053	0.047	0.04	0.048
28	0.045	0.044	0.045	0.046
29	0.043	0.038	0.056	0.042
30	0.047	0.053	0.044	0.054
31	0.045	0.045	0.046	0.044
32	0.05	0.038	0.048	0.049
33	0.052	0.054	0.043	0.053
34	0.037	0.048	0.047	0.037
35	0.042	0.041	0.041	0.047
36	0.055	0.039	0.05	0.038
37	0.038	0.056	0.045	0.042
38	0.044	0.043	0.052	0.053
39	0.045	0.042	0.048	0.051
40	0.05	0.052	0.053	0.041
41	0.042	0.047	0.046	0.047
42	0.055	0.042	0.048	0.049
43	0.049	0.049	0.049	0.043
44	0.058	0.045	0.047	0.046
45	0.042	0.039	0.045	0.051
46	0.053	0.044	0.051	0.049
47	0.047	0.055	0.041	0.049
48	0.051	0.048	0.054	0.038
49	0.057	0.05	0.045	0.047
50	0.037	0.042	0.047	0.047
51	0.057	0.048	0.04	0.048
52	0.046	0.049	0.046	0.053
53	0.051	0.044	0.048	0.043
54	0.048	0.052	0.049	0.049
55	0.037	0.047	0.055	0.048
56	0.05	0.045	0.035	0.045
57	0.049	0.046	0.045	0.047
58	0.048	0.051	0.045	0.044
59	0.044	0.047	0.05	0.049
60	0.048	0.045	0.048	0.042

Median	0.047
Average	0.046
SD	0.005
(N)	240



LIPODERM PROPERTIES	
pH	3-9
Specific Gravity	
Viscosity	
Physical Format	Cream
Color	Yellow
Transdermal Penetration	
API Compatibility	
Typical Applications	Male & Female Hormone Replacement



# Metered Dose Applicator - Accuracy Study



## Accuracy and Precision Study

For this study, flowable transdermal composition<sup>1</sup> was transferred to the Ticker<sup>®</sup> applicator, packaged and labeled, then allowed to settle overnight in order to eliminate air pockets. On the day of the study, each applicator unit was tapped for 30 seconds to further remove air pockets, and a visual test was conducted to confirm removal. After each dosage (5 CLICKS) was dialed, a 10-second interval was introduced prior to collecting the following sample.

- ♦ Priming: 4g of composition expelled, (80 CLICKS).
- ♦ All applicator units were filled with composition to the max; ~37g
- ♦ Data Collection: August 11, 2016
- ♦ Calibrated Balance Used: OHAUS<sup>®</sup> Adventurer Pro
- ♦ Volumetric Output Measured in weight as grams (g)
- ♦ Base Examined: Transderma HRT Base Flowable

(90 Degree rotation)

### 5-CLICKS

A (g)	B (g)	C (g)	D(g)
0.227	0.245	0.241	0.254
0.249	0.238	0.253	0.246
0.244	0.245	0.242	0.259
0.256	0.242	0.247	0.248
0.251	0.260	0.241	0.246
0.251	0.251	0.244	0.245
0.249	0.246	0.238	0.248
0.250	0.254	0.251	0.249
0.226	0.242	0.237	0.245
0.253	0.248	0.251	0.258
0.253	0.245	0.241	0.241
0.225	0.259	0.205	0.258
0.245	0.246	0.244	0.248
0.251	0.251	0.246	0.252
0.255	0.245	0.237	0.248
0.247	0.263	0.257	0.255
0.246	0.244	0.237	0.250
0.250	0.219	0.250	0.256
0.247	0.245	0.240	0.249
0.253	0.258	0.239	0.251
0.244	0.243	0.246	0.250
0.239	0.241	0.234	0.249
0.253	0.255	0.250	0.212
0.255	0.244	0.220	0.244
0.244	0.248	0.250	0.254
0.246	0.242	0.242	0.230
0.256	0.254	0.244	0.237
0.242	0.240	0.236	0.247
0.255	0.242	0.248	0.257
0.240	0.240	0.240	0.241
0.252	0.253	0.250	0.238
0.220	0.237	0.244	0.265
0.230	0.247	0.246	0.241
0.255	0.218	0.238	0.254
0.246	0.254	0.247	0.244
0.250	0.227	0.235	0.258
0.245	0.253	0.256	0.248
0.248	0.239	0.210	0.249
0.242	0.257	0.244	0.256
0.250	0.235	0.238	0.246

Average	0.245
Median	0.246
SD	0.009
(N)	160

0g



### HRT HEAVY PROPERTIES

pH	5.0
Specific Gravity	0.99
Viscosity	23,900 cps
Physical Format	Cream
Color	White
Typical Applications	Male & Female Hormone Replacement

