

# Accuracy of preparations compounded by a robotic system in comparison to manual compounding

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## Introduction

In antineoplastic chemotherapy, the accuracy of preparation interferes with the patient safety. Accuracy of manually compounded preparations depends on the skills of the operator and the precision of the devices used as the operator prepares the dose by volumetric measures.

A robotic system, performing gravimetric controls, could improve accuracy and consequently patient safety, when assuming that the accuracy of the preparations automatically compounded is better than those compounded manually.

The main goal of this study was to compare the accuracy of preparations compounded by an automated robotic system (Apoteca™) with preparations compounded manually.



## Material and Method

For automated compounding with Apoteca™, 3 types of syringes with different sizes (3 ml, 10 ml and 50 ml) are stipulated.

8 different doses (1.0 ml, 1.5 ml, 2.0 ml, 2.5 ml, 3.0 ml, 10.0 ml, 10.5 ml and 50.0 ml) of sterile water were added to 250 ml bags prefilled with 0.9 % NaCl solution.

For each dose, 10 bags were compounded. All bags were weighed before and after compounding on an external balance with a precision of 0.01 g.

In parallel, bags with the same nominal doses were prepared following standard manual procedures:

- In the first series, the same types of syringes like in the robot were used (3 ml, 10 ml and 50 ml).

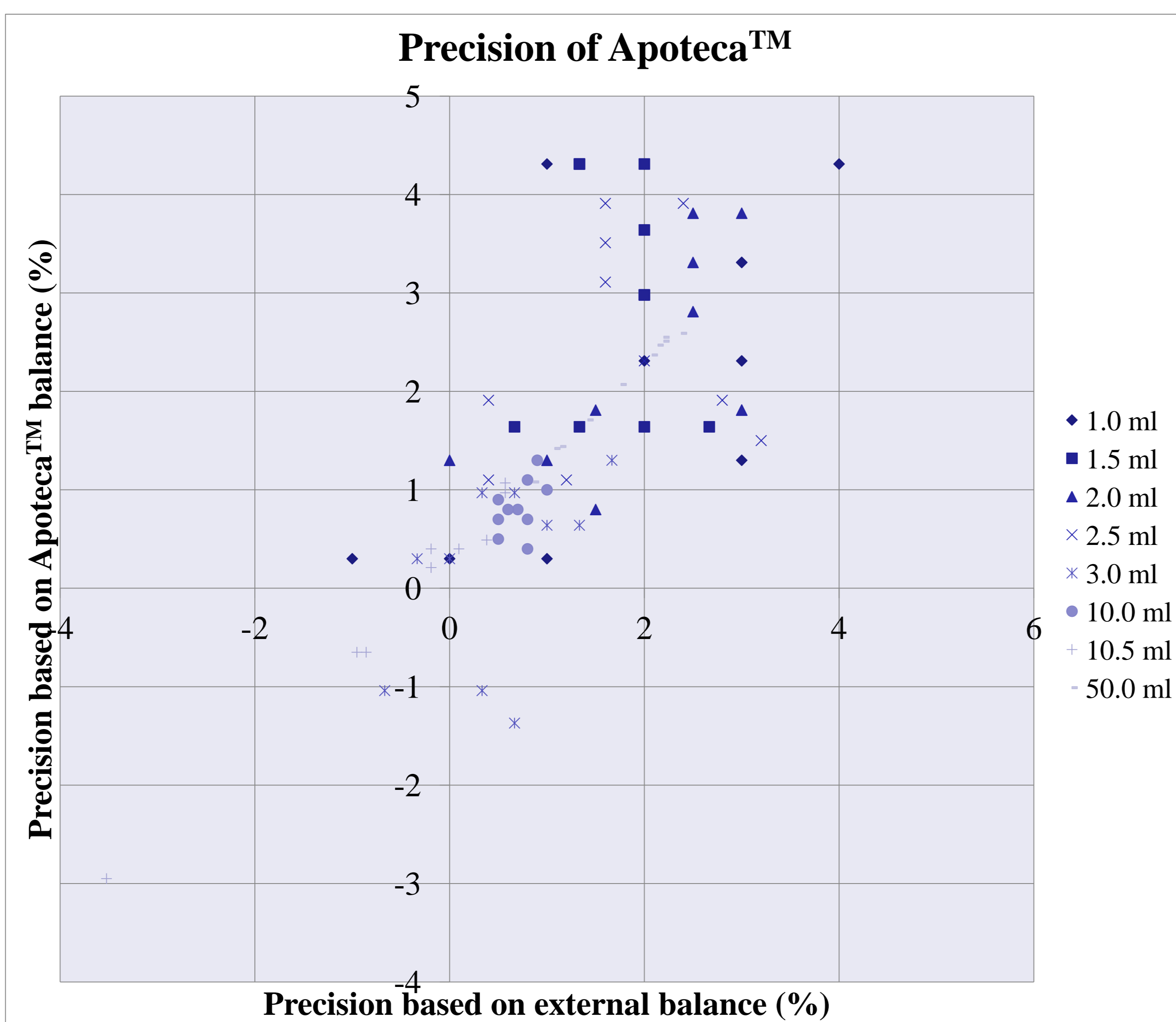
- In the second series, syringes were used in accordance with the standard operating procedures of manual compounding in our facility (1 ml, 2 ml, 3 ml, 10 ml, 20 ml and 50 ml).

The precision was calculated as percentage rate of the deviation of the nominal value.

## Results and discussion

### Automated compounding with Apoteca™

None of the bags compounded with Apoteca™ during this study failed with accept limit for precision set as  $\pm 5\%$



## Results and discussion

Volume injected	Syringe used	External balance		Apoteca™ balance	
		Precision (mean, n=10)	Standard deviation	Precision (mean, n=10)	Standard deviation
1.0 ml	3 ml - BD	1.90 %	1.60	2.21 %	1.60
1.5 ml	3 ml - BD	1.73 %	0.56	2.91 %	1.20
2.0 ml	3 ml - BD	2.05 %	1.01	2.26 %	1.10
2.5 ml	3 ml - BD	1.72 %	0.92	2.43 %	1.10
3.0 ml	10 ml - BD	0.50 %	0.72	0.17 %	0.96
10.0 ml	10 ml - BD	0.71 %	0.18	0.82 %	0.27
10.5 ml	50 ml - BD	- 0.43 %	1.21	- 0.05 %	1.17
50.0 ml	50 ml - BD	1.73 %	0.56	2.02 %	0.56

### Manual compounding using syringes similar to Apoteca™

Volume injected	Syringe used	Manual compounding using syringes similar to Apoteca™	
		Precision (mean, n=10)	Standard deviation
1.0 ml	3 ml – B.Braun	0.20 %	1.62
1.5 ml	3 ml – B.Braun	0.53 %	0.76
2.0 ml	3 ml – B.Braun	0.00 %	0.58
2.5 ml	3 ml – B.Braun	- 0.92 %	0.53
3.0 ml	10 ml - BD	- 0.53 %	0.71
10.0 ml	10 ml - BD	- 2.53 %	0.14
10.5 ml	50 ml – B.Braun	- 2.50 %	0.38
50.0 ml	50 ml – B.Braun	- 1.40 %	0.11

### Manual compounding with syringes of our facility

Volume injected	Syring used	Manual compounding using syringes of our facility	
		Precision (mean, n=10)	Standard deviation
1.0 ml	1 ml – B.Braun	- 4.70 %	0.95
1.5 ml	2 ml – B.Braun	- 1.20 %	1.36
2.0 ml	2 ml – B.Braun	- 1.40 %	0.70
2.5 ml	3 ml – B.Braun	- 0.92 %	0.53
3.0 ml	3 ml – B.Braun	- 0.77 %	0.57
10.0 ml	10 ml - BD	- 2.53 %	0.14
10.5 ml	20 ml – B.Braun	- 1.61 %	0.41
50.0 ml	50 ml – B.Braun	- 1.40 %	0.11

•The accuracy of the products compounded by the robotic system is similar to the accuracy obtained by the manual compounding process.

•There were small differences in the weight of the products compounded manually and the products compounded with the robot, but all the doses remained in an acceptance failure level of 5 %.

•The accuracies of the preparations prepared manually with both sizes of syringes are slightly different.

• Compared to an external balance, the precision of the Apoteca™ balance is reduced (balance in the working area of the robot, with a high air flow and vibrations from the ventilators or from other moving parts of the machine), however the results didn't show any false positive or false negative preparations.

• The standard deviations related to manual compounding tends to be lower than those related to robotic compounding, which means that the manual compounded doses tend to be closer to the mean than the doses compounded automatically.

## Conclusion

The accuracy of robotic preparation with Apoteca™ is highly acceptable compared to manual preparation.