



AIT Bioscience

Transforming the Process. Partnering for Results.

BIOANALYTICAL SOLUTIONS FOR BIOTHERAPEUTICS AND SMALL MOLECULE THERAPEUTICS

SMALL MOLECULE -
SCREENING LEVEL ASSAY

Speed *with* science for success

Purpose

Our screening level assay serves to provide “yes/no” or “go/no-go” data for early discovery and screening level work. It is semi-quantitative and is not intended to be compared across runs.

When to Use

- Discovery screening
- Lead optimization
- Early exploratory Tox

Advantages

- Ability to make an informed decision earlier in process (fail fast/fail cheap)
- Data within 5 days of sample receipt
- Fit-for-purpose pricing balances budgets with intended use of data

What do I get?

AIT Bioscience provides an Excel report outlining:

- Intra-run performance across 6 calibration standards (run in triplicate)
- Sample data
- Method summary
- Graphic representation of regression with calculated fit

What do I pay?

75% less than the cost of well-qualified method

When do I get it?

- Within 5 days of sample receipt
- Expedited analysis = 3 days (additional costs may apply)

Targeted Performance

- 30% CV, 40% at LLOQ
- Use of surrogate internal standard (supplied by sponsor or chosen by AITB)

Our Differentiators



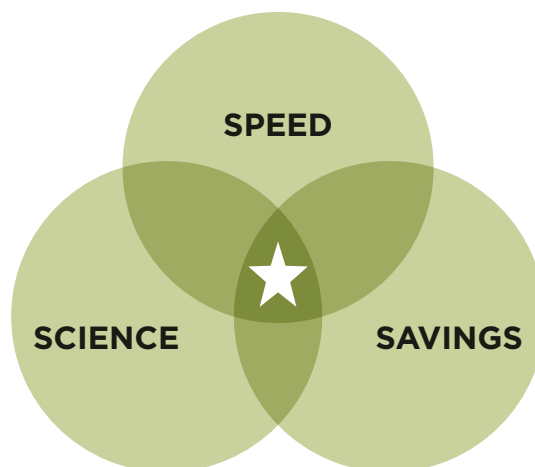
- Speed plus science



- Using chemistry experience to choose appropriate conditions



- Not using a one-size-fits-all approach or relying solely on ‘auto-tune’ feature



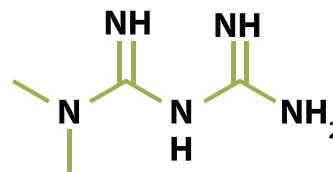
Representations below show the value added by our scientific preview process.

Typical one-size-fits-all methods used by competitors would not have provided comparable performance (% CV and % Bias) for two such chemically different molecules.

Metformin (Highly polar, low molecular weight example)

Analytical Performance of Metformin Quality Control Samples in Human Plasma (Study 8888-1234)

Run Date	Run ID	LOW QC 15.0 ng/mL	%Bias	HIGH QC 3750 ng/mL	%Bias
20-Mar-17	2	15.9	6	2330	-37.9
		13	-13.3	4430	18.1
		14.6	-2.7	4210	12.3
Mean		14.5		3660	
S.D.		1.45		1150	
%CV		10		31.4	
%Theoretical		96.7		97.6	
%Bias		-3.3		-2.4	
n		3		3	



Method

Column: Polar column option

Mobile Phase A: water, 0.1% formic acid Mobile Phase B: ACN, 0.1% formic acid

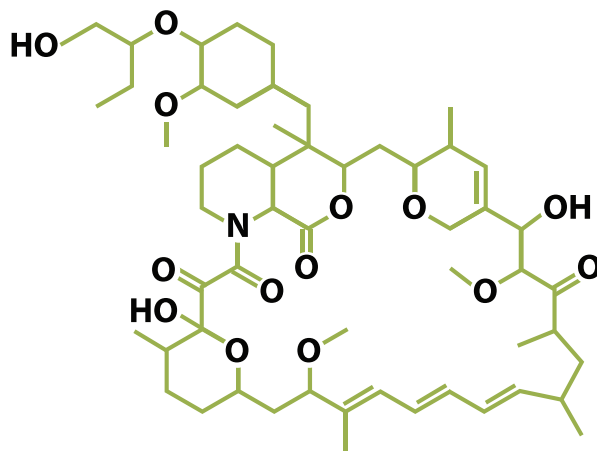
IS: Stable-labelled analog of analyte

Combination of method preview and in-lab scientific expertise led to selection of polar column option for increased compound retention.

Everolimus (Macrocyclic, hydrophobic example)

Analytical Performance of Everolimus Quality Control Samples in Rat Plasma (Study 8888-2345)

Run Date	Curve Number	LOW QC 3.00 ng/mL	%Bias	HIGH QC 750 ng/mL	%Bias
26-May-17	1	3.16	5.3	749	-0.1
		3.07	2.3	717	-4.4
		3.1	3.3	733	-2.3
Mean		3.11		733	
S.D.		0.0458		16	
%CV		1.5		2.2	
%Theoretical		103.7		97.7	
%Bias		3.7		-2.3	
n		3		3	



Method

Column: C18

Mobile Phase A: water, 0.1% formic acid Mobile Phase B: Methanol, 0.1% formic acid

IS: Atorvastatin as analog IS chosen in Scientific Preview

Scientific Preview provided insights on an appropriate analog IS as well as the need to start the gradient with a higher portion of mobile phase B than would be used in a typical screening method.

Learn more at www.aitbioscience.com or contact us to get pricing at screening@aitbioscience.com