



lecessary but lon't evaluate	eal-time f	Overall WEAK specification Test method	•C; Batch	#1234.		Too few time- points	
stability?			Specifiction	0	Time-point 1	2	
low can this be useful?	Appearance	Visual inspection	red/orange turbid solution	complies	complies	complies	1
	Identity	Phenotypic marker (flow cytometry)	complies	complies	complies	complies	What does this really tell you?
Is this assay sensitive to change?	Viability	Trypan blue (manual count)	≥ 70%	95	94	92 🤞	
	Potency	Bioassay	$\ge 4 \text{ U}/10^{6} \text{ cells}$	12.1	9.8	6.8	
Is this taking up too much o the DP?	f	EP/USP	No growth	No growth	NT	No growth	

		CBI	MP – Be	etter	?		
	Attribute	Test method	Specifiction	0	Time-point 1	2	
	Appearance	Visual inspection	red/orange turbid solution	complies	complies	complies	
Now viabilit can be	ldentity	Phenotypic marker (flow cytometry)	complies	complies	complies	complies	Viability fair stable
	Viability	Trypan blue (manual count)	≥ 70%	95	94	92 🥖	
	Content	Manual cell count	≥ 10 <sup>6</sup> cells/mL	2.1 × 10 <sup>6</sup>	1.8 × 10 <sup>6</sup>	1.1 × 10 <sup>6</sup>	
	Potency	Bioassay	≥ 4 U/10 <sup>6</sup> cells	12.1	9.8	6.8	Nearly 50%
	Sterility	EP/USP	No growth	No growth	NT	No growth	cells lost
• Pr m	esenting eaningless • <i>Yet I see</i>	viability as s. e this often	a percent	age w	ithout	total c	ells is
CAL	Consulting on Advanced Biologicals						

	CB	MP -	Differe	nt way	s to	pres	ent	data		
		Attribute	Test method	Specifiction	0	Time-point 1	2	A measure of		
		Appearance	Visual inspection	red/orange turbid solution	complies	complies	complies	identity is quantitative		
		<del>ldentity</del> Purity	Phenotypic marker (flow cytometry)	<del>complies</del> >80 %	<del>complies</del> 95%	<del>complies</del> 93%	somplies	and likely to be stability- indicating.		
Produ	Product-related Impurity	Viability	<del>Trypan blue</del> <del>(manual count)</del>	<del>≥ 70%</del>	<del>95</del>	<del>9</del> 4	<del>92</del>			
		Non-viable cells	Trypan blue (manual count)	≤ 0.3 × 10 <sup>6</sup> non- viable cells/mL	0.1 × 10 <sup>6</sup>	0.1 × 10 <sup>6</sup>	0.1 × 10 <sup>6</sup>	Total cell		
		Content	Manual cell count	≥ 10 <sup>6</sup> -cells/mL	<del>2.1 × 10<sup>6</sup></del>	<del>1.8 × 10<sup>6</sup></del>	<del>1.1 × 10<sup>6</sup></del>	content could be total cells		
		Content	Manual cell count	≥ 10 <sup>6</sup> viable cells/mL	2.0 × 10 <sup>6</sup>	1.7 × 10 <sup>6</sup>	1.0 × 10 <sup>6</sup>	cells.		
		Potency	Bioassay	≥ 4 U/10 <sup>6</sup> cells	12.1	9.8	6.8			
		Sterility	EP/USP	No growth	No growth	NT	No growth			
	• Note: this is not a recommendation, merely to make the point that you need to									
5	consuler the best way to present data. Consulting on Advanced Etologicals									



























