IVD Technologies

Analysis Report

ANTIBIOTICS – MICROBIAL ASSAYS

The activity (potency) of this sample was demonstrated by its inhibitory effect on microorganisms under suitable conditions.

Prepared for	Sample ID	Report No.	Antibiotic
Example Report	#####	#####.#.#	AAAA

PN	LN	Label	Bottle
AA####	####	AAAA	##

Storage	Received	Substance Type	Color
2 to 8 C	dry, bottle	dry, powder	white, off white

USP Chapter	Method
<81> ANTIBIOTICS – MICROBIAL ASSAYS	Cylinder-plate assay

	Specifications	Assay 1	Assay 2	Assay 2
USP Chapter	USP <81> ANTIBIOTICS-MICROBIAL ASSAYS	USP <81> ANTIBIOTICS-MICROBIAL ASSAYS	USP <81> ANTIBIOTICS-MICROBIAL ASSAYS	USP <81> ANTIBIOTICS-MICROBIAL ASSAYS
Method	cylinder-plate assay	cylinder-plate assay	cylinder-plate assay	
Stock standard solutions	separately prepared for each assay	separately prepared for each assay	separately prepared for each assay	separately prepared for each assay
Sample standard solutions	separately prepared for each assay	separately prepared for each assay	separately prepared for each assay	separately prepared for each assay
Reference standard	USP RS or Equivalent	RS lot, potency	RS lot, potency	RS lot, potency
Organism	ATCC #### *Example Organism*	ATCC #### *Example Organism*	ATCC #### *Example Organism*	ATCC #### *Example Organism*
Harvest stock suspension	sterile saline ts	sterile saline ts	sterile saline ts	sterile saline ts
Initial solvent, standard RS	water	water	water	water
Standard solutions storage	2 – 8 C	2 – 8 C	2 – 8 C	2 – 8 C
Final Concentration, Stock	1 mg/mL	1 mg/mL	1 mg/mL	1 mg/mL
Use within, standards solutions	7 days	7 days	7 days	7 days
Final Diluent, standards solutions	B.2	B.2	B.2	B.2
Standard concentration	1:1.25	1:1.25	1:1.25	1:1.25

increasing ratio				
Standard set	5	5	5	5
Replicates	3	3	3	3
Use within, sample dilution	same day as test	same day as test	same day as test	same day as test
Sample dilution	Equivalent to a median standard concentration	S3	S3	S3
Sample Dilution Factor	obtain concentration equal to the median standard concentration	100	100	100
Petri dish	Glass or plastic petri dish	Glass	Glass	Glass
Petri dish size	100 x 20 mm with lids	100 x 20 mm with lids	100 x 20 mm with lids	100 x 20 mm with lids
Cylinder Type	Stainless Steel or Ceramic	Stainless Steel	Stainless Steel	Stainless Steel
Cylinder Size	8mm $\pm$ 0.1 mm o.d.; 6mm $\pm$ 0.1 mm i.d.; 10 mm $\pm$ 0.1mm high	8mm $\pm$ 0.1 mm o.d.; 6mm $\pm$ 0.1 mm i.d.; 10 mm $\pm$ 0.1mm high	8mm $\pm$ 0.1 mm o.d.; 6mm $\pm$ 0.1 mm i.d.; 10 mm $\pm$ 0.1mm high	8mm $\pm$ 0.1 mm o.d.; 6mm $\pm$ 0.1 mm i.d.; 10 mm $\pm$ 0.1mm high
Harvest suspenion used per mL seed layer	25% transmittance or determined during method verificaiton	determined during method verificaiton	determined during method verificaiton	determined during method verificaiton
Medium, base layer	Medium #	Medium #	Medium #	Medium #
Medium, seed layer	Medium #	Medium #	Medium #	Medium #
Medium, base layer target mL	10 mL	10 mL	10 mL	10 mL
Medium, seed layer target mL	4 mL	4 mL	4 mL	4 mL
dispense per cylinder	no reccomendation	100 uL	100 uL	100 uL
Incubation temp	32 – 35 C	32 – 35 C	32 – 35 C	32 – 35 C
Incubation time	5 days	5 days	5 days	5 days
Relative Standard Deviation, %RSD	NMT 10%	##.##%	#.##%	#.##%
Coefficient of Determination, $\%R^2$	NLT 95%	##.##%	##.##%	##.##%
Potency value of sample, relatie to S3	80 – 125%	##.##%	##.##%	##.##%
ZOI size	11 – 19 mm, reccomended	#.## - #.## mm	#.## - #.## mm	#.## - #.## mm

Median concentration ZOI	14 – 16 mm, reccomended	#.## - #.## mm	#.## - #.## mm	#.## - #.## mm
Potency, on the anhydrous basis	NLT 950 µg/mg	###.# µg/mg	###.# µg/mg	###.# µg/mg
Sample relative Potency	not applicable	92.14 %	99.58%	

Assay 1 Data

	µg/mL		S3 Reference, 3				mm				Sample			mm	
Standard	Concentration	Plate Replicate	Zone 1	Zone 3	Zone 5	Mean	SD	%RSD	Zone 2	Zone 4	Zone 6	Mean	SD	%RSD	Corrected
1		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
2		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
4		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
5		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
						#.##									
Unknown		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
		2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				

Assay 2 Data

	µg/mL		S3 Reference, 3			mm				Sample			mm	
Standard	Concentration	Plate Replicate	Zone 1	Zone 3	Zone 5	Mean	SD	%RSD	Zone 2	Zone 4	Zone 6	Mean	SD	%RSD	Corrected
1		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
2		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
4		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
5		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
						#.##									
Unknown		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
		2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				

Assay 3 Data

	µg/mL		S3 Reference, 3			mm				Sample			mm	
Standard	Concentration	Plate Replicate	Zone 1	Zone 3	Zone 5	Mean	SD	%RSD	Zone 2	Zone 4	Zone 6	Mean	SD	%RSD	Corrected
1		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
2		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
4		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
5		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
	#.##	2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				
						#.##									
Unknown		1	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##	#.##
		2	#.##	#.##	#.##				#.##	#.##	#.##				
		3	#.##	#.##	#.##				#.##	#.##	#.##				

The performed analysis and report has been reviewed by our Quality Assurance Department and has met specifications for release.

Quality Control Verifier:
Date: ##/##/####
Signature: