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Omadacycline *In Vitro* Activity against Skin and Skin Structure, Respiratory, and Urinary Tract Pathogens Collected from the United States and Europe During the 2017 SENTRY Surveillance Program

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INTRODUCTION

- Omadacycline is an aminomethylcycline antibacterial in development for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP) that recently completed Phase 3 clinical trials (oral and intravenous formulations)
- A new drug application was submitted February 2, 2018, to the US Food and Drug Administration for oral and intravenous omadacycline to treat pneumonia and skin infections
- The omadacycline spectrum of activity includes a broad range of gram-positive (staphylococci, streptococci, and enterococci) and many gram-negative bacterial pathogens (*Haemophilus influenzae* and *Moraxella catarrhalis*) commonly associated with ABSSSI and CABP
- Omadacycline remains active against bacterial clinical isolates expressing common resistance mechanisms to tetracyclines, penicillins, fluoroquinolones, and macrolides including staphylococci, streptococci (*Streptococcus pneumoniae* and β-hemolytic streptococci [BHS]), enterococci, *H. influenzae*, and *M. catarrhalis*
- The *in vitro* susceptibility results for omadacycline and comparator agents against 14,000 gram-positive and -negative bacterial clinical isolates collected from patients in medical centers in the United States (US) and Europe participating in a global surveillance program during 2017 are presented

MATERIALS AND METHODS

- A total of 14,000 (non-duplicate) gram-positive and gram-negative bacterial isolates were collected from patients with multiple infection types in medical centers in the United States and Europe during 2017 and represented only 1 isolate per patient/infection episode
- Bacterial isolates were initially identified by the submitting laboratories and confirmed by JMI Laboratories using a matrix-assisted laser desorption/ionization-time of flight mass spectrometry (Bruker Daltonics, Bremen, Germany)
- Susceptibility testing was performed according to CLSI (M07, 2018) reference broth microdilution methodology and results were interpreted using CLSI (M100, 2018) and EUCAST (2018) breakpoint interpretive criteria
  - CLSI quality control (QC) reference strains were tested concurrently and included *Staphylococcus aureus* ATCC 29213; *Enterococcus faecalis* ATCC 29212; *Escherichia coli* ATCC 25922 and ATCC 35218; *Klebsiella pneumoniae* ATCC 700603; *S. pneumoniae* ATCC 49619; *H. influenzae* ATCC 49247; and *Pseudomonas aeruginosa* ATCC 27853

RESULTS

- Cumulative percent inhibition data for omadacycline against key gram-positive and gram-negative bacterial pathogens collected from patients in the United States and Europe during 2017 representing multiple infection types are presented in Table 1
- Omadacycline demonstrated potent activity against gram-positive clinical isolates that included *S. aureus* (n=2,684), MRSA (n=892), *Streptococcus agalactiae* (n=261), *S. pyogenes* (n=299), *S. pneumoniae* (n=968), viridans group streptococci (n=132), *E. faecalis* (n=427), and *E. faecium* (n=218) with $MIC_{50/90}$ values of ≤0.12/≤0.25 µg/mL (Table 1)
- Coagulase negative staphylococci were inhibited by low levels of omadacycline (90.1% inhibited at ≤0.5 µg/mL; Table 1)
- Omadacycline was equally active against *S. aureus* isolates from ABSSSI ($MIC_{50/90}$, 0.12/0.25 µg/mL; Table 2) and respiratory tract infections (RTI) ($MIC_{50/90}$ 0.12/0.25 µg/mL; Table 3) and retained a high level of activity against isolates displaying tetracycline-(doxycycline and tetracycline), fluoroquinolone- (levofloxacin), macrolide- (erythromycin), lincosamide- (clindamycin), and/or oxacillin-resistance
  - Corresponding resistance rates (CLSI) against *S. aureus* were 0.6%-1.0% for doxycycline, 5.0%-5.8% for tetracycline, 9.0%-16.3% for clindamycin, 25.6%-31.9% for levofloxacin, 37.4%-43.1% for erythromycin, and 32.0%-36.5% for oxacillin (Tables 2-3)
- Against MRSA isolates from ABSSSI, omadacycline (MIC_{50} 0.25 µg/mL) was 4-fold more active than vancomycin (MIC_{90}, 1 µg/mL) and 8-fold more active than linezolid (MIC_{90}, 2 µg/mL) (Table 2)

Table 1 Antimicrobial activity of omadacycline against key gram-positive and -negative bacterial pathogens collected from patients in medical centers in the United States and Europe during 2017

Organisms (no. tested)	No. of isolates at MIC (µg/mL; cumulative %)														MIC_{50}	MIC_{90}
	≤0.015	0.03	0.06	0.12	0.25	0.5	1	2	4	8	16	32	>			
Staphylococcus aureus (2,684)	0 0.0	3 0.1	194 7.3	2,125 86.5	**289**[a] **97.3**	39 98.7	31 99.9	1 99.9	1 100.0						0.12	0.25
MRSA (892)	0 0.0	1 0.1	82 9.3	650 82.2	**101** **93.5**	27 96.5	28 99.7	2 99.9	1 100.0						0.12	0.25
Coagulase-negative staphylococci (373)	2 0.5	9 2.9	94 28.2	105 56.3	40 67.0	**86** **90.1**	36 99.7	1 100.0							0.12	0.5
Enterococcus faecalis (427)	0 0.0	23 5.4	139 37.9	172 78.2	**81** **97.2**	10 99.5	0 99.5	2 100.0							0.12	0.25
Enterococcus faecium (218)	1 0.5	12 6.0	110 56.4	**75** **90.8**	12 96.3	7 99.5	1 100.0								0.06	0.12
Streptococcus pneumoniae (968)	7 0.7	119 13.0	633 78.4	**195** **98.6**	14 100.0										0.06	0.12
Viridans group streptococci (132)	2 1.5	27 22.0	64 70.5	**29** **92.4**	9 99.2	0 99.2	0 99.2	1 100.0							0.06	0.12
Streptococcus pyogenes (299)		0 0.0	206 68.9	**86** **97.7**	6 99.7	1 100.0									0.06	0.12
Streptococcus agalactiae (261)		0 0.0	62 23.8	163 86.2	**36** **100.0**										0.12	0.25
Enterobacteriaceae (5,993)			0 0.0	3 0.1	97 1.7	1,480 26.4	1,865 57.5	1,202 77.5	558 86.9	**305** **91.9**	277 96.6	153 99.1	53 100.0	1	8
Escherichia coli (2,581)			0 0.0	1 <0.1	81 3.2	1,325 54.5	763 84.1	**303** **95.8**	86 99.1	10 99.5	11 >99.9	1 100.0		0.5	2
ESBL-phenotype *Escherichia coli* (522)				0 0.0	11 2.1	159 32.6	187 68.4	112 89.8	**41** **97.7**	5 98.7	6 99.8	1 100.0		1	4
Klebsiella pneumoniae (1,269)				0 0.0	4 0.3	52 4.4	531 46.3	370 75.4	154 87.5	**101** **95.5**	39 98.6	13 99.6	5 100.0	2	8
ESBL-phenotype *Klebsiella pneumoniae* (414)					0 0.0	15 3.6	94 26.3	103 51.2	98 74.9	**66** **90.8**	22 96.1	11 98.8	5 100.0	2	8
Enterobacter cloacae species complex (488)				0 0.0	2 0.4	3 1.0	116 24.8	294 85.0	**30** **91.2**	22 95.7	17 99.2	4 100.0		2	4
Citrobacter spp. (253)[b]					0 0.0	60 23.7	116 69.6	**53** **90.5**	10 94.5	9 98.0	5 100.0			1	2
Acinetobacter baumannii (227)			0 0.0	8 3.5	36 19.4	19 27.8	10 32.2	38 48.9	63 76.7	**44** **96.0**	7 99.1	2 100.0		4	8
Stenotrophomonas maltophilia (129)						0 0.0	1 0.8	7 6.2	36 34.1	55 76.7	**20** **92.2**	9 99.2	1 100.0	4	8
Haemophilus influenzae (556)				1 0.2	13 2.5	298 56.1	**213** **94.4**	30 99.8	1 100.0					0.5	1
Moraxella catarrhalis (313)				236 75.4	**77** **100.0**									≤0.12	0.25

[a] MIC_{50} values are bold.
[b] Contains 1 *Citrobacter amalonaticus*, 5 *C. amalonaticus*/*farmeri*, 142 *C. freundii* species complex, 91 *C. koseri*, and 1 unspecified *Citrobacter* spp.

- Omadacycline was very active against BHS from ABSSSI, including *S. agalactiae* ($MIC_{50/90}$, 0.12/0.25 µg/mL; Table 2) and *S. pyogenes* ($MIC_{50/90}$, 0.06/0.12 µg/mL; Table 2)
  - These BHS were susceptible (CLSI) to all comparator agents tested except tetracycline (20.0%-80.9% susceptible), clindamycin (62.4%-95.7% susceptible), erythromycin (48.2%-87.0% susceptible), and levofloxacin (97.6%-100.0% susceptible; Table 2)
- Omadacycline was very active against enterococci, including *E. faecalis* ($MIC_{50/90}$, 0.12/0.25 µg/mL; 1.0% vancomycin-resistant) and *E. faecium* ($MIC_{50/90}$, 0.12/0.25 µg/mL; 29.3% vancomycin-resistant), from ABSSSI and its activity was unaffected against isolates displaying resistance to vancomycin (Table 2)
  - Corresponding resistance rates (CLSI) for comparators ranged from 36.6%-67.6% for minocycline, 68.3%-77.5% for tetracycline, 0%-85.4% for ampicillin, and 28.4%-90.2% for levofloxacin (Table 2)
- *Streptococcus pneumoniae* isolates from RTI (including penicillin-resistant strains) were highly susceptible to omadacycline ($MIC_{50/90}$, 0.06/0.12 µg/mL), whereas 22.3%, 34.6%, and 16.9% of *S. pneumoniae* were resistant to tetracycline, erythromycin, and clindamycin, respectively (Table 3)
- *Haemophilus influenzae* and *M. catarrhalis* isolates from RTI were inhibited by low levels of omadacycline with $MIC_{50/90}$ values of 0.5/1 µg/mL and ≤0.12/0.25 µg/mL, respectively (Table 3)
- Omadacycline was active against *Enterobacteriaceae* (including UTI isolates), inhibiting 86.9% of isolates at ≤4 µg/mL (Table 1); corresponding doxycycline, minocycline, and tetracycline MIC_{90} values against UTI isolates were ≥16 µg/mL (Figure 1)
- *Escherichia coli* isolates (including ESBL-phenotype and isolates from UTI) were susceptible to omadacycline ($MIC_{50/90}$, 0.5/2 µg/mL; Table 1); corresponding doxycycline, minocycline, and tetracycline MIC_{90} values against UTI isolates were ≥8 µg/mL (Figure 2)

Table 2 Antimicrobial activity of omadacycline and comparators against ABSSSI pathogens collected from medical centers in the United States and Europe during 2017

Organism (no. tested) antimicrobial agent	MIC_{50}	MIC_{90}	Range	CLSI[a]		EUCAST[a]	
				%S	%R	%S	%R
Staphylococcus accuracy (1,266)							
Omadacycline	**0.12**	**0.25**	**0.06 to 2**	—	—	—	—
Doxycycline	0.12	0.25	≤0.06 to >8	97.3	1.0	95.3	3.1
Tetracycline	≤0.5	≤0.5	≤0.5 to >8	93.1	5.8	92.3	7.3
Tigecycline	0.06	0.12	0.03 to 0.5	100.0[b]	—	100.0	0.0
Oxacillin	0.5	>2	≤0.06 to >2	68.0	32.0	68.0	32.0
Levofloxacin	0.25	>4	0.06 to >4	74.3	25.6	74.3	25.7
Erythromycin	0.25	>8	≤0.06 to >8	59.6	37.4	60.0	38.8
Clindamycin	0.06	0.12	≤0.03 to >2	91.0	9.0	90.8	9.0
Linezolid	1	2	0.25 to 4	100.0	0.0	100.0	0.0
Daptomycin	0.25	0.25	≤0.12 to 1	100.0		100.0	0.0
Vancomycin	1	1	0.25 to 2	100.0	0.0	100.0	0.0
MRSA (405)							
Omadacycline	**0.12**	**0.25**	**0.06 to 2**	—	—	—	—
Doxycycline	≤0.06	1	≤0.06 to >8	94.1	2.5	91.9	6.2
Tetracycline	≤0.5	>8	≤0.5 to >8	88.4	10.6	87.4	11.9
Tigecycline	0.06	0.12	0.03 to 0.5	100.0[b]	—	100.0	0.0
Levofloxacin	>4	>4	0.12 to >4	33.3	66.7	33.3	66.7
Erythromycin	>8	>8	0.12 to >8	24.0	74.3	24.0	74.3
Clindamycin	0.06	>2	≤0.03 to >2	76.5	23.5	76.5	23.5
Linezolid	1	2	0.25 to 4	100.0	0.0	100.0	0.0
Daptomycin	0.25	0.25	≤0.12 to 1	100.0	—	100.0	0.0
Vancomycin	1	1	0.5 to 2	100.0	0.0	100.0	0.0
Streptococcus agalactiae (85)							
Omadacycline	**0.12**	**0.25**	**0.06 to 0.25**	—	—	—	—
Tetracycline	>4	>4	0.12 to >4	20.0	78.8	20.0	80.0
Tigecycline	0.06	0.12	0.03 to 0.12	100.0[b]	—	100.0	0.0
Levofloxacin	1	1	0.5 to >4	97.6	2.4	97.6	2.4
Erythromycin	0.5	>16	0.03 to >16	48.2	49.4	48.2	49.4
Clindamycin	≤0.25	>2	≤0.25 to >2	62.4	34.1	65.9	34.1
Linezolid	1	2	0.5 to 2	100.0	—	100.0	0.0
Daptomycin	0.12	0.25	≤0.06 to 0.25	100.0	—	100.0	0.0
Vancomycin	0.5	0.5	0.25 to 0.5	100.0	—	100.0	0.0
Streptococcus pyogenes (162)							
Omadacycline	**0.06**	**0.12**	**0.06 to 0.25**	—	—	—	—
Tetracycline	0.5	>4	0.12 to >4	80.9	19.1	80.2	19.1
Tigecycline	0.06	0.06	0.03 to 0.12	100.0[b]	—	100.0	0.0
Levofloxacin	0.5	1	0.25 to 2	100.0	0.0	100.0	0.0
Erythromycin	0.03	1	≤0.015 to >16	87.0	12.3	87.0	12.3
Clindamycin	≤0.25	≤0.25	≤0.25 to >2	95.7	2.5	97.5	2.5
Linezolid	1	2	0.5 to 2	100.0	—	100.0	0.0
Daptomycin	≤0.06	≤0.06	≤0.06 to 0.12	100.0	—	100.0	0.0
Vancomycin	0.5	0.5	0.25 to 1	100.0	—	100.0	0.0
Enterococcus faecalis (102)							
Omadacycline	**0.12**	**0.25**	**0.03 to 0.5**	—	—	—	—
Minocycline	>8	>8	≤0.06 to >8	25.5	67.6	—	—
Tetracycline	>16	>16	≤0.12 to >16	21.6	77.5	—	—
Tigecycline	0.12	0.12	0.03 to 0.25	100.0[d]	—	100.0	0.0
Ampicillin	1	1	0.25 to 2	100.0	0.0	100.0	0.0
Levofloxacin	1	>4	0.25 to >4	71.6	28.4	71.6	28.4[c]
Linezolid	1	2	0.5 to 4	99.0	0.0	100.0	0.0
Vancomycin	1	2	0.5 to >16	99.0	1.0	99.0	1.0
E. faecium (41)							
Omadacycline	**0.12**	**0.25**	**0.03 to 1**	—	—	—	—
Minocycline	8	>8	≤0.06 to >8	41.5	36.6	—	—
Tetracycline	>16	>16	≤0.12 to >16	31.7	68.3	—	—
Tigecycline	0.06	0.12	0.03 to 0.5	—	—	95.1	0.0
Ampicillin	>16	>16	1 to >16	14.6	85.4	12.2	85.4
Levofloxacin	>4	>4	0.5 to >4	9.8	90.2	9.8	90.2[c]
Linezolid	2	2	0.5 to 2	100.0	0.0	100.0	0.0
Vancomycin	1	>16	0.5 to >16	70.7	29.3	70.7	29.3

[a] Criteria as published by CLSI 2018 and EUCAST 2018.
[b] Breakpoints from FDA Package Insert revised 06/2016.
[c] Uncomplicated UTI only.
[d] Breakpoints from FDA Package Insert revised 06/2016 applied to all *E. faecalis* but approved for vancomycin-susceptible isolates only.

CONCLUSIONS

- Omadacycline was highly active against *S. aureus* and MRSA that included isolates from ABSSSI and RTI ($MIC_{50/90}$ values, 0.12/0.25 µg/mL) as well as strains displaying resistance to tetracyclines, fluoroquinolones, macrolides, and lincosamides
- Streptococci, including viridans group, β-hemolytic streptococci (*S. agalactiae* and *S. pyogenes*) from ABSSSI and *S. pneumoniae* from RTI, were inhibited by low levels of omadacycline ($MIC_{50/90}$ values of ≤0.12/≤0.25 µg/mL)
  - Omadacycline remained highly active against tetracycline-resistant isolates of *S. pneumoniae* from RTI (22.3% tetracycline-resistant) and *S. agalactiae* (78.8%-80.0% tetracycline-resistant) and *S. pyogenes* (19.1% tetracycline-resistant) from ABSSSI

Table 3 Antimicrobial activity of omadacycline and comparators against RTI pathogens collected from medical centers in the United States and Europe during 2017

Organism (no. tested) antimicrobial agent	MIC_{50}	MIC_{90}	Range	CLSI[a]		EUCAST[a]	
				%S	%R	%S	%R
Staphylococcus aureus (540)							
Omadacycline	**0.12**	**0.25**	**0.03 to 4**	—	—	—	—
Doxycycline	0.12	0.5	≤0.06 to >8	97.8	0.6	95.4	2.6
Tetracycline	≤0.5	1	≤0.5 to >8	94.6	5.0	93.1	5.7
Tigecycline	0.06	0.12	≤0.015 to 0.5	100.0[b]	—	100.0	0.0
Oxacillin	0.5	>2	≤0.06 to >2	63.5	36.5	63.5	36.5
Levofloxacin	0.25	>4	0.06 to >4	68.1	31.9	68.1	31.9
Erythromycin	0.25	>8	≤0.06 to >8	51.7	43.1	52.0	45.7
Clindamycin	0.06	>2	≤0.03 to >2	83.1	16.3	83.0	16.9
Linezolid	1	2	0.25 to 4	100.0	0.0	100.0	0.0
Daptomycin	0.25	0.25	≤0.12 to 2	99.8	—	99.8	0.2
Vancomycin	1	1	0.5 to 2	100.0	0.0	100.0	0.0
MRSA (197)							
Omadacycline	**0.12**	**0.5**	**0.03 to 4**	—	—	—	—
Doxycycline	0.12	2	≤0.06 to >8	94.9	0.5	89.8	5.6
Tetracycline	≤0.5	>8	≤0.5 to >8	89.3	10.7	86.8	11.2
Tigecycline	0.06	0.25	≤0.015 to 0.5	100.0[b]	—	100.0	0.0
Levofloxacin	>4	>4	0.06 to >4	25.9	74.1	25.9	74.1
Erythromycin	>8	>8	≤0.06 to >8	19.3	76.1	19.3	77.7
Clindamycin	0.06	>2	≤0.03 to >2	59.4	40.1	59.4	40.6
Linezolid	1	2	0.25 to 2	100.0	0.0	100.0	0.0
Daptomycin	0.25	0.25	≤0.12 to 2	99.5	—	99.5	0.5
Vancomycin	1	1	0.5 to 2	100.0	0.0	100.0	0.0
Streptococcus pneumoniae (874)							
Omadacycline	**0.06**	**0.12**	**≤0.015 to 0.25**	—	—	—	—
Tetracycline	0.5	>4	0.12 to >4	77.5	22.3	77.5	22.3
Tigecycline	0.06	0.06	0.015 to 0.12	94.3[b]	—	—	—
Levofloxacin	1	2	0.25 to >4	98.3	1.5	98.3	1.7
Penicillin	0.03	2	≤0.008 to >4	66.0 66.0.	12.0[c] 34.0[e]	66.0 66.0	34.0[e] 4.3[f]
Ceftriaxone	0.03	1	≤0.015 to >2	86.4	3.2[g]	86.4	0.3
Erythromycin	0.03	>16	≤0.015 to >16	65.0	34.6	65.0	34.6
Clindamycin	≤0.25	>2	≤0.25 to >2	82.7	16.9	83.1	16.9
Linezolid	1	2	0.25 to 2	100.0	—	100.0	0.0
Haemophilus influenzae (605)							
Omadacycline	**0.5**	**1**	**≤0.12 to 4**	—	—	—	—
Tetracycline	0.5	1	0.12 to >8	98.3	1.7	98.3	1.7
Tigecycline	0.25	0.5	0.03 to 1	88.5[h]	—	—	—
Amoxicillin-clavulanic acid	1	2	≤0.06 to 4	100.0	0.0	93.3	6.7
Ampicillin	1	>8	≤0.12 to >8	65.7	30.0	65.7	34.3
Azithromycin	1	2	≤0.12 to >8	98.5	—	98.5[h]	—
Ceftriaxone	0.004	0.015	≤0.002 to 0.25	100.0	—	99.8	0.2
Levofloxacin	0.015	0.03	0.008 to >2	99.4	—	98.7	1.3
Trimethoprim-sulfamethoxazole	0.12	>4	≤0.06 to >4	63.1	32.8	63.1	34.6
Moraxella catarrhalis (307)							
Omadacycline	**≤0.12**	**0.25**	**≤0.12 to 0.25**	—	—	—	—
Tetracycline	0.25	0.5	≤0.06 to >8	99.7	0.3	99.7	0.3
Tigecycline	0.06	0.06	0.03 to 0.12	—	—	—	—
Ceftriaxone	0.25	1	0.004 to 2	100.0	—	98.7	0.0
Amoxicillin-clavulanic acid	≤0.25	≤0.25	≤0.25 to 0.5	100.0	0.0	100.0	0.0
Levofloxacin	0.06	0.06	≤0.015 to 2	100.0	—	99.4	0.6
Azithromycin	0.015	0.03	≤0.004 to 0.03	100.0	—	100.0	0.0
Trimethoprim-sulfamethoxazole	0.12	0.25	≤0.06 to 2	97.1	0.0	97.1	1.0

[a] Criteria as published by CLSI 2018 and EUCAST 2018.
[b] Breakpoints from FDA Package Insert revised 06/2016.
[c] Using oral breakpoints
[d] Using meningitis breakpoints
[e] Using parenteral, meningitis breakpoints
[f] Using non-meningitis breakpoints
[g] Percentage of wild type based on ECV: EUCAST version 8.0 (2018).

- Omadacycline exhibited potent activity against vancomycin-susceptible and -resistant isolates of *E. faecalis* ($MIC_{50/90}$ 0.12/0.25 µg/mL) and *E. faecium* ($MIC_{50/90}$ 0.06/0.12 µg/mL), whereas minocycline and tetracycline demonstrated little utility against *E. faecalis* and *E. faecium* isolates (MIC_{90} values >8 µg/mL and >16 µg/mL, respectively)
- *Haemophilus influenzae* and *M. catarrhalis* isolates from RTI were susceptible to omadacycline with $MIC_{50/90}$ values of 0.5/1 µg/mL and ≤0.12/0.25 µg/mL, respectively
- *Escherichia coli* isolates (including ESBL phenotype and UTI isolates) were susceptible to omadacycline (MIC_{90}, 2 µg/mL), whereas doxycycline, minocycline, and tetracycline were less active (MIC_{90}, ≥8 µg/mL)
- Results of this surveillance study support the continued development of omadacycline, especially in infections where these resistant pathogens are likely to be encountered, including ABSSSI, CABP, and UTI

Figure 1 Cumulative % inhibition of omadacycline, minocycline, doxycycline, and tetracycline against 1,276 *Enterobacteriaceae* isolates from UTI

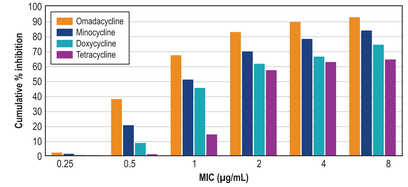
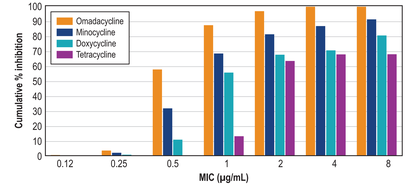


Figure 2 Cumulative % inhibition of omadacycline, minocycline, doxycycline, and tetracycline against 829 *Escherichia coli* isolates from UTI



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