

Target Product Profile – UTI – Therapeutic Product

Variable	Minimal Requirement	Ideal Requirement
Product Indication	Oral treatment of acute UTI confined to the bladder	Oral treatment of acute UTI confined to the bladder, or oral follow-on of iv treatment of pyelonephritis and complicated UTI
Organisms Covered	<i>E. coli</i> and <i>K. pneumoniae</i> including MDR bacteria. Low frequency of resistance and no cross-resistance to other antibiotics	<i>E. coli</i> , <i>K. pneumoniae</i> , other Enterobacterales and <i>P. aeruginosa</i> including MDR bacteria. Low frequency of resistance and no cross-resistance to other antibiotics
Patient Population	Acute UTI confined to the bladder in adult women or men; no signs or symptoms of infection beyond the bladder	Acute UTI confined to the bladder in adult women or men with and without signs or symptoms of infection beyond the bladder
Treatment Duration	Up to 5 days	Up to 5 days for acute UTI confined to the bladder and up to 10 days for pyelonephritis and complicated UTI
Delivery Mode	Oral	Oral or oral and IV
Dosage Form	Tablets/capsules/sachets	Tablets/capsules/sachets or tablets/capsules/sachets and vials
Regimen	Up to TID/day	Up to BID/day
Efficacy	Non-inferior to SOC (nitrofurantoin, trimethoprim-sulfamethoxazole, pivmecillinam and fosfomycin) and quinolones	Non-inferior to SOC (trimethoprim-sulfamethoxazole, quinolones, BL-BLI therapies and cefiderocol)
Risk/Side Effects	Comparable to current therapies with β -lactams, no toxicity signals in preclinical reproduction toxicity studies; 3-5X therapeutic index	Comparable to current therapies with β -lactams, no toxicity signals in preclinical reproduction toxicity studies; >5X therapeutic index
Stability	Heat stable, 3-year shelf life	Heat stable, 3-year shelf life
Cost	Equivalent to current treatment regimens	Equivalent to current treatment regimens
Population Claims	Contraindicated in pregnant women, catheterized patients and patients with comorbidities	Safe in pregnant women, catheterized patients and patients with comorbidities
Overall Value Proposition: Safe, effective and affordable oral therapy against hard-to-treat, antibiotic-resistant UTI infections in HIC and LMICs		