

Spaulding Clinical Research Drug Interaction Experience

Study Type	Dosage Form	Therapeutic Area/Drug Class	N
DDI	Oral Tablet	Anti-infective	24
DDI	Oral Tablet	Anti-infective	20
DDI	Oral Tablet	Renal	32
DDI	Oral Tablet	Renal	40
DDI	Subcutaneous Injection	Anti-viral	5
DDI	IV	Antibiotic Lypoglycopeptide	16
DDI	Oral Capsules	Anti-viral	24
DDI	Oral Tablet	GU	26
DDI	Oral Tablet	ED	72
DDI	Oral Tablet	ED	24
DDI	Oral	Hepatitis C	18
DDI	IV	ABSSSI's	24
DDI	Oral Capsules	Hepatitis C	120
DDI	Oral	Hepatitis C	94
DDI	IV	ABSSSI's	12
DDI	Oral	Hepatitis C	30
DDI	Oral	Acute tx of migraines	30
DDI	Oral	NASH	108
DDI	Oral	rGERD	15

Spaulding Clinical Research

Drug Interaction Studies conducted with the following drugs:

Alcohol	Mexilitine
Aspirin	Midazolam
Atorvastatin	Moxifloxacin
Bidil	Nitroglycerine
Caffeine	Norethindrone Acetate and Ethinyl Estradiol
Cyclosporine	Omeprazole
Dextromethorphan	Quinidine
Digoxin	Ranolazine
Diltiazem	Repaglinide
Dofetilide	Rifampin
Fluconazole	Rilpivirine
Gemfibrozil	Ritonavir
Granisetron	Rosuvastatin
Grapefruit Juice	Sildenafil
Isavuconazole	Sofosbuvir
Itraconazole	Telaprevir
Ketoconazole	Tolbutamide
Ledipasvir	Verapamil
Lidocaine	Voriconazole
Metoclopramide	Warfarin

Spaulding Clinical Research FIH/SAD/MAD Study Experience

Study Type/Design	Dosage Form	Therapeutic Area/Drug Class	NCE Yes/No	N
TQT/SAD	Topical/Derm	Anti-Infective	Y	81
TQT/SAD	IV	Anti-Infective - Aminoglycoside	Y	64
TQT/SAD	Oral Tablet	Anti-Infective	Y	48
TQT/SAD	Oral Tablet	Anti-Infective/MRSA	Y	32
TQT/SAD	Topical/Derm	Dermatology	Y	56
TQT/MAD	Oral Tablet	Anti-Infective/MRSA	Y	48
TQT/FIH	Inhaled	Antiviral/Hepatitis C	Y	179
SAD/MAD	Ophthalmic	Anti-Infective	Y	48
SAD/MAD	Oral Capsules	Moderate to Severe Pain Relief	Y	24
SAD/MAD	IV	Analgesic	Y	12
SAD/MAD	Oral Tablet	Liver Impairment	Y	24
SAD/MAD	Oral Capsules	Hyperlipidemia	Y	118
SAD	Topical/Derm	Dermatology	Y	18
SAD	Oral Tablet	Lipid Lowering Agent	Y	48
SAD	IV	Anti-Infective	Y	56
SAD	SubQ/IV	Neutropenia Cancer	Y	48
SAD	IV	Antibiotic/ABSSSI's	Y	26
MAD	IV	Antibiotic/ABSSSI's	N	14
MAD	Oral	GI - Colonoscopy prep	Y	66
FIH/SAD/MAD	Oral	Pulmonary Atrial Hypertension	Y	104
FIH	IV	Analgesic	Y	24
FIH	Oral Tablet	Pain Relief	Y	24
FIH	Oral (liquid)	Galectin-3 Inhibitor	Y	36
FIH	IV	Anesthesiology	Y	8
FIH	Oral	Neurologic Factor	Y	48
SAD/MAD	Oral	Cognitive Impairment	Y	62
SAD	IV	MDR	Y	86
SAD/MAD	Oral	Fibromyalgia, neuropathy	N	16
SAD	IV	Pancreatitis	N	8
MAD	IV	Pancreatitis	N	24
MAD	IV	Antibiotic	N	40
SAD	IV	HSPC/Myelopreservation	N	78
SAD	Oral	Mannose Phosphate Isomerase (MPI) deficiency, a type of the Congenital Disorder of Glycosylation (CDG)	N	16
MAD	Intra-Anal	Fecal incontinence (FI)	N	40

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TQT/Concentration-QT Experience

Study Type/Design	Dosage Form	Therapeutic Area/Drug Class	N	# of ECG's Collected
TQT	IV	Antibiotic	64	6,984
TQT	SubQ Injection	Antiemetic	56	10,176
CEM QT	Topical	Anti-Infective	81	4,920
TQT	IV	CNS/Tardive Dyskinesia	128	9,600
TQT	Topical	Chemo/antiemetic	240	17,241
TQT	Oral	Antioxidant/CKD	180	12,441
TQT	IV	Antibiotic	150	8,469
TQT	Oral	Antibiotic	48	5,552
TQT	Inhaled	Antiviral	179	15,253
CEM QT	SubQ Injection	Biologic	14	973
TQT	Oral	Analgesic	171	53,254
CEM QT	Oral/IV	Antiarrhythmic	22	6,270
TQT	Oral	First in class/hepatic	192	29,085
TQT	Oral	Antiemetic	48	6,912
TQT	Oral	Antiviral	48	7,515
TQT	Oral	Cardiovascular	162	18,954
TQT	Oral	Cardiovascular	88	17,892
TQT	Oral	Anti-arrhythmic, Anti-angina	22	5,211
TQT	Oral	Antibiotic	48	5,535
TQT	Oral	Antiviral and antiarrhythmic	60	6,151
TQT	Oral	Antiretroviral (ARV) therapy	48	10,471
TQT	Oral	Antiviral	48	7,390
TQT	Topical	Dermatology	56	5,760
TQT	IV	Antibiotic	64	7,905
CEM QT	Oral	Anthelmintic	60	2,700
TQT	IV	Antibiotic	60	4,752
TQT	Oral	Analgesic	72	11,676
TQT	Oral	Tyrosine Kinase Dysregulator	52	7,752