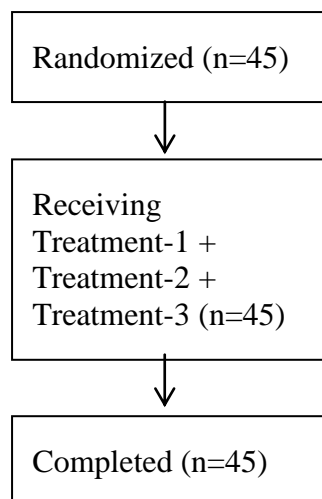


SUBJECT DISPOSITION



Treatment-1= Sildenafil 100 mg Oral Film administered without water under fed conditions;

Treatment 2= Sildenafil 100 mg Oral Film administered without water under fasting conditions;

Treatment-3= Viagra[®] 100 mg film-coated tablet administered with water under fasting conditions.

BASELINE CHARACTERISTICS

Table 1 Demographic characteristics of the safety and pharmacokinetic sets (n=45) at baseline

		Treatment-1 (N=45)	Treatment-2 (N=45)	Treatment-3 (N=45)	Overall (N=45)
Age (years)	N	45	45	45	45
	Mean (SD)	35 (8)	35 (8)	35 (8)	35 (8)
	Median	36.0	36.0	36.0	36.0
	Min, Max	18, 45	18, 45	18, 45	18, 45
Gender [n(%)]	MALE	45 (100.0)	45 (100.0)	45 (100.0)	45 (100.0)
Ethnicity [n(%)]	HISPANIC OR LATINO	19 (42.2)	19 (42.2)	19 (42.2)	19 (42.2)
	NOT HISPANIC OR LATINO	26 (57.8)	26 (57.8)	26 (57.8)	26 (57.8)
Race [n(%)]	WHITE	42 (93.3)	42 (93.3)	42 (93.3)	42 (93.3)
	ASIAN	1 (2.2)	1 (2.2)	1 (2.2)	1 (2.2)
	OTHER	1 (2.2)	1 (2.2)	1 (2.2)	1 (2.2)
	BLACK OR AFRICAN	1 (2.2)	1 (2.2)	1 (2.2)	1 (2.2)
	AMERICAN				
Weight (kg)	N	45	45	45	45
	Mean (SD)	78.0 (9.5)	78.0 (9.5)	78.0 (9.5)	78.0 (9.5)
	Median	78.50	78.50	78.50	78.50
	Min, Max	56.8, 94.7	56.8, 94.7	56.8, 94.7	56.8, 94.7
Height (cm)	N	45	45	45	45
	Mean (SD)	173.6 (6.6)	173.6 (6.6)	173.6 (6.6)	173.6 (6.6)
	Median	172.30	172.30	172.30	172.30
	Min, Max	160.2, 192.0	160.2, 192.0	160.2, 192.0	160.2, 192.0
Body Mass Index (kg/m ²)	N	45	45	45	45
	Mean (SD)	25.9 (2.9)	25.9 (2.9)	25.9 (2.9)	25.9 (2.9)
	Median	26.70	26.70	26.70	26.70
	Min, Max	18.8, 29.7	18.8, 29.7	18.8, 29.7	18.8, 29.7

OUTCOME MEASURES

Table 2 Mean plasma sildenafil pharmacokinetic parameters – Comparative Bioavailability (Treatment-2 vs Treatment-3) Under Fasting Conditions

PARAMETER	Treatment-2 (n=45)		Treatment-3 (n=45)			
	MEAN	C.V. (%)	MEAN	C.V. (%)	Ratio (%)	90% CI
C _{max} (ng/mL)	503.47	(37.7)	466.29	(42.1)	108.55	99.19 - 118.79
AUC _{0-T} (ng·h/mL)	1876.41	(36.1)	1585.95	(34.0)	116.68	111.09 - 122.55
AUC _{0-∞} (ng·h/mL)	1902.41	(36.3)	1609.85	(34.2)	116.52	110.97 - 122.34
T _{max} (hours)	1.33	(0.33-5.00)	1.00	(0.33-4.00)		

Notes: Values are mean, except for T_{max}, median (range). Ratio, test/reference ratio of geometric means.

Abbreviations: AUC, area under the curve; CI, confidence interval; C_{max}, maximum serum concentration; T_{max}, time to maximum serum concentration.

Table 3 Mean plasma sildenafil pharmacokinetic parameters – Food Effect Assessment (Treatment-1 vs Treatment-2)

PARAMETER	Treatment-1 (Fed) (n=45)		Treatment-2 (Fast) (n=45)			
	MEAN	C.V. (%)	MEAN	C.V. (%)	Ratio (%)	90% CI
C _{max} (ng/mL)	277.73	(46.4)	503.47	(37.7)	54.68	49.96 - 59.84
AUC _{0-T} (ng·h/mL)	1691.77	(33.5)	1876.41	(36.1)	91.07	86.70 - 95.65
AUC _{0-∞} (ng·h/mL)	1725.79	(33.8)	1902.41	(36.3)	91.57	87.22 - 96.15
T _{max} (hours)	3.00	(0.50-8.00)	1.33	(0.33-5.00)		

ADVERSE EVENTS

Table 4 Treatment-Emergent Adverse Events by System Organ Class Experienced by at Least Two Subjects per Treatment Group (≥2% of Subjects)

System Organ Class MedDRA Preferred Term	Treatment-1 (N=45) n (%)	Treatment-2 (N=45) n (%)	Treatment-3 (N=45) n (%)
Subjects with at least one TEAE	10 (22)	14 (31)	7 (16)
Nervous system disorders	7 (16)	8 (18)	2 (4)
Dizziness	3 (7)	3 (7)	1 (2)
Headache	4 (9)	2 (4)	0

System Organ Class MedDRA Preferred Term	Treatment-1 (N=45) n (%)	Treatment-2 (N=45) n (%)	Treatment-3 (N=45) n (%)
Somnolence	1 (2)	2 (4)	1 (2)
Paraesthesia	0	2 (4)	0
General disorders and administration site conditions	2 (4)	4 (9)	3 (7)
Fatigue	1 (2)	2 (4)	0
Reproductive system and breast disorders	2 (4)	2 (4)	2 (4)
Erectile Dysfunction	2 (4)	2 (4)	2 (4)
Eye disorders	1 (2)	2 (4)	1 (2)
Visual Impairment	0	2 (4)	0
Gastrointestinal disorders	2 (4)	0	1 (2)
Musculoskeletal and connective tissue disorders	0	1 (2)	2 (4)

Note: Each TEAE was counted only once for each subject within each SOC and MedDRA PT