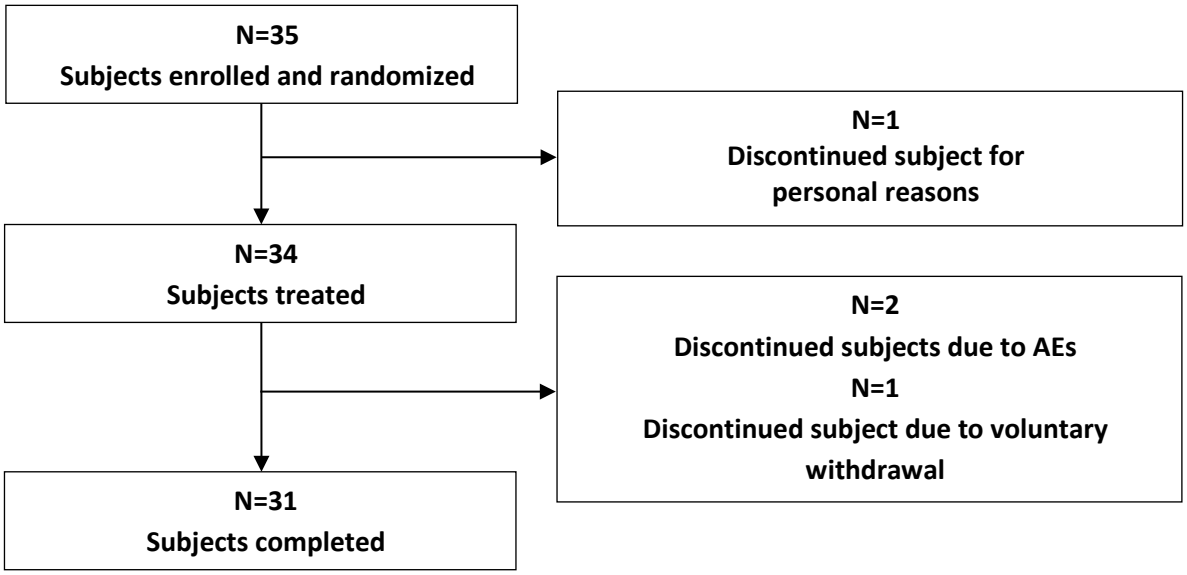
Participant flow



All 34 treated subjects were included in the safety set as follows:

- 33 received at least one dose of Viagra® 100 mg film-coated tablet (R) under fed conditions
- 32 received at least one dose of Sildenafil IBSA 100 mg oral film without water (T1) under fed conditions
- 31 received at least one dose of Sildenafil IBSA 100 mg oral film with water (T2) under fed conditions

Baseline characteristics

Demographic data	Enrolled set N=35
Age (years)	
Mean ± SD	36.1±10.5
Median (range)	37.0 (18-55)
Body weight (kg)	
Mean ± SD	78.95±12.08
Range	78.50 (58.3-104.6)
Height (cm)	
Mean ± SD	176.0±7.0
Median (range)	175.0 (165-196)
Body Mass Index (kg/m^2)	
Mean ± SD	25.43±3.19
Median (range)	25.40 (18.6-30.0)
Race	
White – n (%)	34 (97.1)
Black – n (%)	1 (2.9)

Outcome measures

Primary outcome

Results of the statistical analysis of plasma sildenafil pharmacokinetic parameters for T1 *vs.* R, T2 *vs.* R and T1 *vs.* T2 administered under fed conditions are presented in the table below:

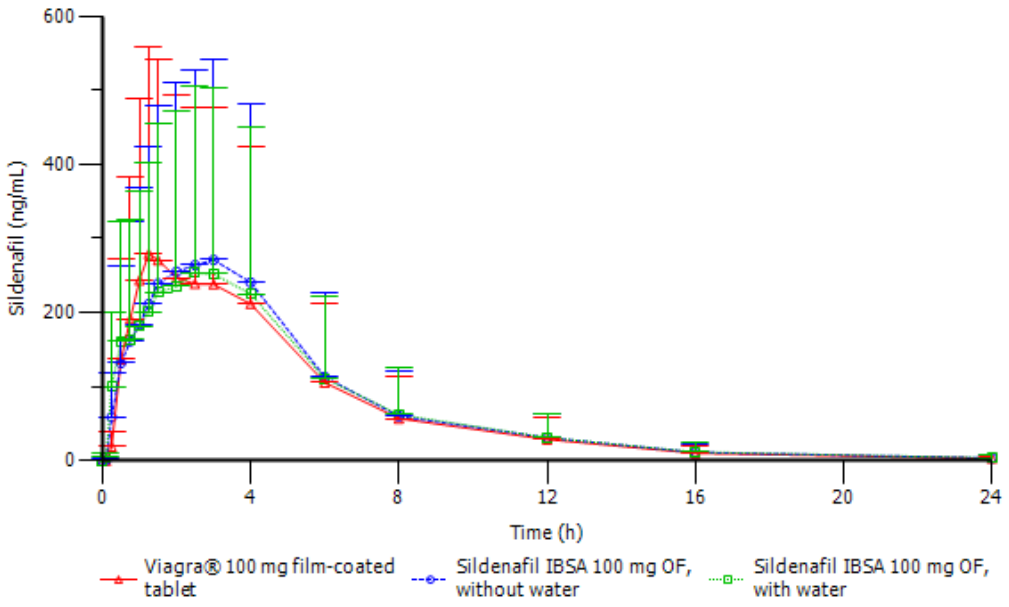
Parameter	T1 *vs.* R N=32		T2 *vs.* R N=30		T1 *vs.*T2 N=30	
	PE%	**90% CI**	**PE%**	**90% CI**	**PE%**	**90% CI**
C_{max}	86.86%	77.50 – 97.35	83.37%	73.75 – 94.24	105.28%	96.75 – 114.57
AUC_{0-t}	107.67%	100.45 – 115.41	108.24%	101.90 – 114.96	101.67%	95.50 – 108.25
$AUC_{0-\infty}$	107.62%	100.22 – 115.56	108.39%	102.01 – 115.16	101.66%	95.25 – 108.51

T1: single dose of Sildenafil IBSA 100 mg oral film without water; T2: single dose of Sildenafil IBSA 100 mg oral film with water; R: single dose of Viagra® 100 mg film-coated tablet. PE: Point Estimate, calculated as ratio of geometric means; CI: confidence interval

Secondary outcome

Sildenafil pharmacokinetic profile

Mean sildenafil plasma concentration-time profiles for T1, T2 and R are shown in the figure below:



Descriptive statistics of sildenafil plasma pharmacokinetic parameters are presented in the table below:

Pharmacokinetic parameters	**T1 N=32**	**T2 N=30**	**R N=32**
C_{max} (ng/mL)	317.48±105.39	295.54±95.13	393.40±226.03
AUC_{0-t} (ng/mL×h)	1708.91±591.32	1671.91±587.58	1624.08±733.39
$AUC_{0-\infty}$ (ng/mL×h)	1752.54±596.06*	1698.36±595.75	1646.67±737.11
t_{max} (h)	3.00 (0.50–4.00)	2.50 (0.25–4.00)	1.50 (0.50–6.00)
$t_{½}$ (h)	4.07±0.65*	4.04±0.99	3.87±0.90
λ_z (1/h)	0.17±0.03*	0.18±0.04	0.19±0.04

*T1: single dose of Sildenafil IBSA 100 mg oral film without water; T2: single dose of Sildenafil IBSA 100 mg oral film with water; R: single dose of Viagra® 100 mg film-coated tablet. Values are arithmetic means ± SD, except for t_{max}: median (min-max); *: N=31*

Sildenafil relative bioavailability (F_{rel}), calculated as ratio of AUC_{0-t}, is summarized below:

Pharmacokinetic set	**T1/R N=32**	**T2/R N=30**	**T1/T2 N=30**
$F_{rel\ (\%)}$	110.59±25.86	110.28±21.06	103.21±21.66

T1: single dose of Sildenafil IBSA 100 mg oral film without water; T2: single dose of Sildenafil IBSA 100 mg oral film with water; R: single dose of Viagra® 100 mg film-coated tablet. Values are arithmetic means ± SD

Adverse events

Number of subjects reporting and number of reported treatment-emergent adverse events (TEAEs) by treatment, system organ class (SOC) and preferred term (PT) after single dose of Sildenafil IBSA 100 mg oral film without water (T1), Sildenafil IBSA 100 mg oral film with water (T2) and Viagra® 100 mg film-coated tablet (R). Safety set

MedDRA description SOC and PT term	T1 N=32		T2 N=31		R N=33	
	AEs n	Subjects n (%)	AEs n	Subjects n (%)	AEs n	Subjects n (%)
Total number of AEs and of subjects with at least one AE	**5**	**4 (12.5)**	**8**	**6 (19.4)**	**5**	**5 (15.2)**
Nervous system disorders	**2**	**2 (6.3)**	**5**	**4 (12.9)**	**2**	**2 (6.1)**
Headache	2	2 (6.3)	2	2 (6.5)	1	1 (3.0)
Dizziness	0	0 (0.0)	1	1 (3.2)	0	0 (0.0)
Presyncope	0	0 (0.0)	1	1 (3.2)	0	0 (0.0)
Sinus headache	0	0 (0.0)	0	0 (0.0)	1	1 (3.0)
Syncope	0	0 (0.0)	1	1 (3.2)	0	0 (0.0)
Gastrointestinal disorders	**3**	**3 (9.4)**	**2**	**2 (6.5)**	**2**	**2 (6.1)**
Dyspepsia	2	2 (6.3)	1	1 (3.2)	2	2 (6.1)
Hemorrhoids	0	0 (0.0)	1	1 (3.2)	0	0 (0.0)
Nausea	1	1 (3.1)	0	0 (0.0)	0	0 (0.0)
General disorders and administration site conditions	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (3.0)**
Swelling	0	0 (0.0)	0	0 (0.0)	1	1 (3.0)
Investigations	**0**	**0 (0.0)**	**1**	**1 (3.2)**	**0**	**0 (0.0)**
Alanine aminotransferase increase	0	0 (0.0)	1	1 (3.2)	0	0 (0.0)

Number of TEAEs and number of subjects with TEAEs after single dose of Sildenafil IBSA 100 mg oral film without water (T1), Sildenafil IBSA 100 mg oral film with water (T2) and Viagra® 100 mg film-coated tablet (R). Safety set

Category	T1 N=32		T2 N=31		R N=33		Overall N=34	
	N AEs	n (%) subjects	N AEs	n (%) subjects	N AEs	n (%) subjects	N AEs	n (%) subjects
All TEAEs	5	4 (12.5)	8	6 (19.4)	5	5 (15.2)	18	10 (29.4)
Related	3	3 (9.4)	6	5 (16.1)	2	2 (6.1)	11	8 (23.5)
Not related	2	2 (6.3)	2	2 (6.5)	3	3 (9.1)	7	6 (17.6)
Leading to discontinuation	1	1 (3.1)	2	1 (3.2)	0	0 (0.0)	3	2 (5.9)
SAEs	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)