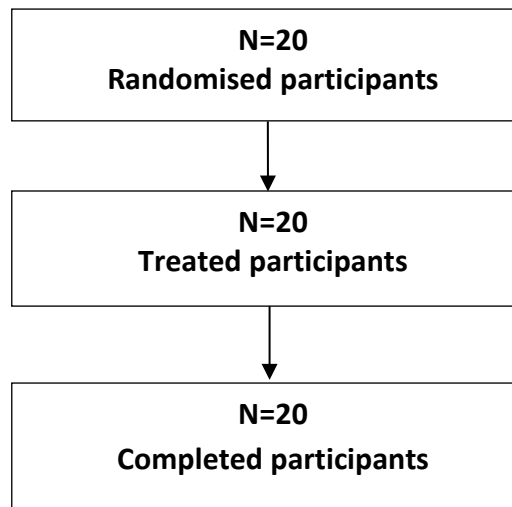


Participant flow



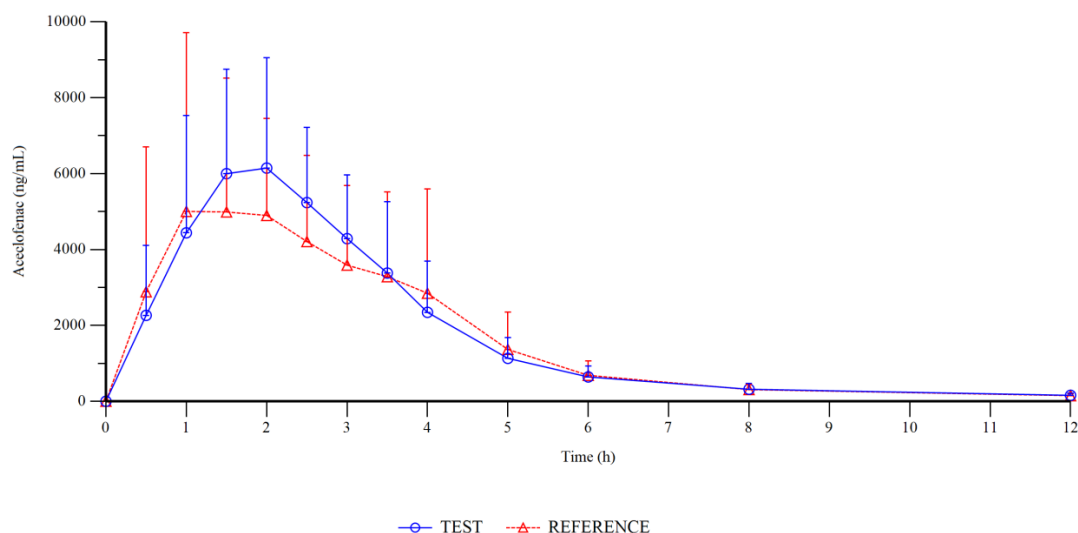
Baseline characteristics

Demographic data	Randomised, safety and pharmacokinetic sets N=20
Sex	
Male – n (%)	10 (50.0)
Female – n (%)	10 (50.0)
Age (years)	
Mean ± standard deviation	41.9 ± 12.2
Median (range)	48.0 (20 - 55)
Body weight (kg)	
Mean ± standard deviation	71.24 ± 7.44
Median (range)	70.55 (59.0 - 86.5)
Height (cm)	
Mean ± standard deviation	169.9 ± 10.9
Median (range)	173.0 (152 - 191)
Body Mass Index (kg/m²)	
Mean ± standard deviation	24.74 ± 2.20
Median (range)	24.25 (21.8 - 29.1)
<i>n (%): number and percentage of participants are shown for qualitative measures; mean ± standard deviation are shown for quantitative measures</i>	

Outcome measures

Pharmacokinetics results

Mean (+ standard deviation) aceclofenac plasma concentration-time profiles after single dose of test and reference are shown in linear scale below (N=20):



Test: Aceclofenac 100 mg film-coated tablets; Reference: Gladio® 100 mg film-coated tablets

Descriptive statistics of aceclofenac plasma pharmacokinetic parameters after single dose of test and reference are presented in the table below (N=20):

Pharmacokinetic parameters	Test	Reference
C_{max} (ng/mL)	8044.738 ± 1880.306	9026.796 ± 2120.656
AUC_{0-t} (ng/mL×h)	20985.324 ± 4396.188	20170.141 ± 3320.231
$AUC_{0-\infty}$ (ng/mL×h)	21380.283 ± 4556.343	20544.757 ± 3456.490
t_{max} (h)	1.75 (1 – 3.5)	1.75 (0.5 – 4)
$t_{1/2}$ (h)	1.751 ± 0.296	1.786 ± 0.641
λ_z (1/h)	0.410 ± 0.086	0.433 ± 0.143
F_{rel} (%) (AUC_{0-t} T/R ratio)	103.661 ± 8.481	

Test: Aceclofenac 100 mg film-coated tablets; Reference: Gladio® 100 mg film-coated tablets. Values are arithmetic means ± standard deviation, except for t_{max} : median (min-max).

Results of the statistical comparison of aceclofenac pharmacokinetic parameters between test and reference are presented in the table below (N=20):

Comparison	Parameter	PE (%)	90% CIs (%)
Test vs. reference	C_{max}	89.46%	80.68 – 99.20
	AUC_{0-t}	103.33%	99.96 – 106.80
	$AUC_{0-\infty}$	103.34%	99.92 – 106.87

Test: Aceclofenac 100 mg film-coated tablets; Reference: Gladio® 100 mg film-coated tablets. PE: Point Estimate, calculated as ratio of geometric means; CI: Confidence Interval

Adverse events

The number of treatment-emergent adverse events (TEAEs) and the number of participants with TEAEs are shown in the table below:

Category	Test N=20	
	n AEs	n (%) participants
All TEAEs	1	1 (5.0)
Related	0	0 (0.0)
Not related	1	1 (5.0)
Leading to discontinuation	0	0 (0.0)
SAEs	0	0 (0.0)

Test: Aceclofenac 100 mg film-coated tablets

Number of treatment-emergent adverse events (TEAEs) and number and percentage of participants with TEAEs by treatment, system organ class (SOC) and preferred term (PT). Safety set

SOC	Test N=20	
	n Adverse Events	n (%) participants
PT		
All TEAEs – all SOCs	1	1 (5.0)
Nervous system disorders	1	1 (5.0)
Dizziness	1	1 (5.0)

Test: Aceclofenac 100 mg film-coated tablets

No TEAE occurred after Reference administration.