

Subject inclusion criteria:

- men and women aged 18-45 years inclusive;
- body mass index (BMI) is within normal limits (≥ 18.5 kg/m² and ≤ 30 kg/m²);
- verified diagnosis "healthy": absence of pathology from the gastrointestinal tract, liver, kidneys, cardiovascular system, central nervous system, endocrine system (preliminary standard clinical, laboratory and instrumental studies did not reveal the presence of any diseases; no deviations from standards based on the results of laboratory and instrumental examination methods, including ECG);
- for women, a negative pregnancy test. Women of childbearing age and male participants use barrier methods of contraception. If hormonal contraceptives are used, they should be discontinued while participating in the study;
- availability of written informed consent from the volunteer to participate in the study;
- thermometry (temperature should be from 36.0° to 36.6°).

Criteria for non-inclusion of subjects:

- thermometry (temperature should be from 36.0° to 36.6°);
- complicated allergy history, drug intolerance;
- hypersensitivity to Omeprazole and other components of the drug;
- galactose intolerance, lactase deficiency, glucose-galactose deficiency;
- systolic blood pressure less than 100 mm Hg. and more than 130 mm Hg; diastolic blood pressure less than 70 mm Hg. and more than 90 mm Hg; Heart rate is less than 60 beats/min and more than 90 beats/min at rest;
- surgical interventions on the gastrointestinal tract (with the exception of appendectomy);
- acute infectious diseases (influenza) less than 4 weeks before the start of the study;
- regular intake of medications (including vitamins, dietary supplements, medicinal herbs) less than 2 weeks before the start of the study;
- taking medications that have a pronounced effect on hemodynamics, liver function, etc. (barbiturates, omeprazole, cimetidine, etc.) less than 30 days before the start of the study;
- donation (450 ml of blood or plasma or more) less than 2 months before the start of the study;
- patients with chronic alcohol consumption (within the last 2 years), severe gastrointestinal, kidney, liver or cardiovascular diseases, tuberculous epilepsy, asthma (within 5 years), diabetes, psychosis or glaucoma;
- smoking more than 10 cigarettes per day;
- participation in a clinical trial of drugs less than 3 months before the start of the study;
- positive test for drugs and alcohol;
- positive test for HIV, Hepatitis B and C and syphilis (microreaction);
- pregnancy and breastfeeding period.

Criteria for stopping subjects from participating in the study:

The Principal Investigator may remove a volunteer from the study at any time if:

- the researcher decided that the volunteer should be excluded in the interests of the volunteer himself;

- adverse events have occurred that, due to their severity, make further participation of the volunteer in the study impossible;
- refusal on the part of the volunteer to follow the requirements of the protocol and carry out research procedures, inclusion of a volunteer in violation of the rules of the protocol (research error);
- the volunteer receives/needs additional treatment that may affect the pharmacokinetics of the study drug;
- the volunteer requires hospital treatment during the study;
- volunteers arrive at the clinic later than the appointed time (more than 1 hour late), which violates the protocol requirements;
- if the volunteer's health deteriorates;
- positive test for drug abuse and drug use;
- positive breath alcohol test;
- positive pregnancy test.

Table S1. Comparative assessment of the release kinetics of omeprazole, dosage 20 mg.

No.	Time, min	Test drug		Reference drug	
		Release, average, %	RSD, %	Release, average, %	RSD, %
Acid resistance stage in pH 1.2					
1.	120	8,68	0,64	3,27	2,38
Buffer stage in pH 6.8					
2.	0	0	0	0	0
3.	10	84,53	10,10	90,16	4,00
4.	15	90,22	8,44	100,16	2,27
5.	20	91,35	6,96	100,78	1,07
6.	30	93,07	5,97	101,72	1,47
7.	45	93,97	3,97	100,41	1,31

Table S2. Comparative assessment of the release kinetics of omeprazole, dosage 40 mg.

No.	Time, min	Test drug		Reference drug	
		Release, average, %	RSD, %	Release, average, %	RSD, %
Acid resistance stage in pH 1.2					
1.	120	11,90	7,78	13,82	17,66
Buffer stage in pH 6.8					
2.	0	0	0	0	0
3.	10	86,34	3,94	68,64	2,70
4.	15	88,12	3,42	81,09	0,79
5.	20	90,10	1,45	85,18	1,36

5.	30	88,90	1,57	86,69	1,47
7.	45	87,11	1,42	88,88	1,84
f2		50,03			

Table S3. Long-term stability study results of Omeprazole Viva Pharm, enteric capsules, 20 mg and 40 mg (batch size: 45.68 kg size/200 000 caps. (20 mg)/100 000 caps. (40 mg). Conditions: Temperature: 25°C ± 2°C, and the relative humidity (RH) 60% ± 5%.

Test	Method	Specification	Dosage	Type of package	Results/Months				
					0	3	6	9	12
Appearance	Visual Inspection	Hard gelatin, cylindrical capsules no. 2 (for dosage 20 mg) and no.0 (for dosage 40 mg), with a cap and body of white or almost white color. The contents of the capsules are a mixture of white or off-white pellets with a cream tint.	20 mg capsules	HDP bottles	Conforms	Conforms	Conforms	Conforms	Conforms
				Alu/Alu blisters	Conforms	Conforms	Conforms	Conforms	Conforms
			40 mg capsules	HDP bottles	Conforms	Conforms	Conforms	Conforms	Conforms
				Alu/Alu blisters	Conforms	Conforms	Conforms	Conforms	Conforms
Average of capsule contents mass and Uniformity of mass	Weighing	Deviation from the average weight is allowed for 18 capsules out of 20 no more than ± 10.0% and for 2 capsules out of 20 no more than ± 20% (for dosage 20 mg). Deviation from the average weight is allowed for 18 capsules out of 20 no more than ± 7.5% and for 2 capsules out of 20 no more than ± 15% (for dosage 40 mg).	20 mg capsules	HDP bottles	234,1 mg 20/20 + 2,3 %: - 2,3 %	235,0 mg 20/20 - 5,0 %: + 2,9 %	234,9 mg 20/20 -4,1%: +3,7%	229,0 mg; 19/20 +7,6%; -4,2% 1/20: - 12,0%	234,8 mg 20/20 -4,6%: +3,8%
				Alu/Alu blisters	235,1 mg 20/20 + 3,3%: - 4,1%	234,8 mg 20/20 - 2,0%: + 2,7%	234,7 mg 20/20 -3,1%: +4,2%	234,9mg 20/20 -5,1%: +3,8%	235,0 mg 20/20 -4,2%: +4,8%
			40 mg capsules	HDP bottles	458,5 mg 20/20 + 1,0%; - 1,2%	460,2 mg 20/20 - 2,2%; +1,4%	459,3 mg 20/20 -1,2%; +1,9%	457,2 mg 20/20 -1,9%; +1,8%	459,7 mg 20/20 -1,0%; +1,7%
				Alu/Alu blisters	459,6 mg 20/20 + 1,7%; - 1,7%	458,2 mg 20/20 - 1,2%; +1,6%	459,1 mg 20/20 -2,0%; +1,9%	456,3 mg 20/20 -1,6%; +2,0%	458,7 mg 20/20 -1,0%; +1,3%

Dissolution Acid Resistance stage	HPLC	No more than 15 % after 2 ч	20 mg capsules	HDP bottles	from 7,5 to 14,6 %	from 3,6 to 5,4 %	from 3,6 to 5,4%	from 3,9 to 6,4%	from 4,2 to 6,5%
				Alu/Alu blisters	from 5,5 to 7,8 %	from 5,9 to 8,3 %	from 3,7 to 5,4%	from 4,8 to 7,2%	from 4,8 to 6,9%
			40 mg capsules	HDP bottles	from 7,6 to 11,8 %	from 8,4 to 12,4 %	from 7,6 to 11,9%	from 7,7 to 11,0%	from 7,0 to 11,2%
				Alu/Alu blisters	from 7,5 to 10,8 %	from 7,9 to 11,3 %	from 7,7 to 10,4%	from 7,8 to 11,2%	from 7,8 to 10,9%
Dissolution Buffer Stage	HPLC	No less than 75 % (for dosage 20 mg) and 70 % (for dosage 40 mg) after 2,5 ч	20 mg capsules	HDP bottles	from 75,6 to 78,3%	from 99,5 to 103,4%	from 85,6 to 98,2%	from 99,2 to 101,4%	from 88,6 to 99,1%
				Alu/Alu blisters	from 80,9 to 91,3 %	from 86,5 to 101,4 %	from 86,5 to 101,4%	from 88,5 to 99,3 %	from 91,2 to 100,1%
			40 mg capsules	HDP bottles	from 85,6 to 93,3%	from 89,9 to 99,8%	from 75,7 to 99,8%	from 88,2 to 100,0%	from 77,7 to 95,1%
				Alu/Alu blisters	from 75,9 to 89,3%	from 89,9 to 100,9%	from 75,9 to 95,2%	from 76,2 to 93,0%	from 88,0 to 95,1%
Impurities: - sum of impurities F and G - 5-methoxy-1H-benzimidazole-2-thiol - any other impurity - total impurities	HPLC	≤ 0,5 % ≤ 0,5 % ≤ 0,5 % ≤ 2,0 %	20 mg capsules	HDP bottles	not detected	0,17%	0,16%	0,19%	0,18%
					not detected	0,18%	not detected	0,04%	0,1%
					0,1%	0,09%	0,09%	0,12%	0,12%
					0,1%	0,14%	0,23%	0,08%	0,15%
			40 mg capsules	Alu/Alu blisters	not detected	0,05 %	0,06%	0,06%	0,05%
					not detected	not detected	0,02%	0,03%	0,1%
					not detected	0,04%	not detected	0,04%	0,09%
					not detected	0,1%	0,08%	0,1%	0,11%
40 mg capsules	HDP bottles	0,1%	0,05%	0,1%	0,1%	0,15%			
		not detected	not detected	0,08%	not detected	0,08%			
		not detected	not detected	0,09%	0,11%	0,1%			
		not detected	not detected	0,12%	0,09%	0,1%			
40 mg capsules	Alu/Alu blisters	not detected	0,04%	0,05%	0,1%	0,1%			
		not detected	0,05%	0,05%	0,03%	0,08%			
		not detected	not detected	0,04%	0,05%	0,1%			
		not detected	not detected	not detected	0,1%	0,11%			
Assay:	HPLC			HDP bottles	20,9	19,7	21,5	21,5	21,0

- omeprazole		From 18,0 to 22,0 mg/caps (for dosage 20 mg) From 36,0 to 44,0 mg/caps (for dosage 20 mg)	20 mg capsules	Alu/Alu blisters	19,9	19,9	21,3	21,0	20,8
			40 mg capsules	HDP bottles	39,3	40,2	41,4	39,2	39,9
				Alu/Alu blisters	38,1	41,5	40,9	40,9	39,2
Total Aerobic Microbial Count (TAMC), cfu/1 g	Direct	$\leq 10^3$	20 mg capsules	HDP bottles	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
				Alu/Alu blisters	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
			40 mg capsules	HDP bottles	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
				Alu/Alu blisters	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Total Combined Yeasts and Moulds Count, cfu/1 g	Direct	$\leq 10^2$	20 mg capsules	HDP bottles	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
				Alu/Alu blisters	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
			40 mg capsules	HDP bottles	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
				Alu/Alu blisters	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Escherichia coli in 1 g	Direct	Absence in 1 g	20 mg capsules	HDP bottles	not detected	not detected	not detected	not detected	not detected
				Alu/Alu blisters	not detected	not detected	not detected	not detected	not detected
			40 mg capsules	HDP bottles	not detected	not detected	not detected	not detected	not detected
				Alu/Alu blisters	not detected	not detected	not detected	not detected	not detected

Table S4. Accelerated stability study results of Omeprazole Viva Pharm, enteric capsules, 20 mg and 40 mg (batch size: 45.68 kg size/200 000 caps. (20 mg)/100 000 caps. (40 mg). Conditions: Temperature: 40°C ± 2°C, and the relative humidity (RH) 75% ± 5%.

Test	Method	Specification	Dosage	Type of package	Results/Months				
					0	1	2	3	6
Appearance	Visual Inspection	Hard gelatin, cylindrical capsules no. 2 (for dosage 20 mg) and no.0 (for dosage 40 mg), with a cap and body of white or almost white color. The contents of the capsules are a mixture of white or off-white pellets with a cream tint.	20 mg capsules	HDP bottles	Conforms	Conforms	Conforms	Conforms	Conforms
				Alu/Alu blisters	Conforms	Conforms	Conforms	Conforms	Conforms
			40 mg capsules	HDP bottles	Conforms	Conforms	Conforms	Conforms	Conforms
				Alu/Alu blisters	Conforms	Conforms	Conforms	Conforms	Conforms
Average of capsule contents mass and Uniformity of mass	Weighing	Deviation from the average weight is allowed for 18 capsules out of 20 no more than ± 10.0% and for 2 capsules out of 20 no more than ± 20% (for dosage 20 mg). Deviation from the average weight is allowed for 18 capsules out of 20 no more than ± 7.5% and for 2 capsules out of 20 no more than ± 15% (for dosage 40 mg).	20 mg capsules	HDP bottles	235,2 mg 20/20 + 4,3 %: - 2,8 %	235,2 mg 20/20 - 2,3 %: + 2,8 %	232,8 mg 20/20 -5,2%: +4,1%	230,0 mg; 19/20 +6,6%; -5,3% 1/20: - 12,0%	229,0 mg; 19/20 +7,6%; -4,2% 1/20: - 12,0%
				Alu/Alu blisters	239,1 mg 20/20 + 2,3%: - 428%	239,8 mg 20/20 - 3,0%: + 2,9%	238,6 mg 20/20 -3,8%: +5,1%	239,9mg 20/20 -3,1%: +4,1%	238,0 mg 20/20 -2,2%: +4,6%
			40 mg capsules	HDP bottles	459,0 mg 20/20 + 2,0%; - 2,7%	459,2 mg 20/20 - 2,2%; +2,7%	457,7 mg 20/20 -2,2%; +1,9%	458,5 mg 20/20 -1,9%; +1,9%	458,9 mg 20/20 -2,1%; +2,8%
				Alu/Alu blisters	460,1 mg 20/20: + 1,9%; - 1,3%	459,0 mg 20/20 - 1,3%; +1,6%	457,3 mg 20/20 -1,9%; +2,8%	457,9 mg 20/20 -1,8%; +1,0%	458,6 mg 20/20 -1,8%; +1,3%
Dissolution Acid Resistance stage	HPLC	No more than 15 % after 2 ч	20 mg capsules	HDP bottles	from 7,7 to 10,9 %	from 5,5 to 7,1 %	from 4,0 to 5,3%	from 3,8 to 6,4%	from 4,9 to 6,8%
				Alu/Alu blisters	from 5,5 to 6,9 %	from 6,0 to 7,1 %	from 4,7 to 6,5%	from 5,5 to 7,0%	from 4,0 to 6,0%

			40 mg capsules	HDP bottles	from 7,7 to 11,1 %	from 7,3 to 12,0 %	from 6,6 to 10,0%	from 7,1 to 12,0%	from 7,7 to 10,3%
				Alu/Alu blisters	from 7,8 to 11,8 %	from 6,9 to 10,2 %	from 7,6 to 9,9%	from 6,8 to 11,5%	from 7,5 to 11,2%
Dissolution Buffer Stage	HPLC	No less than 75 % (for dosage 20 mg) and 70 % (for dosage 40 mg) after 2,5 ч	20 mg capsules	HDP bottles	from 77,7 to 79,6%	from 88,7 to 99,8%	from 89,0 to 101,1%	from 88,0 to 99,3%	from 88,8 to 99,1%
				Alu/Alu blisters	from 80,9 to 92,7 %	from 88,5 to 100,0 %	from 86,5 to 101,2%	from 86,0 to 99.2 %	from 90,2 to 99,0%
			40 mg capsules	HDP bottles	from 76,6 to 91,7%	from 80,9 to 95,7%	from 79,7 to 96,6%	from 80,2 to 99,0%	from 79,9 to 96,9%
				Alu/Alu blisters	from 78,0 to 89,9%	from 79,9 to 101.0%	from 80,2 to 96,2%	from 79,5 to 95,0%	from 79,9 to 99,1%
Impurities: - sum of impurities F and G - 5-methoxy-1H-benzimidazole-2-thiol - any other impurity - total impurities	HPLC	≤ 0,5% ≤ 0,5 % ≤ 0,5 % ≤ 2,0 %	20 mg capsules	HDP bottles	not detected	0,19%	0,16%	0,1%	0,19%
					not detected	0,19%	0,18%	0,1%	0,18%
					not detected	0,09%	0,1%	0,12%	0,15%
					not detected	0,13%	0,18%	0,15%	0,15%
			40 mg capsules	Alu/Alu blisters	not detected	0,05 %	0,05%	0,06%	0,06%
					0,05 not detected 0,08	not detected not detected not detected	not detected not detected 0,08%	0,04% 0,1%	0,08% 0,12%
Assay: - omeprazole	HPLC	From 18,0 to 22,0 mg/caps (for dosage 20 mg)	20 mg capsules	HDP bottles	19,9	19,7	20,4	21,4	21,0
				Alu/Alu blisters	20,9	19,8	20,5	21,2	20,7
				HDP bottles	40,1	41,0	41,4	40,2	39,8

		From 36,0 to 44,0 mg/caps (for dosage 20 mg)	40 mg capsules	Alu/Alu blisters	39,2	40,5	39,9	40,2	40,2
Total Aerobic Microbial Count (TAMC), cfu/1 g	Direct	$\leq 10^3$	20 mg capsules	HDP bottles	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
				Alu/Alu blisters	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
			40 mg capsules	HDP bottles	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
				Alu/Alu blisters	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Total Combined Yeasts and Moulds Count, cfu/1 g	Direct	$\leq 10^2$	20 mg capsules	HDP bottles	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
				Alu/Alu blisters	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
			40 mg capsules	HDP bottles	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
				Alu/Alu blisters	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Escherichia coli in 1 g	Direct	Absence in 1 g	20 mg capsules	HDP bottles	not detected	not detected	not detected	not detected	not detected
				Alu/Alu blisters	not detected	not detected	not detected	not detected	not detected
			40 mg capsules	HDP bottles	not detected	not detected	not detected	not detected	not detected
				Alu/Alu blisters	not detected	not detected	not detected	not detected	not detected

Table S5. Concentrations of omeprazole in the blood plasma of volunteers (ng/ml) after a single dose of the drug Omeprazole (test drug "T").

Time (t) after drug administra- tion (planned) , h																																
	03	04	06	07	08	10	11	14	18	20	22	24	01	02	05	09	12	13	15	16	17	19	21	23	Mean	Gmean	Media na	Mini mum	Maxi mum	SD	CV	
	I	I	I	I	I	I	I	I	I	I	I	I	II	II	II	II	II	II	II	II	II	II	II	II								
0.00	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	-	
0.50	0.000	0.000	32.971	39.655	31.270	28.607	0.000	29.866	0.000	27.647	26.454	0.000	26.006	26.675	27.007	0.000	0.000	0.000	33.565	25.100	0.000	29.910	0.000	25.554	17.095	29.073	25.780	0.000	39.655	15.064	88.1	
1.00	251.71 2	239.15 2	335.29 8	377.578	195.235	196.051	142.800	100.453	302.82 2	365.50 9	255.96 2	228.90 8	253.23 6	191.33 0	289.06 1	236.99 8	191.10 6	254.03 8	280.08 9	309.05 0	295.45 2	369.28 3	286.34 4	255.60 4	258.46 2	248.32 4	254.82 1	100.45 3	377.57 8	68.843	26.6	
1.50	992.64 0	945.66 6	1316.1 84	1066.06 0	529.150	528.569	398.066	224.889	505.03 0	594.79 1	945.32 1	684.75 5	531.83 9	652.05 8	593.36 7	801.06 7	549.49 0	1052.6 95	968.46 3	809.20 0	434.36 7	519.21 7	501.64 6	939.26 0	711.82 5	662.39 9	623.42 4	224.88 9	1316.1 84	265.75 0	37.3	
2.00	1218.6 14	1167.6 36	1597.8 60	1716.50 2	740.815	738.469	698.520	677.078	736.78 8	878.40 0	1143.9 76	1315.0 34	770.16 8	994.80 4	983.77 7	1227.5 25	947.00 0	1139.1 29	1492.4 15	1062.5 76	707.91 1	914.24 7	689.66 3	1140.2 86	1029.1 33	990.33 0	989.29 1	677.07 8	1716.5 02	298.05 3	29.0	
2.50	1223.8 86	1147.9 88	1688.3 30	1734.93 4	1269.30 3	1264.71 5	945.489	0	1286.59 05	1050.2 30	1210.0 24	1038.8 91	1165.8 9	881.89 8	893.40 63	1235.6 03	1092.9 74	1095.6 70	1040.8 44	1154.7 04	1380.7 2	928.66 89	1314.9 1	906.57 80	1038.8 98	1166.2 21	1148.1 66	1151.3 9	881.89 34	1734.9 7	219.61 7	18.8
3.00	915.75 4	902.31 2	1426.0 38	1432.50 4	1401.14 8	1399.64 8	894.313	2	1352.89 91	1220.1 22	1405.4 9	868.54 05	1044.6 1	971.54 2	794.77 55	1293.0 2	968.86 9	903.26 5	865.39 3	956.26 7	987.94 11	1505.9 91	1984.0 57	1470.1 7	869.21 7	1159.7 44	1125.2 93	1016.2 76	794.77 2	1984.0 91	300.94 6	25.9
4.00	684.70 9	647.18 6	1088.8 30	1086.96 3	871.999	883.226	484.315	8	1112.96 740.16	856.62 9	687.99 6	797.99 3	729.85 2	532.51 1	782.67 4	655.79 0	507.07 4	658.79 0	665.97 4	545.02 7	986.93 1	1301.4 58	940.21 4	697.97 0	789.46 9	763.61 6	735.01 0	484.31 5	1301.4 58	211.78 0	26.8	
5.00	358.63 8	353.76 6	511.00 4	701.817	464.526	368.952	237.565	771.882	329.29 6	374.58 6	458.83 8	474.96 6	445.98 1	434.51 0	500.83 3	533.80 5	378.51 7	468.95 4	480.22 8	387.04 7	368.57 7	487.14 6	349.53 0	465.88 3	446.11 9	433.32 6	452.40 9	237.56 5	771.88 2	114.09 7	25.6	
6.00	248.58 4	236.57 2	353.42 6	341.990	266.492	279.976	212.185	456.730	263.90 4	299.00 9	321.67 4	280.67 6	210.00 0	236.73 4	212.19 4	290.20 3	244.94 9	326.65 1	230.60 1	225.63 2	231.06 3	308.11 6	221.32 3	330.03 3	276.19 6	270.83 8	265.19 8	210.00 0	456.73 0	58.807	21.3	
8.00	126.51 1	122.09 5	184.60 5	175.873	140.769	143.230	77.541	268.062	103.27 5	117.54 3	115.50 6	123.87 9	105.90 6	136.51 1	120.56 4	169.14 9	93.598	113.42 4	140.30 1	136.22 6	104.73 0	141.43 5	98.727	117.29 1	132.36 5	128.00 7	122.98 7	77.541	268.06 2	38.530	29.1	
12.0	28.774	28.545	42.327	41.486	28.590	25.312	0.000	26.863	27.388	30.931	31.333	27.312	0.000	0.000	27.813	27.850	28.243	27.763	25.952	0.000	30.367	39.978	28.922	32.376	25.339	30.065	28.046	0.000	42.327	12.436	49.1	

Table S6. Concentrations of omeprazole in the blood plasma of volunteers (ng/ml) after a single dose of Losec® (reference drug “R”).

Time (t) after drug admini- stration (plan- ned), h																									Mea- n	Gm- ean	Medi- ana	Min- imu- m	Max- imu- m	SD	CV	
	01	02	05	09	12	13	15	16	17	19	21	23	03	04	06	07	08	10	11	14	18	20	22	24								
	I	I	I	I	I	I	I	I	I	I	I	I	II	II	II	II	II	II	II	II	II	II	II	II								
0.0	0.00	0.00	0.00						0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-	0.00	0.00	0.00	0.00	-
0.5	31.6	28.5	30.3	29.51	25.28				26.9	0.00	0.00	0.00	0.00	0.00	27.1	0.00	0.00	0.00	0.00	0.00	44.6	39.6	31.6	33.1	14.5	31.2	0.00	0.00	44.6	16.5	114.	
0	23	07	89	8	4	0.000	0.000	0.000	34	0	0	0	0	0	88	0	0	0	0	0	80	40	84	07	23	56	0	0	80	72	1	
1.0	217.	279.	225.	221.9	237.4	262.5	241.6	209.8	278.	341.	307.	228.	184.	200.	263.	281.	279.	292.	193.	247.	332.	413.	330.	354.	267.	262.	262.	184.	413.	57.2		
0	944	541	365	42	35	13	55	29	455	168	071	244	154	758	287	593	651	748	578	877	190	725	300	387	725	161	900	154	725	33	21.4	
1.5	862.	1094	897.	885.8	889.1	1069.	985.2	636.1	933.	573.	511.	674.	604.	424.	904.	601.	579.	612.	557.	1012	1132	1067	880.	913.	796.	767.	871.	424.	1132	212.		
0	526	.910	765	81	47	999	75	79	500	383	818	184	581	628	271	901	299	259	921	.103	.124	.719	643	513	064	491	584	628	.124	641	26.7	
2.0	1301	1343	1159	1327.	817.4	1163.	1066.	1187.	1221	1075	739.	1288	926.	590.	1375	866.	742.	1007	933.	1101	1698	1404	1153	1183	1111	1082	1156	590.	1698	252.		
0	.387	.552	.069	830	10	493	764	371	.420	.465	502	.543	910	397	.391	924	674	.402	018	.525	.926	.304	.976	.633	.537	.035	.522	397	.926	874	22.7	
2.5	1201	1387	1431	1145.	1146.	1069.	978.9	1280.	1121	1215	1061	1151	831.	697.	1237	1015	999.	1270	1055	1008	1352	1789	1500	1563	1188	1165	1148	697.	1789	238.		
0	.919	.052	.989	142	325	933	85	577	.534	.542	.367	.065	391	287	.065	.503	300	.354	.676	.836	.077	.898	.225	.254	.012	.069	.695	287	.898	776	20.1	
3.0	1067	941.	1441	1017.	839.1	867.1	859.8	1129.	873.	1440	1218	994.	742.	782.	1106	1109	1068	1315	850.	862.	1130	1311	1077	1130	1049	1031	1068	742.	1441	198.		
0	.688	309	.788	964	20	18	59	343	473	.801	.077	018	327	761	.697	.844	.367	.246	573	632	.949	.268	.753	.640	.151	.637	.027	327	.788	122	18.9	
4.0	640.	657.	666.	661.6	527.3	710.3	645.5	719.9	648.	874.	738.	767.	505.	589.	764.	840.	798.	812.	477.	664.	825.	716.	589.	627.	686.	678.	665.	477.	874.	105.		
0	195	128	690	56	90	18	48	78	721	455	605	802	912	269	785	954	013	555	413	936	816	983	933	210	344	269	813	413	455	607	15.4	
5.0	367.	400.	388.	388.5	303.4	477.1	434.9	425.7	504.	392.	324.	452.	409.	295.	625.	490.	476.	524.	358.	447.	578.	444.	325.	458.	428.	421.	430.	295.	625.	82.3		
0	148	458	010	34	99	42	69	05	649	903	664	244	027	643	222	737	579	700	633	873	868	327	530	826	995	531	337	643	222	68	19.2	
6.0	243.	269.	263.	263.6	221.7	334.6	307.3	250.5	352.	321.	261.	270.	221.	172.	331.	246.	235.	218.	218.	317.	278.	299.	249.	258.	266.	263.	262.	172.	352.	44.1		
0	352	081	242	22	26	27	39	13	498	426	736	570	361	400	847	324	386	674	156	128	843	997	889	044	991	437	489	400	498	95	16.6	
8.0	137.	138.	146.	147.1	118.1	116.6	105.5	109.0	124.	125.	100.	122.	128.	86.2	200.	124.	119.	117.	82.4	109.	174.	183.	151.	155.	130.	127.	124.	82.4	200.	28.6		
0	400	536	170	33	48	16	70	22	996	990	858	840	476	97	759	073	777	077	06	538	550	778	708	995	321	430	534	06	759	75	22.0	
12.	28.6	30.0	31.7	31.11		29.27	25.24		34.4	35.4	28.8	26.8	0.00	0.00	38.5	0.00	0.00	28.3	25.2	26.7	36.4	31.6	26.2	28.2	22.6	29.9	28.3	0.00	38.5	13.7		
0	65	31	26	4	0.000	5	8	0.000	03	65	84	50	0	0	89	0	0	77	49	41	87	30	49	47	35	50	12	0	89	67	60.8	

Table S7. Pharmacokinetic parameters of omeprazole in the blood plasma of volunteers after a single dose of the drug Omeprazole (test drug "T").

Randomized №	Period	T _{1/2} h	t _{max} h	C _{max} ng/ml	AUC _{0→t} ng/ml×h	AUC _{0→∞} ng/ml×h	AUMC ng/ml×h ²	MR T h	C _{max} /AUC _{0→t} h ⁻¹	C _{max} /AUC _{0→∞} h ⁻¹
01	II	1.4	3.0							
		2	0	971.541	3556.97	3773.22	12477.07	3.51	0.2731	0.2575
02	II	1.9	2.0							
		7	0	994.804	3433.85	3821.40	12016.47	3.50	0.2897	0.2603
03	I	1.9	2.5	1223.88						
		3	0	6	4383.54	4463.54	16175.37	3.69	0.2792	0.2742
04	I	1.9	2.0	1167.63						
		4	0	6	4206.14	4286.13	15563.72	3.70	0.2776	0.2724
05	II	2.0	3.0	1293.05						
		2	0	5	4553.35	4634.51	17139.70	3.76	0.2840	0.2790
06	I	1.9	2.5	1688.33						
		5	0	0	6323.29	6442.65	23617.43	3.73	0.2670	0.2621
07	I	1.9	2.5	1734.93						
		6	0	4	6454.10	6571.64	24258.01	3.76	0.2688	0.2640
08	I	1.7	3.0	1401.14						
		8	0	8	4649.50	4723.05	18256.00	3.93	0.3014	0.2967
09	II	1.8	2.0	1227.52						
		0	0	5	4593.94	4666.20	18124.87	3.95	0.2672	0.2631
10	I	1.7	3.0	1399.64						
		1	0	8	4580.40	4642.86	17912.63	3.91	0.3056	0.3015
11	I	1.4	2.5							
		7	0	945.489	2880.87	3044.90	9917.61	3.44	0.3282	0.3105
12	II	1.8	2.5	1095.67						
		1	0	4	3659.38	3732.96	13906.22	3.80	0.2994	0.2935
13	II	1.7	2.0	1139.12						
		8	0	9	4405.93	4477.10	16612.19	3.77	0.2585	0.2544
14	I	1.5	3.0	1352.89						
		1	0	2	5601.97	5660.30	25055.75	4.47	0.2415	0.2390
15	II	1.7	2.0	1492.41						
		3	0	5	4646.75	4711.56	17092.75	3.68	0.3212	0.3168
16	II	1.7	2.5	1380.70						
		6	0	4	3941.02	4286.97	13014.88	3.30	0.3503	0.3221
17	II	2.0	3.0	1505.91						
		7	0	1	4389.66	4480.54	16843.04	3.84	0.3431	0.3361
18	I	1.9	3.0	1220.19						
		0	0	1	4042.49	4117.68	15443.35	3.82	0.3018	0.2963
19	II	2.0	3.0	1984.09						
		6	0	1	5816.93	5935.61	22372.25	3.85	0.3411	0.3343
20	I	1.9	3.0	1405.42						
		0	0	2	4686.47	4771.20	17742.79	3.79	0.2999	0.2946
21	II	2.0	3.0	1470.15						
		7	0	7	4270.49	4356.94	16214.14	3.80	0.3443	0.3374
22	I	1.8	2.0	1143.97						
		3	0	6	4395.21	4477.85	16705.70	3.80	0.2603	0.2555
23	II	1.8	2.0	1140.28						
		4	0	6	4427.23	4513.33	16916.86	3.82	0.2576	0.2526
24	I	1.7	2.0	1315.03						
		9	0	4	4600.98	4671.58	17472.25	3.80	0.2858	0.2815
Mean		1.8	2.5	1320.57						
		3	4	8	4520.85	4635.99	17118.79	3.77	0.2936	0.2856
Gmean		1.8	2.5	1299.25						
		2	0	0	4448.57	4571.08	16732.26	3.76	0.2921	0.2842

	1.8	2.5	1304.04						
Mediana	4	0	5	4416.58	4496.93	16879.95	3.79	0.2878	0.2803
	1.4	2.0							
Minimum	2	0	945.489	2880.87	3044.90	9917.61	3.30	0.2415	0.2390
	2.0	3.0	1984.09						
Maximum	7	0	1	6454.10	6571.64	25055.75	4.47	0.3503	0.3374
	0.1	0.4							
SD	8	4	249.011	840.65	814.21	3737.72	0.22	0.0311	0.0292
		17.							
CV	9.8	3	18.9	18.6	17.6	21.8	5.7	10.6	10.2

Table S8. Pharmacokinetic parameters of omeprazole in the blood plasma of volunteers after a single dose of Losec® (reference drug "R").

Randomized №	Period	T _{1/2} h	t _{max} h	C _{max} ng/ml	AUC ₀ →t ng/ml×h	AUC ₀ →∞ ng/ml×h	AUMC ng/ml×h ²	MR T h	C _{max} /AUC 0→t h ⁻¹	C _{max} /AUC ₀ →∞ h ⁻¹
		1.9	2.0	1301.3	4450.3	4529.8	16542.1			
01	I	2	0	87	7	9	1	3.72	0.2924	0.2873
		1.8	2.5	1387.0	4709.6	4791.2	17261.5			
02	I	8	0	52	4	6	3	3.67	0.2945	0.2895
		1.9	2.0	926.91	3205.7	3571.6	11270.7			
03	II	7	0	0	2	3	3	3.52	0.2891	0.2595
		1.7	3.0	782.76	2773.4	2988.4				
04	II	3	0	1	1	9	9719.34	3.50	0.2822	0.2619
		1.9	3.0	1441.7	4905.1	4994.5	18232.1			
05	I	5	0	88	5	2	8	3.72	0.2939	0.2887
		1.8	2.0	1375.3	5300.8	5406.2	21144.6			
06	II	9	0	91	6	0	6	3.99	0.2595	0.2544
		1.4	3.0	1109.8	4040.5	4298.5	14252.6			
07	II	4	0	44	9	4	8	3.53	0.2747	0.2582
		1.4	3.0	1068.3	3849.1	4099.5	13621.5			
08	II	5	0	67	8	7	6	3.54	0.2776	0.2606
		1.9	2.0	1327.8	4517.8	4604.7	17072.2			
09	I	4	0	30	8	8	5	3.78	0.2939	0.2884
		2.0	3.0	1315.2	4651.0	4733.9	17492.9			
10	II	2	0	46	7	6	1	3.76	0.2828	0.2778
		1.7	2.5	1055.6	3469.0	3533.5	12931.5			
11	II	7	0	76	2	5	6	3.73	0.3043	0.2988
		2.2	2.5	1146.3	3368.7	3744.4	11348.0			
12	I	0	0	25	7	1	0	3.37	0.3403	0.3061
		1.7	2.0	1163.4	4531.1	4603.3	17125.6			
13	I	1	0	93	1	7	8	3.78	0.2568	0.2527
		1.7	2.0	1101.5	4302.7	4370.8	16210.4			
14	II	6	0	25	4	0	7	3.77	0.2560	0.2520
		1.7	2.0	1066.7	4189.9	4252.4	15747.6			
15	I	1	0	64	7	0	9	3.76	0.2546	0.2509
		1.4	2.5	1280.5	4134.4	4364.4	14046.3			
16	I	6	0	77	6	6	9	3.40	0.3097	0.2934
		1.8	2.0	1221.4	4571.9	4664.6	17550.9			
17	I	7	0	20	4	7	1	3.84	0.2672	0.2618
		1.8	2.0	1698.9	5547.7	5642.9	20732.1			
18	II	1	0	26	8	6	0	3.74	0.3062	0.3011

		1.9	3.0	1440.8	4881.7	4982.1	18667.4			
19	I	6	0	01	8	9	2	3.82	0.2951	0.2892
		1.8	2.5	1789.8	5566.9	5650.5	20568.9			
20	II	3	0	98	9	7	3	3.69	0.3215	0.3168
		1.9	3.0	1218.0	4039.6	4121.0	15391.4			
21	I	5	0	77	5	8	6	3.81	0.3015	0.2956
		1.8	2.5	1500.2	4554.6	4625.2	16795.1			
22	II	6	0	25	5	5	0	3.69	0.3294	0.3244
		1.8	2.0	1288.5	4464.6	4534.5	16943.7			
23	I	0	0	43	5	1	8	3.80	0.2886	0.2842
		1.8	2.5	1563.2	4869.5	4942.9	18099.4			
24	II	0	0	54	1	7	2	3.72	0.3210	0.3163
		1.8	2.4	1273.8	4370.7	4502.1	16198.7			
Mean		2	4	37	0	7	0	3.69	0.2914	0.2821
		1.8	2.4	1253.0	4313.6	4456.1	15915.5			
Gmean		1	0	36	9	5	9	3.69	0.2905	0.2812
		1.8	2.5	1284.5	4491.2	4568.9	16869.4			
Mediana		5	0	60	6	4	4	3.72	0.2932	0.2878
		1.4	2.0	782.76	2773.4	2988.4				
Minimum		4	0	1	1	9	9719.34	3.37	0.2546	0.2509
		2.2	3.0	1789.8	5566.9	5650.5	21144.6			
Maximum		0	0	98	9	7	6	3.99	0.3403	0.3244
		0.1	0.4	233.31						
SD		8	3	1	695.23	640.08	2960.81	0.15	0.0233	0.0226
			17.							
CV		9.9	4	18.3	15.9	14.2	18.3	4.0	8.0	8.0