Clinical trial results:
An Ascending Bioavailability of a New Oral Suspension of E3810
Summary

EudraCT number	2016-001896-63
Trial protocol	Outside EU/EEA
Global end of trial date	23 July 2005

Results information

Result version number	v1 (current)
This version publication date	28 July 2016
First version publication date	28 July 2016

Trial information

Trial identification

Sponsor protocol code	E3810-A001-015

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eisai Medical Research Inc.
Sponsor organisation address	100 Tice Boulevard, Woodcliff Lake, United States, 07677
Public contact	Eisai Medical Information, Eisai Medical Research Inc., 1 8882472378, esi_medinfo@eisai.com
Scientific contact	Eisai Medical Information, Eisai Medical Research Inc., 1 8882472378, esi_medinfo@eisai.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000055-PIP01-07
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 July 2005
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 July 2005
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the bioavailability of a new rabeprazole formulation, consisting of enteric-coated microgranules, relative to the currently marketed 10-mg tablet formulation.

Protection of trial subjects:

This study was conducted in accordance with standard operating procedures (SOPs) of the sponsor (or designee), which are designed to ensure adherence to Good Clinical Practice (GCP) guidelines as required by the following:
- Principles of the World Medical Association Declaration of Helsinki (World Medical Association, 2008)
- International Council on Harmonisation (ICH) E6 Guideline for GCP (CPMP/ICH/135/95) of the European Agency for the Evaluation of Medicinal
Products, Committee for Proprietary Medicinal Products, International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
- Title 21 of the United States (US) Code of Federal Regulations (US 21 CFR) regarding clinical studies, including Part 50 and Part 56 concerning informed subject consent and Institutional Review Board (IRB) regulations and applicable sections of US 21 CFR Part 312
- European Good Clinical Practice Directive 2005/28/EC and Clinical Trial Directive 2001/20/EC for studies conducted within any European Union (EU) country. All suspected unexpected serious adverse reactions were reported, as required, to the Competent Authorities of all involved EU member states.
- Article 14, Paragraph 3, and Article 80-2 of the Pharmaceutical Affairs Law (Law No. 145, 1960) for studies conducted in Japan, in addition to Japan’s GCP Subject Information and Informed Consent.

Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	28 June 2005
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 16
Worldwide total number of subjects	16
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	16
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This was an open-label, 2-period, 2-sequence crossover study. Sixteen participants, 15 of whom received both formulations, were enrolled at one investigative center. Participants were randomized to one of two sequences: Reference (10-mg tablet) follow by Test (new enteric-coated microgranule formulation), or Test followed by Reference.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Reference/Test then Test/Reference

Arm description:

Period 1: Participants were randomized to either rabeprazole tablet (Reference) or enteric-coated microgranule rabeprazole oral suspension (Test). After at least a 1 week washout, participants returned to the clinic and entered into Period 2. In Period 2, participants who received Reference study drug in Period 1 crossed over to Test study drug. Participants who received Test study drug in Period 1 crossed over to Reference study drug.

Arm type	Experimental
Investigational medicinal product name	Rabeprazole sodium tablet
Investigational medicinal product code	E3810
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Period 1: Following a 10-hour overnight fast participants were randomized to receive either 10-mg rabeprazole sodium tablet or 10-mg oral suspension of enteric-coated microgranule rabeprazole sodium oral suspension. Period 2: Following at least a 1 week washout period, and 10-hour overnight fast, participants received the other formulation of study drug, either 10-mg rabeprazole sodium tablet (if they received the oral suspension formulation in Period 1) or enteric-coated microgranule 10-mg rabeprazole sodium oral suspension (if they received the tablet formulation in Period 1).

Number of subjects in period 1	Reference/Test then Test/Reference
Started	16
Completed	15
Not completed	1
Physician decision	1

Baseline characteristics

Reporting groups	
Reporting group title	Reference/Test then Test/Reference

Reporting group description:

Period 1: Participants were randomized to either rabeprazole tablet (Reference) or enteric-coated microgranule rabeprazole oral suspension (Test). After at least a 1 week washout, participants returned to the clinic and entered into Period 2. In Period 2, participants who received Reference study drug in Period 1 crossed over to Test study drug. Participants who received Test study drug in Period 1 crossed over to Reference study drug.

Reporting group values	Reference/Test then Test/Reference	Total	
Number of subjects	16	16	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	30.6		
full range (min-max)	22 to 43	-	
Gender categorical Units: Subjects			
Female	6	6	
Male	10	10	

End points

End points reporting groups

Reporting group title	Reference/Test then Test/Reference

Reporting group description:

Period 1: Participants were randomized to either rabeprazole tablet (Reference) or enteric-coated microgranule rabeprazole oral suspension (Test). After at least a 1 week washout, participants returned to the clinic and entered into Period 2. In Period 2, participants who received Reference study drug in Period 1 crossed over to Test study drug. Participants who received Test study drug in Period 1 crossed over to Reference study drug.

Subject analysis set title	Rabeprazole sodium (Reference)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Evaluable population included all participants who satisfied all inclusion and none of the exclusion criteria, completed both study periods, and had no compliance or assay issues.

Subject analysis set title	Enteric-coated microgranule rabeprazole sodium (Test)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Evaluable population included all participants who satisfied all inclusion and none of the exclusion criteria, completed both study periods, and had no compliance or assay issues. Within 5 minutes of taking study drug, participants were asked to fill out a questionnaire regarding its palatability.

Primary: Mean Area Under the Concentration Curve from Time 0 to Time t (AUC)(0-t))

End point title	Mean Area Under the Concentration Curve from Time 0 to Time t (AUC)(0-t))

End point description:

Blood samples were drawn at specific time points then analyzed for the amount of rabeprazole sodium in the plasma using a liquid chromatography/tandem mass spectrometry system (LC/MS/MS) and a validated method. The pharmacokinetic (PK) parameter, AUC(0-t), where 't' represents the time of last quantifiable plasma concentration, was calculated using the trapezoidal rule and summarized using descriptive statistics. The average bioequivalence (BE) was used for testing bioequivalence of AUC.

End point type	Primary

End point timeframe:

Day 1 of Period 1 and 2; Predose (-1 hour) and at 30 minutes, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 10, 12, 14, and 16 hours postdose.

End point values	Rabeprazole sodium (Reference)	Enteric-coated microgranule rabeprazole sodium (Test)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: ng*hr/mL				
geometric mean (standard deviation)	334.5 (± 38.01)	321.9 (± 34.83)		

Statistical analyses

Statistical analysis title	Statistical Analysis of AUC (0-t)

Statistical analysis description:

Per Food and Drug Administration (FDA) recommended criteria, the 90% confidence interval (CI) for the geometric Test/Reference mean had to be within the 80% to 125% interval in order to have a conclusion of average bioequivalence of the two formulas. Due to the nature of normal theory CIs, this is equivalent to performing two one-sided test of hypothesis at the 5% level of confidence.

Comparison groups	Enteric-coated microgranule rabeprazole sodium (Test) v Rabeprazole sodium (Reference)
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	equivalence[1]
P-value	= 0.295 [2]
Method	t-test, 2-sided
Parameter estimate	Ratio of Test/Reference
Point estimate	93
Confidence interval	
level	90 %
sides	2-sided
lower limit	81.63
upper limit	104.36

Notes:

[1] - The bioequivalence of rabeprazole sodium tablet (Reference) and rabeprazole sodium enteric-coated microgranules (Test) was analyzed.
[2] - Statistical tests were two-sided and at the significance alpha level of less than or equal to 0.05.

Primary: Mean Log Transformed Values for AUC(0-t)

End point title	Mean Log Transformed Values for AUC(0-t)

End point description:

End point type	Primary

End point timeframe:

Day 1 of Period 1 and 2; Predose (-1 hour) and at 30 minutes, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 10, 12, 14, and 16 hours postdose

End point values	Rabeprazole sodium (Reference)	Enteric-coated microgranule rabeprazole sodium (Test)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: ng*hr/mL				
geometric mean (standard deviation)	2.475 (± 0.057)	2.46 (± 0.059)		

Statistical analyses

Statistical analysis title	Statistical Analysis of Log Transformed AUC(0-t)

Statistical analysis description:

Per Food and Drug Administration (FDA) recommended criteria, the 90% confidence interval (CI) for the geometric Test/Reference mean had to be within the 80% to 125% interval in order to have a

conclusion of average bioequivalence of the two formulas. Due to the nature of normal theory CIs, this is equivalent to performing two one-sided test of hypothesis at the 5% level of confidence.

Comparison groups	Rabeprazole sodium (Reference) v Enteric-coated microgranule rabeprazole sodium (Test)
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	equivalence[3]
P-value	= 0.3325 [4]
Method	t-test, 2-sided
Parameter estimate	Ratio Test/Reference
Point estimate	92.35
Confidence interval	
level	90 %
sides	2-sided
lower limit	80.29
upper limit	106.23

Notes:

[3] - The bioequivalence of rabeprazole sodium tablet (Reference) and rabeprazole sodium enteric-coated microgranules (Test) was analyzed.
[4] - Statistical tests were two-sided and at the significance alpha level of less than or equal to 0.05.

Primary: Mean Area Under the Concentration Curve from Time 0 to Infinity (AUC(0 - ∞))

End point title	Mean Area Under the Concentration Curve from Time 0 to Infinity (AUC(0 - ∞))

End point description:

Blood samples were drawn at specific time points then analyzed for the amount of rabeprazole sodium in the plasma using a liquid chromatography/tandem mass spectrometry system (LC/MS/MS) and a validated method. The PK parameter, AUC(0-∞), was determined, where AUC = AUC(0-t) + C(t)/λz and C(t) is the last measurable concentration and λz is the apparent terminal disposition rate constant. PK parameters were summarized using descriptive statistics. The average bioequivalence (BE) was used for testing bioequivalence of AUC. For this endpoint participants 11, 12, 14, and 15 for E3810 analyte were excluded due to missing or non-reportable PK parameters.

End point type	Primary

End point timeframe:

Day 1 of Period 1 and 2; Predose (-1 hour) and at 30 minutes, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 10, 12, 14, and 16 hours postdose

End point values	Rabeprazole sodium (Reference)	Enteric-coated microgranule rabeprazole sodium (Test)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12[5]	12[6]		
Units: ng*hr/mL				
geometric mean (standard deviation)	378.4 (± 42.59)	340.8 (± 38.79)		

Notes:

[5] - Participants 11, 12, 14, and 15 were excluded due to missing or non-reportable PK parameters.

[6] - Participants 11, 12, 14, and 15 were excluded due to missing or non-reportable PK parameters.

Statistical analyses

Statistical analysis title	Statistical Analysis of AUC (0 - ∞)

Statistical analysis description:

Per Food and Drug Administration (FDA) recommended criteria, the 90% confidence interval (CI) for the geometric Test/Reference mean had to be within the 80% to 125% interval in order to have a conclusion of average bioequivalence of the two formulas. Due to the nature of normal theory CIs, this is equivalent to performing two one-sided test of hypothesis at the 5% level of confidence.

Comparison groups	Rabeprazole sodium (Reference) v Enteric-coated microgranule rabeprazole sodium (Test)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	equivalence[7]
P-value	= 0.2471 [8]
Method	t-test, 2-sided
Parameter estimate	Ratio of Test/Reference
Point estimate	91.71
Confidence interval	
level	90 %
sides	2-sided
lower limit	79.48
upper limit	103.93

Notes:

[7] - The bioequivalence of rabeprazole sodium tablet (Reference) and rabeprazole sodium enteric-coated microgranules (Test) was analyzed.
[8] - Statistical tests were two-sided and at the significance alpha level of less than or equal to 0.05.

Primary: Mean Maximum Drug Plasma Concentration (Cmax)

End point title	Mean Maximum Drug Plasma Concentration (Cmax)

End point description:

Cmax is the highest plasma drug concentration observed on the plasma concentration-time curve. The maximum observed plasma concentration of E3810 was obtained directly from the data, with and without interpolation. PK parameters were summarized using descriptive statistics. The average bioequivalence (BE) was used for testing bioequivalence of AUC.

End point type	Primary

End point timeframe:

Day 1 of Period 1 and 2; Predose (-1 hour) and at 30 minutes, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 10, 12, 14, and 16 hours postdose.

End point values	Rabeprazole sodium (Reference)	Enteric-coated microgranule rabeprazole sodium (Test)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: ng/mL				
geometric mean (standard deviation)	256.4 (± 28.51)	173.6 (± 20.12)		

Statistical analyses

Statistical analysis title	Statistical Analysis of Cmax

Statistical analysis description:

Per Food and Drug Administration (FDA) recommended criteria, the 90% confidence interval (CI) for the geometric Test/Reference mean had to be within the 80% to 125% interval in order to have a conclusion of average bioequivalence of the two formulas. Due to the nature of normal theory CIs, this is equivalent to performing two one-sided test of hypothesis at the 5% level of confidence.

Comparison groups	Rabeprazole sodium (Reference) v Enteric-coated microgranule rabeprazole sodium (Test)
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	equivalence[9]
P-value	= 0.0017 [10]
Method	t-test, 2-sided
Parameter estimate	Ratio of Test/Reference
Point estimate	65.89
Confidence interval	
level	90 %
sides	2-sided
lower limit	50.61
upper limit	81.17

Notes:

[9] - The bioequivalence of rabeprazole sodium tablet (Reference) and rabeprazole sodium enteric-coated microgranules (Test) was analyzed.
[10] - Statistical tests were two-sided and at the significance alpha level of less than or equal to 0.05.

Primary: Mean Log Transformed Values for Cmax

End point title	Mean Log Transformed Values for Cmax

End point description:

End point type	Primary

End point timeframe:

Day 1 of Period 1 and 2; Predose (-1 hour) and at 30 minutes, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 10, 12, 14, and 16 hours postdose

End point values	Rabeprazole sodium (Reference)	Enteric-coated microgranule rabeprazole sodium (Test)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: ng/mL				
geometric mean (standard deviation)	2.36 (± 0.056)	2.181 (± 0.067)		

Statistical analyses

Statistical analysis title	Statistical Analysis for Log Cmax

Statistical analysis description:

Per Food and Drug Administration (FDA) recommended criteria, the 90% confidence interval (CI) for the geometric Test/Reference mean had to be within the 80% to 125% interval in order to have a

conclusion of average bioequivalence of the two formulas. Due to the nature of normal theory CIs, this is equivalent to performing two one-sided test of hypothesis at the 5% level of confidence.

Comparison groups	Rabeprazole sodium (Reference) v Enteric-coated microgranule rabeprazole sodium (Test)
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	equivalence[11]
P-value	= 0.0058 [12]
Method	t-test, 2-sided
Parameter estimate	Ratio of Test/Reference
Point estimate	64.77
Confidence interval	
level	90 %
sides	2-sided
lower limit	51.28
upper limit	81.81

Notes:

[11] - The bioequivalence of rabeprazole sodium tablet (Reference) and rabeprazole sodium enteric-coated microgranules (Test) was analyzed.
[12] - Statistical tests were two-sided and at the significance alpha level of less than or equal to 0.05.

Primary: Mean Elimination of Half-life during the Apparent Terminal Disposition Phase (t1/2λz)

End point title	Mean Elimination of Half-life during the Apparent Terminal Disposition Phase (t1/2λz)

End point description:

The elimination of half-life during the apparent terminal disposition phase was calculated as 0.693/λz. Participants 11, 12, 14, and 15 were excluded due to missing or non-reportable PK parameters.

End point type	Primary

End point timeframe:

Day 1 of Period 1 and 2; Predose (-1 hour) and at 30 minutes, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 10, 12, 14, and 16 hours postdose

End point values	Rabeprazole sodium (Reference)	Enteric-coated microgranule rabeprazole sodium (Test)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: hours				
geometric mean (standard deviation)	0.916 (± 0.136)	0.937 (± 0.071)		

Statistical analyses

Statistical analysis title	Statistical Analysis of Elimination of Half-life

Statistical analysis description:

The bioequivalence of rabeprazole sodium tablet (Reference) and rabeprazole sodium enteric-coated microgranules (Test) was analyzed.

Comparison groups	Rabeprazole sodium (Reference) v Enteric-coated microgranule rabeprazole sodium (Test)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.9797 [13]
Method	t-test, 2-sided

Notes:

[13] - Statistical tests were two-sided and at the significance alpha level of less than or equal to 0.05.

Primary: Mean Time of Maximum Observed Plasma Concentration (Tmax)

End point title	Mean Time of Maximum Observed Plasma Concentration (Tmax)

End point description:

Time of maximum observed plasma concentration of E3810 was obtained directly from the data, with and without interpolation. Evaluable population was used and included all participants who satisfied all inclusion and none of the exclusion criteria, completed both study periods, and had no compliance or assay issues.

End point type	Primary

End point timeframe:

Day 1 of Period 1 and 2; Predose (-1 hour) and at 30 minutes, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 10, 12, 14, and 16 hours postdose.

End point values	Rabeprazole sodium (Reference)	Enteric-coated microgranule rabeprazole sodium (Test)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: hours				
geometric mean (standard deviation)	3.844 (± 0.24)	2.367 (± 0.192)		

Statistical analyses

Statistical analysis title	Statistical Analysis of Tmax
Comparison groups	Enteric-coated microgranule rabeprazole sodium (Test) v Rabeprazole sodium (Reference)
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	equivalence[14]
P-value	= 0 [15]
Method	t-test, 2-sided

Notes:

[14] - The bioequivalence of rabeprazole sodium tablet (Reference) and rabeprazole sodium enteric-coated microgranules (Test) was analyzed.
[15] - Statistical tests were two-sided and at the significance alpha level of less than or equal to 0.05.

Secondary: Overall Acceptance of Palatability of Enteric-Coated Microgranule Rabeprazole sodium

End point title	Overall Acceptance of Palatability of Enteric-Coated Microgranule Rabeprazole sodium

End point description:

The palatability questionnaire was administered within 5 minutes of receiving the enteric-coated microgranule formulation of rabeprazole sodium. The parameters of 'taste', 'smell', 'texture (smoothness)', 'after taste', and 'overall acceptance' were investigated. The final analysis of palatability for all categories was expressed as the percentage of participants who indicated a response of "like", "dislike", "like very much", and "neither like nor dislike". Only participants who received the enteric-coated microgranule formulation of rabeprazole sodium oral suspension.

End point type	Secondary

End point timeframe:

Within 5 minutes of receiving enteric-coated microgranule formulation of rabeprazole sodium

End point values	Enteric-coated microgranule rabeprazole sodium (Test)			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Percentage of participants				
number (not applicable)				
Dislike (n = 1)	6.7			
Like (n = 7)	46.7			
Like very much (n = 4)	26.7			
Neither like nor dislike (n = 2)	13.3			
Missing (n = 1)	6.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Palatability Taste Test Ratings of Enteric-Coated Microgranule Rabeprazole sodium

End point title	Palatability Taste Test Ratings of Enteric-Coated Microgranule Rabeprazole sodium

End point description:

The palatability questionnaire was administered within 5 minutes of receiving the enteric-coated microgranule formulation of rabeprazole sodium. The parameters of 'taste', 'smell', 'texture (smoothness)', 'after taste', and 'overall acceptance' were investigated. The final analysis of palatability for all categories was expressed as the percentage of participants who indicated a response of "like", "dislike", "like very much", and "neither like nor dislike". Only participants who received the enteric-coated microgranule formulation of rabeprazole sodium oral suspension.

End point type	Secondary

End point timeframe:

Within 5 minutes of receiving enteric-coated microgranule formulation of rabeprazole sodium

End point values	Enteric-coated microgranule rabeprazole sodium (Test)			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Percentage of participants				
number (not applicable)				
Dislike (n = 2)	13.3			
Like (n = 7)	46.7			
Like very much (n = 4)	26.7			
Neither like nor dislike (n = 2)	13.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Palatability Texture (Smoothness) Test Ratings of Enteric-Coated Microgranule Rabeprazole sodium

End point title	Palatability Texture (Smoothness) Test Ratings of Enteric-Coated Microgranule Rabeprazole sodium

End point description:

The palatability questionnaire was administered within 5 minutes of receiving the enteric-coated microgranule formulation of rabeprazole sodium. The parameters of 'taste', 'smell', 'texture (smoothness)', 'after taste', and 'overall acceptance' were investigated. The final analysis of palatability for all categories was expressed as the percentage of participants who indicated a response of “like”, “dislike”, “like very much”, and “neither like nor dislike”. Only participants who received the enteric-coated microgranule formulation of rabeprazole sodium oral suspension.

End point type	Secondary

End point timeframe:

Within 5 minutes of receiving enteric-coated microgranule formulation of rabeprazole sodium

End point values	Enteric-coated microgranule rabeprazole sodium (Test)			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Percentage of participants				
number (not applicable)				
Dislike very much (n = 1)	6.7			
Like (n = 5)	33.3			
Like very much (n = 2)	13.3			
Neither like nor dislike (n = 7)	46.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Palatability After Taste Test Ratings of Enteric-Coated Microgranule Rabeprazole sodium

End point title	Palatability After Taste Test Ratings of Enteric-Coated Microgranule Rabeprazole sodium

End point description:

The palatability questionnaire was administered within 5 minutes of receiving the enteric-coated microgranule formulation of rabeprazole sodium. The parameters of 'taste', 'smell', 'texture (smoothness)', 'after taste', and 'overall acceptance' were investigated. The final analysis of palatability for all categories was expressed as the percentage of participants who indicated a response of “like”, “dislike”, “like very much”, and “neither like nor dislike”. Only participants who received the enteric-coated microgranule formulation of rabeprazole sodium oral suspension.

End point type	Secondary

End point timeframe:

Within 5 minutes of receiving enteric-coated microgranule formulation of rabeprazole sodium

End point values	Enteric-coated microgranule rabeprazole sodium (Test)			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Percentage of participants				
number (not applicable)				
Dislike (n = 2)	13.3			
Like (n = 4)	26.7			
Like very much (n = 4)	26.7			
Neither like nor dislike (n = 5)	33.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Palatability Smell Test Ratings of Enteric-Coated Microgranule Rabeprazole sodium

End point title	Palatability Smell Test Ratings of Enteric-Coated Microgranule Rabeprazole sodium

End point description:

The palatability questionnaire was administered within 5 minutes of receiving the enteric-coated microgranule formulation of rabeprazole sodium. The parameters of 'taste', 'smell', 'texture (smoothness)', 'after taste', and 'overall acceptance' were investigated. The final analysis of palatability for all categories was expressed as the percentage of participants who indicated a response of “like”, “dislike”, “like very much”, and “neither like nor dislike”. Only participants who received the enteric-coated microgranule formulation of rabeprazole sodium oral suspension.

End point type	Secondary

End point timeframe:

Within 5 minutes of receiving enteric-coated microgranule formulation of rabeprazole sodium

End point values	Enteric-coated microgranule rabeprazole sodium (Test)			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Percentage of participants				
number (not applicable)				
Dislike (n = 1)	6.7			
Like (n = 6)	40			
Like very much (n = 1)	6.7			
Neither like nor dislike (n = 7)	46.7			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from the day of signed informed consent to the discharge study visit, or for approximately 12 days.

Adverse event reporting additional description:

Adverse events were recorded as treatment-emergent signs and symptoms (TESS), which is the same as treatment-emergent adverse events for this study. The Safety Population included all participants who took at least one dose of either formulation of rabeprazole sodium.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	7.1

Reporting groups

Reporting group title	Rabeprazole sodium tablet

Reporting group description:

Participants were administered 10-mg rabeprazole tablet followed by a 1-week washout period after which they were administered 10-mg rabeprazole microgranule formulation.

Reporting group title	Rabeprazole sodium (microgranule formula)

Reporting group description:

Participants were administered 10-mg rabeprazole microgranule formulation followed by a 1-week washout period after which they were administered 10-mg rabeprazole tablet.

Serious adverse events	Rabeprazole sodium tablet	Rabeprazole sodium (microgranule formula)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Rabeprazole sodium tablet	Rabeprazole sodium (microgranule formula)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported