

Demography

Date of Birth |__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|
 Month Day Year

Sex 1__M 2__F

Ethnicity 1 Hispanic or Latino 2 Not Hispanic or Latino

Race: 1 White 4 Asian
 2 Black or African American 5 Native Hawaiian/Other Pacific Islander
 3 American Indian/Alaska Native 6 Other

Date Consent Signed |__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|
 Month Day Year

DNA Dyspepsia 0__No 1__Yes
 Mayo 0__No 1__Yes
 Outside Mayo 0__No 1__Yes

Relevant Medical History/Current Medical Conditions

- Please list all relevant medical history and current medical conditions not related to the study indication, until the start of the study drug.
- Where possible please give the diagnosis, not the symptom.
- If there are none, enter **NONE**.

Active Problem
 0=No
 1=Yes

History/Condition (use precise medical terminology)	Date of Diagnosis/Surgery (partial if necessary)	Active Problem at Start of Study Drug
1. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
2. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
3. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
4. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
5. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
6. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
7. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
8. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
9. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
10. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
11. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____
12. _____	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Month Day Year	_____

Is an additional Relevant Medical History/Current Medical Conditions page used? 0__No 1__Yes

Relevant Medical History/Current Medical Conditions—cont.

- Please list all relevant medical history and current medical conditions not related to the study indication, until the start of the study drug.
- Where possible please give the diagnosis, not the symptom.
- If there are none, enter **NONE**.

Active Problem 0=No 1=Yes
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History/Condition (use precise medical terminology)	Date of Diagnosis/Surgery (partial if necessary)	Active Problem at Start of Study Drug																				
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Month	Day	Year																				
Is an additional Relevant Medical History/Current Medical Conditions page used?		0 ___ No 1 ___ Yes																				

Allergies: (If there are none, enter **NONE**.)

Reaction:

- | | |
|---|---|
| 1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____ | _____

_____ |
|---|---|

Is there an additional allergy page used?

0 ___ No 1 ___ Yes

Concomitant Medication/Significant Non-Drug Therapies

- Please list all medication and significant non-drug therapies.
- If there are none, enter **NONE**.

Medication/Non-Drug Therapy (use trade name if possible & dose)	Reason (Including Prophylaxis)
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____
6. _____	_____
7. _____	_____
8. _____	_____
9. _____	_____
10. _____	_____
11. _____	_____
12. _____	_____
13. _____	_____
14. _____	_____
15. _____	_____
16. _____	_____
17. _____	_____

Is an additional Concomitant Medications/Significant Non-Drug Therapies page used? 0__No 1__Yes

Please ensure that the data on this page are consistent with the data on the Relevant Medical History/Current Medical Conditions page.

Exclusion Criteria (To be eligible, all answers should be a No response)

	0=No	1=Yes
1. In the past year, patient has had a history of endoscopic esophagitis.	_____	_____
2. In the past year, patient has had a history of predominant heartburn or acid regurgitation (GERD).	_____	_____
3. In the past year, patient has had an adequate response to antisecretory therapy.	_____	_____
4. Patient has a documented peptic ulcer.	_____	_____
5. Patient has regularly used non-steroidal anti-inflammatory drugs (except long term low dose aspirin \leq 325 mg/day).	_____	_____
6. Patient is undergoing psychiatric treatment.	_____	_____
7. Patient has a history of drug or alcohol abuse.	_____	_____
8. Patient is taking psychotropic medication	_____	_____
9. Patient has a history of abdominal surgery (except appendectomy, cholecystectomy, or hysterectomy).	_____	_____
10. Patient has a concurrent major physical illness (e.g. cardiac disease, liver disease, diabetes, inflammatory bowel disease, glaucoma, urinary retention, active thyroid disease, vasculitis, lactose intolerance).	_____	_____
11. Patient has a concurrent psychotic illness or eating disorder.	_____	_____
12. Patient has literary skills that are insufficient to complete self report questionnaires.	_____	_____
13. Patient is pregnant.	_____	_____
14. Patient refuses to apply adequate contraceptive measures during the trial. Adequate contraceptive measures include use condoms in addition to birth control such as birth control pills, diaphragm, or intrauterine device OR use of long acting injection such as medroxyprogesterone acetate (e.g. Depo-Provera).	_____	_____

History

HIB

Has subject been diagnosed with FD (functional dyspepsia)?

___ **0 = No** ___ **1 = Yes**

When was subject diagnosed?

____|____|____|____|____|____|____|____|
Month Day Year

Endoscopy

Date of Endoscopy

____|____|____|____|____|____|____|____|
Month Day Year

Results: _____

0 = Normal
1 = Abnormal
2 = Erythema

EGD

Must have documented EGD in last 5 years, must have results as source document. If no EGD, fill in once the EGD is completed and results are in. Participant has to have EGD with results prior to randomization.

Vital Signs

Please mark if evaluation was not done

Any significant findings after the start of the study drug should be recorded on the Adverse Events page.

Please circle the correct measurement, when applicable.

Height _____ cm. or inches

Weight _____ kg or lb

BMI _____

Waist Measurement _____ cm.

Sitting Pulse _____ bpm

Sitting Blood Pressure _____ / _____
systolic/diastolic
MmHg

Respirations _____ /minute

Temperature _____ degrees Centigrade or Fahrenheit

Physical Examination _____ **0** = Passed

1 = Failed

Specify Abnormality/findings:

ECG

ECG Evaluation

Please mark if evaluation was not done

Any significant findings before the start of the study drug should be recorded on the Current Medical Conditions page.

Date of ECG:

_ _	_ _	_ _ _ _ _
Month	Day	Year

Overall interpretation:

- 1__ Normal
- 2__ Clinically insignificant abnormality
- 3__ Clinically significant abnormality

If clinically significant
please specify one
abnormality per line

- 1. _____
- 2. _____
- 3. _____
- 4. _____
- 5. _____
- 6. _____