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BY DOMAIN

BY VISIT

	☐ NOT DONE
If test was not done, please enter an explanation in the General Comments Log	
Date of assessment: (dd-mmm-yyyy)	/ /
Was supplemental oxygen used during walk?	☐ Yes ☐ No
If yes, specify: (L/min)	
Pre-test oxygen saturation by pulse oximetry: (SpO_2)	
Pre-test heart rate: (BPM)	
Pre-test shortness of breath grade using Borg Scale: (0-10)	
Pre-test fatigue grade using Borg Scale: (0-10)	
Post-test oxygen saturation by pulse oximetry: (SpO_2)	
Post-test heart rate: (BPM)	
Post-test shortness of breath grade using Borg Scale: (0-10)	
Post-test fatigue grade using Borg Scale: (0-10)	
Was a walking aid necessary to perform the 6MWT?	☐ Yes ☐ No
If yes, specify:	☐ Cane ☐ Walker ☐ Other

If Other, specify:	
Distance Walked: (to the nearest foot or meter)	Feet/ Meters
Did subject complete 6-minute walk?	Yes No
If No, duration: (min/sec)	
If subject stopped early, specify reason:	Developed respiratory signs and symptoms requiring termination of test Other
If Other, specify:	

Project Name: GS-US-219-0101
Form: Adverse Events Log *[AE]*
Generated On: Aug-13-2013 06:16:26

Did the subject experience any Adverse Events during the study?	☐ Yes ☐ No
Adverse Event:	
AE serious?	☐ Yes ☐ No
Start Date: (dd-mmm-yyyy)	/ /
Did the AE start after first exposure to study drug?	☐ Yes ☐ No
Duration if less than 24 Hours: *Please record number of hours and minutes of event duration*	
Is AE ongoing?	☐ Yes ☐ No
If No, Stop Date: (dd-mmm-yyyy)	/ /
Related to Study Drug:	☐ Yes ☐ No
If No, Specify Etiology:	
Related to Study Procedures:	☐ Yes ☐ No

Study Drug Action Taken:	☐ No change ☐ Interrupted ☐ Discontinued ☐ Dose Reduced ☐ Dose Increased ☐ Not applicable
Severity:	☐ Mild ☐ Moderate ☐ Severe ☐ Life-Threatening
Other Action Taken (check all that apply):	☐
	☐
	☐
	☐
Check if AE led to study withdrawal:	☐
Derivation for AE.AEDURH.001: Start Date + 1 Day	/ /

Name of antibiotic subject is allergic to:	
Specify symptoms of the allergic reaction below: *(check all that apply)*	
	☐
	☐
	☐
	☐
	☐
	☐
	☐

Record any antibiotic use in the past 12 months

Drug Name:	
Indication:	
Route of Administration:	☐ aural ☐ G-tube ☐ inhalation ☐ intramuscular ☐ intranasal ☐ intravenous ☐ ophthalmic ☐ oral ☐ rectal ☐ subcutaneous ☐ sublingual ☐ topical ☐ transdermal ☐ vaginal ☐ not applicable ☐ unknown
Medication start date: (dd-mmm-yyyy)	/ /
Duration:	
Duration Units:	☐ Day(s) ☐ Week(s) ☐ Month(s) ☐ Year(s)

Reporting method:	☐ subject reported ☐ source verified ☐ subject reported/source verified (combination) ☐ not available
Was this antibiotic used to treat an exacerbation of the subject's bronchiectasis?	☐ Yes ☐ No

Sample Collected?	☐ Yes ☐ No
If Yes, Date Sample Collected: (dd-mmm-yyyy)	/ /

Date of Diagnosis: (dd-mmm-yyyy)	/ /
Please specify Etiology:	☐ ABPA ☐ Aspiration/GERD ☐ Ciliary Dysfunction ☐ Idiopathic ☐ Immune Defect ☐ Post Infection ☐ Rheumatoid Arthritis ☐ Ulcerative Colitis ☐ Young's Syndrome ☐ Other

Bronchodilator Administration

Was a bronchodilator administered?	☐ Yes ☐ No
If yes, where?	☐ In clinic ☐ At home
Time administered: (24 hour clock; hh:mm)	:
Specify the bronchodilator administered:	☐ albuterol / salbutamol ☐ levalbuterol ☐ formoterol ☐ isoetharine ☐ isoproterenol ☐ metaproterenol ☐ pirbuterol ☐ procaterol ☐ terbutaline ☐ salmeterol ☐ Other
If Other, specify:	

Spirometry

Was Spirometry Data Collected?	☐ Yes ☐ No
Time of Spirometry: (24 hour clock; hh:mm)	:
FEV1 Actual: (L)	

FVC: (L)	
FEF 25-75%: (L/sec)	
FEV1 Normal Predicted: (L)	
FEV1 Percent Predicted: (%)	

Bronchodilator Administration

Was a bronchodilator administered?	☐ Yes ☐ No
If yes, where?	☐ In clinic ☐ At home
Time administered: (24 hour clock; hh:mm)	:
Specify the bronchodilator administered:	☐ albuterol / salbutamol ☐ levalbuterol ☐ formoterol ☐ isoetharine ☐ isoproterenol ☐ metaproterenol ☐ pirbuterol ☐ procaterol ☐ terbutaline ☐ salmeterol ☐ Other
If Other, specify:	

Spirometry

Was Spirometry Data Collected?	☐ Yes ☐ No
Time of Spirometry: (24 hour clock; hh:mm)	:
FEV1 Actual: (L)	

FVC: (L)	
FEF 25-75%: (L/sec)	

Was data collected for this page?	☐ Yes ☐ No
Did subject have a Chest X-Ray performed?	☐ Yes ☐ No
Date Chest X-Ray Performed: (dd-mmm-yyyy)	/ /

Project Name: GS-US-219-0101
Form: Concomitant Medications Log *[CM]*
Generated On: Aug-13-2013 06:16:26

Was subject on any medications or therapies at Visit 1 or during the course of the study?	☐ Yes ☐ No
Drug Name:	
Indication:	
Dose: **If dose is a range, please enter the highest value of the range.**	

Unit:

- ☐ caps
- ☐ drops
- ☐ gtts
- ☐ grain
- ☐ gram
- ☐ I/U
- ☐ liter
- ☐ mcg
- ☐ mEq
- ☐ mg
- ☐ mg/kg
- ☐ minutes
- ☐ mL
- ☐ ng
- ☐ ounce
- ☐ puff
- ☐ spray
- ☐ tabs
- ☐ tsp
- ☐ units
- ☐ not applicable
- ☐ unknown

Frequency:

- [ ] bid
- [ ] biw
- [ ] burst
- [ ] continuous
- [ ] L/min
- [ ] prn
- [ ] qam
- [ ] qd
- [ ] qhs
- [ ] qid
- [ ] qmo
- [ ] qod
- [ ] qwk
- [ ] q4h
- [ ] q6h
- [ ] q8h
- [ ] taper
- [ ] tid
- [ ] titrate
- [ ] tiw
- [ ] with meals
- [ ] with snack
- [ ] x1
- [ ] not applicable
- [ ] unknown

Route of Administration:	☐ aural ☐ G-tube ☐ inhalation ☐ intramuscular ☐ intranasal ☐ intravenous ☐ ophthalmic ☐ oral ☐ rectal ☐ subcutaneous ☐ sublingual ☐ topical ☐ transdermal ☐ vaginal ☐ not applicable ☐ unknown
Has subject been taking medication for >30 days?	☐ Yes ☐ No
If No, please enter Start Date: (dd-mmm-yyyy)	/ /
Check if ongoing	☐
If Not, please enter Stop Date: (dd-mmm-yyyy)	/ /
Used to Treat:	☐ Adverse Event ☐ Pre-Existing Condition ☐ Prophylaxis ☐ NA

Project Name: GS-US-219-0101
Form: Death Report *[DEATH]*
Generated On: Aug-13-2013 06:16:26

Date of Death: (DD-MMM-YYYY)	/ /
Immediate Cause of Death:	

Reminder: Please complete an SAE Report for any Death that occurs during study or within 30 days of last dose of study drug.

Project Name: GS-US-219-0101
Form: Demographics *[DM]*
Generated On: Aug-13-2013 06:16:26

Date of Birth: (dd-mmm-yy)	/ /
Sex:	☐ Male ☐ Female
Ethnicity:	☐ Hispanic ☐ Not Hispanic ☐ Not Permitted
Race:	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African Heritage ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Other ☐ Not permitted
Derived Age	

Project Name: GS-US-219-0101
Form: EQ-5D *[QS_EQ5D]*
Generated On: Aug-13-2013 06:16:26

Question	
	☐ Mobility ☐ Self-Care ☐ Usual Activities (e.g. work, study, housework, family or leisure activities) ☐ Pain/Discomfort ☐ Anxiety/Depression ☐ Your own health state today
Response	☐

Related to Form:

- [ ] 6-Minute Walk Test
- [ ] Adverse Events Log
- [ ] Antibiotic Allergy Log
- [ ] Antibiotic Therapy Status Log
- [ ] Blood Sample for Chemistry and Hematology
- [ ] Bronchiectasis Diagnosis
- [ ] Bronchodilator and Spirometry
- [ ] Bronchodilator and Spirometry (Screening)
- [ ] Chest X-Ray
- [ ] Concomitant Medications Log
- [ ] Death Report
- [ ] Demographics
- [ ] EQ-5D
- [ ] Global Rating of Change
- [ ] Hospitalization Log
- [ ] Informed Consent
- [ ] Investigator’s Signature
- [ ] Laboratory Retest Log
- [ ] Medical History Log
- [ ] Non-Study Antibiotics for Worsening Respiratory Signs and Symptoms
- [ ] Paper CRF Administration
- [ ] Physical Examination
- [ ] Pregnancy Report
- [ ] Prescription of Non-Study Antibiotics for Respiratory Indications
- [ ] QOLB
- [ ] Screen Failure
- [ ] Screening Number
- [ ] Screening Status

- [ ] Serum Beta-HCG Pregnancy Test
- [ ] Serum Beta-HCG Pregnancy Test (Screening)
- [ ] Smoking History
- [ ] Spirometry - 60-Min Post-Treatment (Change from Pre-Treatment)
- [ ] Spirometry - Post-Treatment (Change from Pre-Treatment)
- [ ] Sputum Sample for Microbiology
- [ ] Study Completion
- [ ] Study Drug Accountability Log
- [ ] Study Drug Completion
- [ ] Subject Characteristics and Vital Signs
- [ ] Subject Number
- [ ] Subject Study Status
- [ ] Subject Study Status (End of Study)
- [ ] Surgical and Medical Procedures Log
- [ ] Treatment Administration
- [ ] Treatment Dose Prior to Sputum Collection
- [ ] Urine Beta-HCG Pregnancy Test
- [ ] Visit Date

Project Name: GS-US-219-0101
Form: General Comments Log *[CO]*
Generated On: Aug-13-2013 06:16:26

Visit:	☐ Visit 1 ☐ Visit 2 ☐ Visit 3 ☐ Visit 4 ☐ Visit 5 ☐ Visit 6 ☐ Visit 7 ☐ Visit 8 ☐ Visit 9 ☐ Visit 10 ☐ Visit: Early Termination ☐ Visit: Unscheduled ☐ NA
Is this a protocol deviation/violation?	☐ Yes ☐ No
Comment:	

If commenting about a laboratory value, provide the test name and test value (include date, ifapplicable). If commenting about an Adverse Event, provide date of event.

GRCQ Version Number	☐ 2.2 ☐ 3.0
Question	☐ 1. In the last 2 weeks, have there been any changes in your PHYSICAL functioning (e.g., ability to walk and engage in physical activities) related to your bronchiectasis? ☐ 2. In the last 2 weeks, have there been any changes in your RESPIRATORY symptoms (e.g., coughing, mucus production, wheezing) related to your bronchiectasis? ☐ 3. In the last 2 weeks, have there been any changes in your PERCEPTIONS OF YOUR HEALTH (e.g., how healthy you feel) related to your bronchiectasis? ☐ 4. In the last 2 weeks, have there been any changes in your VITALITY (e.g., energy level) related to your bronchiectasis? ☐ 5. In the last 2 weeks, have there been any changes in your ROLE functioning (e.g., ability to keep up with your job, housework or other daily activities) related to your bronchiectasis? ☐ 6. In the last 2 weeks, have there been any changes in your EMOTIONAL funtioning (e.g., how anxious or sad you feel) related to your bronchiectasis? ☐ 7. In the last 2 weeks, have there been any changes in your SOCIAL functioning (e.g., interactions with others, including partners, relatives, and friends) related to your bronchiectasis? ☐ 8. In the last 2 weeks, have there been any changes in your TREATMENT BURDEN (e.g., ability to fit in your treatments) related to your bronchiectasis?
Response	☐

Project Name: GS-US-219-0101
Form: Hospitalization Log *[HOSP]*
Generated On: Aug-13-2013 06:16:27

Reason for Hospitalization:	
Date of Admission: (dd-mmm-yyyy)	/ /
Date of Discharge: (dd-mmm-yyyy)	/ /

Reminder: Please complete an SAE Report for any Hospitalization.

Protocol Version Date: (dd-mmm-yyyy)	/ /
Date Informed Consent signed by subject: (dd-mmm-yyyy)	/ /

Project Name: GS-US-219-0101

Form: Investigator's Signature *[INVSIG]*

Generated On: Aug-13-2013 06:16:27

By entering my Medidata password, I affirm that I have reviewed and evaluated the case reportforms and verify that they accurately reflect the information in the source documents for thissubject. I understand source documentation can include (but is not limited to) medical records,laboratory results, x-rays, electronic communications, etc.	

Sample collected for:	☐ Chemistry ☐ Hematology ☐ Serum Pregnancy ☐ Microbiology
Retest of sample originally scheduled for:	☐ Visit 1 ☐ Visit 2 ☐ Visit 3 ☐ Visit 4 ☐ Visit 5 ☐ Visit 6 ☐ Visit 7 ☐ Visit 8 ☐ Visit 9 ☐ Visit 10 ☐ Visit: Early Termination ☐ Visit: Unscheduled
Date sample collected: (dd-mmm-yyyy)	/ /
Reason for retest:	☐ Follow-up of elevated non-significant value ☐ Follow-up of clinically significant value ☐ Redraw of previously inevaluable sample ☐ Other
If Other, specify:	

Body System:	☐ Head, Neck & Thyroid ☐ Eyes, Ears, Nose, Throat, Mouth & Tongue ☐ Chest (including Breasts) ☐ Respiratory ☐ Cardiovascular ☐ Lymph Nodes ☐ Gastrointestinal (including Hepatic) ☐ Urogenital ☐ Skin, Nails & Hair ☐ Musculoskeletal ☐ CNS (Neurological, Psychiatric) ☐ Endocrine/Metabolic ☐ Other
Condition:	☐
Status:	☐ Ongoing ☐ Resolved

What were the signs and/or symptoms indicating need for antibiotics? (check all that apply)	
Increased sputum production	☐
Increased discoloration of sputum	☐
Increased dyspnea	☐
Increased cough	☐
Fever (> 38 C) measured by a medical provider	☐
Increased malaise, or fatigue	☐
FEV1 (L) or FVC (L) decreased > 10% from Visit 2	☐
New or increased hemoptysis	☐
Other	☐
If Other, specify:	
If there was a hospitalization associated with the above signs and symptoms, enter hospital admission date: (dd-mmm-yyyy)	/ /
Please list all Concomitant Medication log line numbers for medications that were used to treat these symptoms:	

Was the QOL-B administered at this visit?	☐ Yes ☐ No
If yes, was the QOL-B administered prior to all other visit procedures?	☐ Yes ☐ No
Was the GRCQ administered at this visit?	☐ Yes ☐ No ☐ NA
If yes, was the GRCQ administered prior to all other visit procedures?	☐ Yes ☐ No
Was the EQ-5D administered at this visit?	☐ Yes ☐ No ☐ NA
If yes, was the EQ-5D administered prior to all other visit procedures?	☐ Yes ☐ No

Was Physical Exam Performed?	☐ Yes ☐ No
If Yes, were there any abnormal findings?	☐ Yes ☐ No

If Yes, select the appropriate body system(s) for each abnormal finding.

Body System	☐ Head, Neck & Thyroid ☐ Eyes, Ears, Nose, Throat, Mouth & Tongue ☐ Chest (including Breasts) ☐ Respiratory ☐ Cardiovascular ☐ Lymph Nodes ☐ Abdomen ☐ Skin, Nails & Hair ☐ Musculoskeletal ☐ Neurological ☐ Other
Describe abnormal findings:	

Project Name: GS-US-219-0101
Form: Pregnancy Report *[PREGREP]*
Generated On: Aug-13-2013 06:16:27

Last Menstrual Period (LMP): (dd-mmm-yyyy)	/ /
Pregnancy Confirmed: (dd-mmm-yyyy)	/ /
Estimated Date of Delivery (by LMP): (dd-mmm-yyyy)	/ /

Reminder: If pregnancy occurs, please complete as much information as possible on this form. In addition to this eCRF, please complete the 'Pregnancy Report' paper form within 24 hours of learning of the pregnancy and fax to ICON Safety Department. At the conclusion of the pregnancy, complete the paper 'Pregnancy Outcome Report' and submit to ICON Safety Department.

Were Non-Study antibiotics prescribed for worsening respiratory signs and symptoms?	☐ Yes ☐ No

Question

- ☐ 1. Performing vigorous activities, such as gardening or exercising
- ☐ 2. Walking as fast as others (family, friends, etc.)
- ☐ 3. Carrying or lifting heavy things, such as books, groceries, or shopping bags
- ☐ 4. Climbing one flight of stairs
- ☐ 5. You felt well
- ☐ 6. You felt tired
- ☐ 7. You felt anxious
- ☐ 8. You felt energetic
- ☐ 9. You felt exhausted
- ☐ 10. You felt sad
- ☐ 11. You felt depressed
- ☐ Are you currently on any treatments (such as oral or inhaled medications, PEP, of Flutter device, chest PT, or Vest) for bronchiectasis?
- ☐ 12. To what extent do your treatments for bronchiectasis make your daily life more difficult?
- ☐ 13. How much time do you currently spend each day on your treatments for bronchiectasis?
- ☐ 14. How difficult is it for you to fit in your treatments for bronchiectasis each day?
- ☐ 15. How do you think your health is now?
- ☐ 16. I have to limit vigorous activities, such as walking or exercising
- ☐ 17. I have to stay at home more than I want to
- ☐ 18. I am worried about being exposed to others who are sick
- ☐ 19. It is difficult to be intimate with a partner (kissing, hugging, etc.)
- ☐ 20. I lead a normal life
- ☐ 21. I am concerned that my health will get worse
- ☐ 22. I think my coughing bothers others
- ☐ 23. I often feel lonely
- ☐ 24. I feel healthy

	☐ 25. It is difficult to make plans for the future (e.g., vacation, attending family events, etc.) ☐ 26. I feel embarrassed when I am coughing ☐ 27. To what extent did you have trouble keeping up with your job, housework, or other daily activities? ☐ 28. How often does having bronchiectasis get in the way of meeting your work, household, family or personal goals? ☐ 29. Have you felt congestion in your chest? ☐ 30. Have you been coughing during the day? ☐ 31. Have you had to cough up mucus? ☐ 32. Has your sputum been mostly: ☐ 33. Have you had shortness of breath with greater activity, such as housework or yardwork? ☐ 34. Have you been wheezing? ☐ 35. Have you had chest pain? ☐ 36. Have you had shortness of breath when talking? ☐ 37. Have you woken up during the night because you were coughing?
Response	☐

Project Name: GS-US-219-0101
Form: Screen Failure *[SCRFAIL]*
Generated On: Aug-13-2013 06:16:27

Select a Reason for Screen Failure:	☐ Did not meet Inclusion/Exclusion criteria ☐ Withdrew Consent ☐ Other
If Reason is **Other**, please specify:	
For ineligible subjects, specify all criteria notsatisfied:	
Category:	☐ INCLUSION ☐ EXCLUSION

Inclusion/Exclusion criteria:

- ☐ Male/Female >= 18 years old
- ☐ Bronchiectasis confirmed by documented computed tomography (CT) scan within 5 years prior to Visit 1, or by prior approval of the Medical Monitor, without intervening lung resection
- ☐ Reported chronic sputum production on at least 4 days per week during the 4 weeks prior to Visit 1
- ☐ Positive sputum culture for target gram-negative organism(s) at Visit 1
- ☐ Documented history of positive sputum culture (or bronchoscopic culture) for a target gram-negative organism OR documented history of treatment with antibiotics with gram-negative coverage for an exacerbation of bronchiectasis within 5 years prior to Visit 1
- ☐ Chest X-Ray (CXR) obtained and interpreted at Visit 1 or between Visits 1 and 2, without significant acute findings (e.g., no new infiltrate). With prior approval of the Medical Monitor, a CXR obtained within 10 days prior to Visit 1 may be acceptable for study entry
- ☐ Forced expiratory volume in one second (FEV1) >= 20% predicted approximately 15 minutes post-bronchodilator at Visit 1
- ☐ Subject must provide written informed consent prior to any study-related procedures
- ☐ Command of the subject's local language
- ☐ Hospitalization within 14 days prior to Visit 1
- ☐ Reported episode of hemoptysis > 30 mL (approximately 2 tablespoons) within 14 days prior to Visit 1, on the day of Visit 1, and from Visit 1 through Visit 2
- ☐ History of hospitalization for embolization therapy to treat hemoptysis
- ☐ Antibiotics to treat respiratory symptoms (excluding chronic, stable treatment with a macrolide) within 14 days prior to Visit 1, on the day of Visit 1, and from Visit 1 through Visit 2
- ☐ Change in bronchodilator, inhaled corticosteroid, macrolide, or bronchial hygiene therapies within 28 days prior to Visit 1 and through study completion

- [ ] Change in systemic corticosteroid therapy within 28 days prior to Visit 1 and from Visit 1 through Visit 2. After Visit 2, systemic corticosteroid therapy (maximum of 14 days per course) will be allowed to treat worsening respiratory signs and/or symptoms
- [ ] Previous treatment with or exposure to Cayston (AZLI)
- [ ] Serious adverse event between Visits 1 and 2
- [ ] History of cystic fibrosis (CF) (i.e., sweat chloride >= 60 mEq/L OR two well characterized genetic mutations OR abnormal nasal potential difference)
- [ ] Current treatment for nontuberculous mycobacteria (NTM) infection
- [ ] Active mycobacterium tuberculosis (MTB) infection within one year prior to Visit 1
- [ ] Current treatment for, or morbidity related to non-dermatologic malignancy
- [ ] Administration of any investigational drug or use of any investigational device within 28 days prior to Visit 1and through study completion
- [ ] Known local or systemic hypersensitivity to aztreonam
- [ ] Known intolerance to inhaled short-acting bronchodilators
- [ ] History of New York Heart Association (NYHA) Class III or IV heart failure
- [ ] Serum creatinine > 2 times upper limit of normal range (ULN) at Visit 1
- [ ] Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) > 5 times ULN at Visit 1
- [ ] Continuous (24 hours/day) supplemental oxygen greater than 2 L per minute (supplemental oxygen greater than 2 L per minute with activity or at night is allowed)
- [ ] Females of childbearing potential with positive urine pregnancy test at Visit 1
- [ ] Females of childbearing potential who are lactating or are not (in the opinion of the investigator) practicing an acceptable method of birth control; female subjects who utilize hormonal contraceptives as their birth control method must have used the same method for at least 3 months before study dosing

	☐ Male subjects who do not agree to refrain from sperm donation from screening through study completion and for 90 days from the last dose of study drug. Male subjects must agree to use barrier contraception during heterosexual intercourse unless they meet at least one of the following criteria: (1) Have had a vasectomy with documented zero sperm count (2) Female partner is not of childbearing potential (3) Female partner is using one of the protocol specified methods of birth control ☐ Serious or active medical or psychiatric illness, unstable disease, or substance abuse that in the opinion of the investigator would interfere with subject treatment, assessment, or ability to comply with the protocol and study procedures
Criteria not met?	☐

Project Name: GS-US-219-0101
Form: Screening Number *[SCRNNO]*
Generated On: Aug-13-2013 06:16:27

Enter the assigned Screening Number:	
Has subject screened for this study previously?	☐ Yes ☐ No
If yes, please provide previous Screening Number:	

Did subject screen fail at this visit?	☐ Yes ☐ No

Project Name: GS-US-219-0101
Form: Serum - HCG Pregnancy Test *[LB_PTS]*
Generated On: Aug-13-2013 06:16:27

Date: (dd-mmm-yyyy)	/ /
Test Result:	☐ Negative ☐ Positive

***If the result is positive, please complete the Pregnancy Report eCRFs.**

Does subject have a prior history of smoking cigarettes?	☐ Yes ☐ No
If Yes, number of pack years:	
Does subject currently smoke cigarettes?	☐ Yes ☐ No
Does subject have a prior history of other inhaled tobacco use? (i.e. pipe, cigar)	☐ Yes ☐ No
If Yes, number of years:	

Project Name: GS-US-219-0101
Form: Spirometry - 60-Min Post-Treatment (Change from Pre-Treatment) *[SPR_PT60]*
Generated On: Aug-13-2013 06:16:27

Was Spirometry Data Collected?	☐ Yes ☐ No
Time of Spirometry: (24 hour clock; hh:mm)	:
FEV1 Actual: (L)	
FVC: (L)	
FEF 25-75%: (L/sec)	
FEV1 Actual Change from Pre-Treatment: (L)	
FEV1 Percent Change from Pre-Treatment: (%)	

If FEV1 drop was 15% from pre-treatment and not retested at 60 minutes, provide reason on General Comments Log.

Project Name: GS-US-219-0101
Form: Spirometry - Post-Treatment (Change from Pre-Treatment) *[SPR_PT]*
Generated On: Aug-13-2013 06:16:27

Was Spirometry Data Collected?	☐ Yes ☐ No
Time of Spirometry: (24 hour clock; hh:mm)	:
FEV1 Actual: (L)	
FVC: (L)	
FEF 25-75%: (L/sec)	
FEV1 Actual Change from Pre-Treatment: (L)	
FEV1 Percent Change from Pre-Treatment: (%)	

Was the subject able to producesputum?	☐ Yes ☐ No
Was a sample collected?	☐ Yes ☐ No
If Yes, Date Sample Collected:(dd-mmm-yyyy)	/ /

Project Name: GS-US-219-0101
Form: Study Completion *[DS_EOS]*
Generated On: Aug-13-2013 06:16:27

Did the subject complete the protocol-planned duration of the study?	☐ Yes ☐ No
If No, date of study discontinuation:(dd-mmm-yyyy)	/ /
If No, specify reason for study discontinuation:	☐ Safety or Tolerability Reasons ☐ Protocol Violation ☐ Withdrew Consent ☐ Lost to Follow-Up ☐ Investigator's Discretion ☐ Subject Never Dosed with Study Drug ☐ Study Discontinued by Sponsor ☐ Other
If Other, specify:	

Visit Vials Dispensed:	☐ Visit 2 ☐ Visit 5 ☐ Visit 7
Date Vials Dispensed: (dd-mmm-yyyy)	/ /
Number Vials Dispensed:	
Visit Vials Returned/Not Returned:	☐ Visit 4 ☐ Visit 6 ☐ Visit 8 ☐ Early Termination
Date Vials Returned/Not Returned: (dd-mmm-yyyy)	/ /
Number of Inhaled Vials Returned:	
Number of Inhaled Vials Not Returned:	
Number of Non-Inhaled Vials Returned:	
Number of Non-Inhaled Vials Not Returned:	

If all scheduled doses were not taken, explanatory comment is required in the General Comments Log.

Date of last dose: (dd-mmm-yyyy)	/ /
Did the subject complete the study drug treatment through the protocol-planned duration of thestudy?	☐ Yes ☐ No
If No, specify reason for early discontinuation of study drug treatment:	☐ Safety or Tolerability Reasons ☐ Protocol Violation ☐ Withdrew Consent ☐ Lost to Follow-Up ☐ Investigator's Discretion ☐ Subject Never Dosed with Study Drug ☐ Study Discontinued by Sponsor ☐ Other
If Other, specify:	

Project Name: GS-US-219-0101
Form: Subject Characteristics and Vital Signs *[VS]*
Generated On: Aug-13-2013 06:16:27

Was data collected for this page?	☐ Yes ☐ No
Height:	☐ cm/ in
	☐
Weight:	☐ kg/ lb
Temperature:	☐ Celsius/ Fahrenheit
Pulse (beats per minute):	☐
Pulse Units:	☐
Systolic Blood Pressure: (mmHg)	☐
Systolic Blood Pressure Units:	☐
Diastolic Blood Pressure: (mmHg)	☐
Diastolic Blood Pressure Units:	☐
Respiration: (breaths per minute)	☐
Respiration Units	☐

Enter the assigned Subject Number:

Did subject withdraw between their last visit and this visit?	☐ Yes ☐ No

Did subject withdraw between their last visit and this visit?	☐ Yes ☐ No
If no, did subject withdraw at this visit?	☐ Yes ☐ No

Body System:	☐ Head, Neck & Thyroid ☐ Eyes, Ears, Nose, Throat, Mouth & Tongue ☐ Chest (including Breasts) ☐ Respiratory ☐ Cardiovascular ☐ Lymph Nodes ☐ Gastrointestinal (including Hepatic) ☐ Urogenital ☐ Skin, Nails & Hair ☐ Musculoskeletal ☐ CNS (Neurological, Psychiatric) ☐ Endocrine/Metabolic ☐ Other
Procedure:	
Date of the procedure (dd-mmm-yyyy):	/ /

Was a clinic treatment dose administered to the subject?	☐ Yes ☐ No

If Yes,

Was sputum collected prior to treatmentadministration?	☐ Yes ☐ No
Date Clinic Dose Administered: (dd-mmm-yyyy)	/ /
START Time Clinic Dose Administered: (24-hour clock; hh:mm, 00:00-23:59)	:
STOP Time Clinic Dose Administered:(24-hour clock; hh:mm, 00:00-23:59)	:
Was the entire treatment dose delivered?	☐ Yes ☐ No
If entire treatment dose was NOT delivered, please indicatereason:	☐ Device malfunction ☐ Subject did not tolerate dose ☐ Other
If reason is Other, please specify:	

Project Name: GS-US-219-0101

Form: Treatment Dose Prior to Sputum Collection *[TDPSPUT]*

Generated On: Aug-13-2013 06:16:27

Was data collected for this page?	☐ Yes ☐ No
Was subject's last treatment dose at least 4 hours before Sputum forMicrobiology collection?	☐ Yes ☐ No

Project Name: GS-US-219-0101
Form: Urine - HCG Pregnancy Test *[LB_PTU]*
Generated On: Aug-13-2013 06:16:27

Check if Test Not Applicable (Check this box for male subjects or female subjects of non-childbearing potential.)	☐
Date: (dd-mmm-yyyy)	/ /
Test Result:	☐ Negative ☐ Positive

***If the result is positive, please complete the serum pregnancy form.**

	☐ NOT DONE
Visit Date: (dd-mmm-yyyy)	/ /

If visit did not occur, please enter an explanation in the General Comments Log