



Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Baseline Evaluations: Record clinically significant findings on the Medical History CRF**

**Clinical Laboratory Tests**

Were clinical labs completed?  Yes  No

**Previous Substance Abuse**

Previous Alcohol Abuse/dependence  Yes  No

**If yes,** in the last 60 days  Yes  No

Previous Drug Abuse/dependence  Yes  No

**If yes,** in the last 60 days  Yes  No

**Past Use of Ecstasy**

Has the subject ever used "Ecstasy"?  Yes  No

**If Yes,** # of Occasions \_\_\_\_\_

**If Yes,** most *recent* use was:

- Within the last six months
- 6 months to 2 years ago
- 2 years to 5 years ago
- More than 5 years ago

**Did subject meet all inclusion criteria?**  Yes  No

If No, Specify \_\_\_\_\_



Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Baseline Evaluations: Record clinically significant findings on the Medical History CRF**

Date of Evaluation \_\_\_\_\_  
 dd mmm yyyy

**CAPS Scoring, PTSD Diagnosis**

Record baseline CAPS, GAF, BDI and PTGI score completed during screening (pre wash out if it is needed)

Criterion A met (traumatic event)	Specify	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No	Frequency	Intensity
B (re-experiencing) sx ( $\geq 1$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
C (Avoidance) ( $\geq 3$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
D (Hyperarousal) ( $\geq 2$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
E (duration in months and is duration $\geq 1$ month)?	Total Months	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
F (Distress/impairment)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
CURRENT PTSD (Criteria A-F)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
PTSD Global	Score			

**Global Functioning Scale**

GAF	
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**Beck Depression Inventory (BDI)**

BDI Score	
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**PTGI**

PTGI Score	
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Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Baseline Evaluations: Record clinically significant findings on the Medical History CRF**

**Post Washout**

**Date of Evaluation** \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ or  **None**  
dd mmm yyyy

**CAPS Scoring**

Record CAPS , GAF, BDI and PTGI score post wash out and pre experimental session. If no washout was needed do not compete, check the None box above.

Criterion A met (traumatic event)			Frequency	Intensity
B (re-experiencing) sx (≥ 1)?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
C (Avoidance) (≥ 3)?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
D (Hyperarousal) (≥ 2)?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
E (duration in months and is duration ≥ 1 month)?	Total Months	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
F(Distress/impairment)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
CURRENT PTSD (Criteria A-F)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
PTSD Global	Score			

**Global Functioning Scale**

GAF	
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**Beck Depression Inventory (BDI)**

BDI Score	
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**PTGI**

PTGI Score	
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Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Previous Therapy**

Record any non drug therapy prior to enrollment. Use the codes provided for type of therapy. If a part of the date is not known write UNK, try to provide at least a year. Record any drug therapy on the Concomitant Medication page.

Type of Psychotherapy (use code 1-10)	If type = Code 10, Specify Other Therapy Type	# Sessions	Per <input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total	Start Date dd-mmm-yyyy	Stop Date dd-mmm-yyyy
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing
			<input type="checkbox"/> Week <input type="checkbox"/> Month <input type="checkbox"/> Total		<input type="checkbox"/> continuing

**Type of Psychotherapy Code**

- 1 = Prolonged Exposure
- 2 = CPT (Cognitive Processing Therapy)
- 3 = Other CBT (Cognitive Behavioral Therapy)
- 4 = EMDR
- 5 = IPT (Interpersonal Therapy)
- 6 = Psychodynamic
- 7 = Holotropic Breathwork
- 8 = Group Psychotherapy
- 9 = Other

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

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**Baseline Evaluations**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**Life Time History (CSSRS)**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 3 Preparatory Session CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Preparatory Sessions**

**General Well Being**

	<b>Visit Date</b>	<b>Subject Demeanor and State of Mind</b> enter code 1-6	<b>Subject currently</b> enter code A-C
<b>Visit 2</b>			
<b>Visit 3</b>			
<b>Visit 4</b>			

- 1= Very stable and calm
- 2= Stable and calm
- 3= Slightly stable and calm
- 4= Slightly distressed
- 5= Distressed
- 6= Very distressed

- A=** Does not face risk of significant deterioration.
- B=** Probably faces risk of significant deterioration.
- C=** Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session # 1**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**Visit 5 Pre Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 5 Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 6 Integrative Session 1 Day Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session # 1**

**Urine Pregnancy Test**

- Positive
- Negative
- Not Applicable

(Subject is Male, or there is Non-child bearing potential, if non childbearing potential clarify in Medical history)

**Dosing Visit 5**

Date of Dose

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
dd          mmm          yyyy

Dose administered, record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Supplemental Administered?

Yes    No

If yes, Record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #1**

**Physiological measures, body temperature and SUDS**

Record result and time of measurement. Body temperature should be recorded in Centigrade.

	<b>Baseline Value (pre-dose)</b>  (____:____) time 24 hr clock	<b>Mid Point (3 hrs +/- 30 Minutes)</b>  (____:____) time 24 hr clock	<b>End Point (7 hrs /+ 30 Minutes)</b>  (____:____) time 24 hr clock
<b>Blood Pressure (mm/Hg)</b>	/		
<b>Pulse (BPM)</b>			
<b>Body Temperature C°</b>			
<b>SUDS</b>			

	<b>Record Time of Highest Value</b> time 24 hr clock	<b>Record Highest Value</b>	<b>Was Value ever over:</b>	<b>If yes, how long? If &lt; than 1 hr record min. only.</b>
<b>Blood Pressure reading where Systolic is highest (mm/Hg)</b>	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Blood Pressure reading where Diastolic is highest (mm/Hg)</b>	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Pulse (BPM)</b>	(____:____)		110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Body Temperature C°</b>	(____:____)		1 degree C° above baseline? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>SUDS</b>	(____:____)			

Subject Number \_\_\_\_\_ Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #1- Integration and Follow up**

Investigator 1 belief of condition assignment	Investigator 2 belief of condition assignment	Subject belief of condition assignment
Investigator name:	Investigator name:	
<input type="checkbox"/> MDMA active placebo <input type="checkbox"/> MDMA 75 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA active placebo <input type="checkbox"/> MDMA 75 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA active placebo <input type="checkbox"/> MDMA 75 mg <input type="checkbox"/> MDMA 125 mg
<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain

**General Well Being- Measured for 7 days post Experimental Session, Complete Visit # if the contact is overlapping a scheduled integrative visit.**

Days Post Experimental Session #1	Date dd-mmm-yyyy	Subject Demeanor and State of Mind enter code 1-6	Subject currently enter code A-C
Day of Experimental Session #1 Post Session (V5)			
Day 1- Day of Integrative Session (V6)			
Day 2 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 3 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 4 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 5 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 6 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 7 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			

1= Very stable and calm  
 2= Stable and calm  
 3= Slightly stable and calm  
 4= Slightly distressed  
 5= Distressed  
 6= Very distressed

A= Does not face risk of significant deterioration.  
 B= Probably faces risk of significant deterioration.  
 C= Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

**Stage 1- Experimental Session #1- Integration and Follow up**

**Spontaneously Reported Side Effects During and Post Session**

Please record the maximum intensity of any spontaneously reported side effects the day of the experimental session and for 7 days after experimental session. Record any reaction still ongoing at day 7 on the Adverse Events Page. If no reactions are present for an entire day, check the "none" box. Only use as many spaces as needed for a given day. For example, if only two reactions are present for a given day, complete two columns and leave the remaining columns blank. Use codes below.

Days Post Exp. Session #1	Check if None	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code
Day of Session #1 (V5)	<input type="checkbox"/>										
Day 1- Day of Integrative session (V6)	<input type="checkbox"/>										
Day 2	<input type="checkbox"/>										
Day 3	<input type="checkbox"/>										
Day 4	<input type="checkbox"/>										
Day 5	<input type="checkbox"/>										
Day 6	<input type="checkbox"/>										
Day 7	<input type="checkbox"/>										

**Reaction Codes-**

- A- Anxiety
- B- Diarrhea
- C- Difficulty concentrating
- D- Dizziness
- E- Drowsiness
- F- Dry Mouth
- G- Fatigue
- H- Headache
- I- Impaired Judgment
- J- Impaired Gait/balance
- K- Increased Irritability
- L- Insomnia
- M- Jaw clenching, tight jaw

- N- Lack of appetite
- O- Low Mood
- P- Muscle tension
- Q- Nausea
- R- Nystagmus
- S- Parasthesias
- T Perspiration
- U- Restlessness
- V- Ruminations
- W- Sensitivity to Cold
- X- Thirst
- Y- Unusual Somatic Sensations
- Z- Weakness

**Intensity Codes-**

- 1= Mild
  - 2= Moderate
  - 3= Severe
- Mild:** no limitation in normal daily activity
- Moderate:** some limitation in normal daily activity
- Severe:** unable to perform normal daily activity

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #1- Integration and Follow up**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**2 Days Post Experimental Session #1 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**7 Days Post Experimental Session #1 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 8 Integrative session post Experimental Session #1 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #1- Integration and Follow up**

**General Well Being:** Complete optional visits if additional integrative sessions are scheduled.

	<b>Date</b> dd-mmm-yyyy	<b>Subject Demeanor and State of Mind</b> enter code 1-6	<b>Subject currently</b> enter code A-C
<b>Visit 7</b>	<input type="checkbox"/> NA if done during 7 days of contact		
<b>Visit 8</b>			
<b>Visit 8.1 Optional</b>	<input type="checkbox"/> NA		
<b>Visit 8.2 Optional</b>	<input type="checkbox"/> NA		

- 1= Very stable and calm
- 2= Stable and calm
- 3= Slightly stable and calm
- 4= Slightly distressed
- 5= Distressed
- 6= Very distressed

- A=** Does not face risk of significant deterioration.
- B=** Probably faces risk of significant deterioration.
- C=** Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session # 2**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**Visit 9 Pre Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 9 Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 10 Integrative Session 1 Day Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session # 2**

**Urine Pregnancy Test**

- Positive
- Negative
- Not Applicable

(Subject is Male or there is Non-child bearing potential,  
if non childbearing potential clarify in Medical history)

**Dosing Visit 9**

Date of Dose

\_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
dd mmm yyyy

Dose administered, record time:

\_\_\_\_\_:\_\_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Supplemental Administered?

Yes  No

If yes, Record time:

\_\_\_\_\_:\_\_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session # 2**

**Physiological measures, body temperature and SUDS**

Record result and time of measurement. Body temperature should be recorded in Centigrade.

	<b>Baseline Value (pre-dose)</b>  (____:____) time 24 hr clock	<b>Mid Point (3 hrs +/- 30 Minutes)</b>  (____:____) time 24 hr clock	<b>End Point (7 hrs +/- 30 Minutes)</b>  (____:____) time 24 hr clock
<b>Blood Pressure (mm/Hg)</b>	/		
<b>Pulse (BPM)</b>			
<b>Body Temperature C°</b>			
<b>SUDS</b>			

	<b>Record Time of Highest Value</b> time 24 hr clock	<b>Record Highest Value</b>	<b>Was Value ever over:</b>	<b>If yes, how long? If &lt; than 1 hr record min. only.</b>
<b>Blood Pressure reading where Systolic is highest (mm/Hg)</b>	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Blood Pressure reading where Diastolic is highest (mm/Hg)</b>	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Pulse (BPM)</b>	(____:____)		110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Body Temperature C°</b>	(____:____)		1 degree C° above baseline? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>SUDS</b>	(____:____)			

Subject Number \_\_\_\_\_ Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #2- Integration and Follow up**

Investigator 1 belief of condition assignment	Investigator 2 belief of condition assignment	Subject belief of condition assignment
Investigator name:	Investigator name:	
<input type="checkbox"/> MDMA active placebo <input type="checkbox"/> MDMA 75 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA active placebo <input type="checkbox"/> MDMA 75 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA active placebo <input type="checkbox"/> MDMA 75 mg <input type="checkbox"/> MDMA 125 mg
<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain

**General Well Being- Measured for 7 days post Experimental Session, Complete Visit # if the contact is overlapping a scheduled integrative visit.**

Days Post Experimental Session #2	Date	Subject Demeanor and State of Mind	Subject currently
	dd-mmm-yyyy	enter code 1-6	enter code A-C
Day of Experimental Session #2 Post Session (V9)			
Day 1- Day of Integrative Session (V10)			
Day 2 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 3 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 4 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 5 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 6 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 7 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			

1= Very stable and calm  
 2= Stable and calm  
 3= Slightly stable and calm  
 4= Slightly distressed  
 5= Distressed  
 6= Very distressed

A= Does not face risk of significant deterioration.  
 B= Probably faces risk of significant deterioration.  
 C= Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

**Stage 1- Experimental Session #2- Integration and Follow up**

**Spontaneously Reported Side Effects During and Post Session**

Please record the maximum intensity of any spontaneously reported side effects the day of the experimental session and for 7 days after experimental session. Record any reaction still ongoing at day 7 on the Adverse Events Page. If no reactions are present for an entire day, check the "none" box. Only use as many spaces as needed for a given day. For example, if only two reactions are present for a given day, complete two columns and leave the remaining columns blank. Use codes below.

Days Post Exp. Session #2	Check if None	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code
Day of Session #2 (V9)	<input type="checkbox"/>										
Day 1- Day of Integrative session (V10)	<input type="checkbox"/>										
Day 2	<input type="checkbox"/>										
Day 3	<input type="checkbox"/>										
Day 4	<input type="checkbox"/>										
Day 5	<input type="checkbox"/>										
Day 6	<input type="checkbox"/>										
Day 7	<input type="checkbox"/>										

**Reaction Codes-**

- A- Anxiety
- B- Diarrhea
- C- Difficulty concentrating
- D- Dizziness
- E- Drowsiness
- F- Dry Mouth
- G- Fatigue
- H- Headache
- I- Impaired Judgment
- J- Impaired Gait/balance
- K- Increased Irritability
- L- Insomnia
- M- Jaw clenching, tight jaw

- N- Lack of appetite
- O- Low Mood
- P- Muscle tension
- Q- Nausea
- R- Nystagmus
- S- Parasthesias
- T Perspiration
- U- Restlessness
- V- Ruminations
- W- Sensitivity to Cold
- X- Thirst
- Y- Unusual Somatic Sensations
- Z- Weakness

**Intensity Codes-**

- 1= Mild
  - 2= Moderate
  - 3= Severe
- Mild:** no limitation in normal daily activity
- Moderate:** some limitation in normal daily activity
- Severe:** unable to perform normal daily activity

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #2- Integration and Follow up**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**2 Days Post Experimental Session #2 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**7 Days Post Experimental Session #2 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 12 Integrative Session Post Experimental Session #2**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #2- Integration and Follow up**

**General Well Being-** Complete optional visits if additional integrative sessions are scheduled.

	<b>Date</b> dd-mmm-yyyy	<b>Subject Demeanor and State of Mind</b> enter code 1-6	<b>Subject currently</b> enter code A-C
<b>Visit 11</b>	<input type="checkbox"/> NA if done during 7 days of contact		
<b>Visit 12</b>			
<b>Visit 12.1 Optional</b>	<input type="checkbox"/> NA		
<b>Visit 12.2 Optional</b>	<input type="checkbox"/> NA		

1= Very stable and calm  
 2= Stable and calm  
 3= Slightly stable and calm 4= Slightly distressed  
 5= Distressed  
 6= Very distressed

**A=** Does not face risk of significant deterioration.  
**B=** Probably faces risk of significant deterioration.  
**C=** Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Follow up- 1 Month Post Experimental Session #2**

**Visit 13**

**Date of Evaluation** \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
dd mmm yyyy

**CAPS Scoring**

Criterion A met (traumatic event)			Frequency	Intensity
B (re-experiencing) sx ( $\geq 1$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
C (Avoidance) ( $\geq 3$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
D (Hyperarousal) ( $\geq 2$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
E (duration in months and is duration $\geq 1$ month)?	Total Months	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
F (Distress/impairment)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>CURRENT PTSD (Criteria A-F)</b>		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
PTSD Global	Score			

**Global Functioning Scale**

GAF	
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**Beck Depression Inventory (BDI)**

BDI Score	
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**PTGI**

PTGI Score	
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Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session # 3**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**Visit 14 Pre Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 14 Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 15 Integrative Session 1 Day Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session # 3**

**Urine Pregnancy Test**

- Positive
- Negative
- Not Applicable

(Subject is Male or there is Non-child bearing potential,  
if non childbearing potential clarify in Medical history)

**Dosing Visit 14**

Date of Dose

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
dd          mmm          yyyy

Dose administered, record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Supplemental Administered?

Yes    No

If yes, Record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session # 3**

**Physiological measures, body temperature and SUDS**

Record result and time of measurement. Body temperature should be recorded in Centigrade.

	<b>Baseline Value (pre-dose)</b>  (____:____) time 24 hr clock	<b>Mid Point (3 hrs +/- 30 Minutes)</b>  (____:____) time 24 hr clock	<b>End Point (7 hrs +/- 30 Minutes)</b>  (____:____) time 24 hr clock
<b>Blood Pressure (mm/Hg)</b>	/		
<b>Pulse (BPM)</b>			
<b>Body Temperature C°</b>			
<b>SUDS</b>			

	<b>Record Time of Highest Value</b> time 24 hr clock	<b>Record Highest Value</b>	<b>Was Value ever over:</b>	<b>If yes, how long? If &lt; than 1 hr record min. only.</b>
<b>Blood Pressure reading where Systolic is highest (mm/Hg)</b>	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Blood Pressure reading where Diastolic is highest (mm/Hg)</b>	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Pulse (BPM)</b>	(____:____)		110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Body Temperature C°</b>	(____:____)		1 degree C° above baseline? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>SUDS</b>	(____:____)			

Subject Number \_\_\_\_\_ Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #3- Integration and Follow up**

Investigator 1 belief of condition assignment	Investigator 2 belief of condition assignment	Subject belief of condition assignment
Investigator name:	Investigator name:	
<input type="checkbox"/> MDMA active placebo <input type="checkbox"/> MDMA 75 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA active placebo <input type="checkbox"/> MDMA 75 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA active placebo <input type="checkbox"/> MDMA 75 mg <input type="checkbox"/> MDMA 125 mg
<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain

**General Well Being- Measured for 7 days post Experimental Session, Complete Visit # if the contact is overlapping a scheduled integrative visit.**

Days Post Experimental Session #3	Date dd-mmm-yyyy	Subject Demeanor and State of Mind enter code 1-6	Subject currently enter code A-C
Day of Experimental Session #3 Post Session (V14)			
Day 1- Day of Integrative Session (V15)			
Day 2 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 3 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 4 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 5 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 6 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 7 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			

1= Very stable and calm  
 2= Stable and calm  
 3= Slightly stable and calm  
 4= Slightly distressed  
 5= Distressed  
 6= Very distressed

A= Does not face risk of significant deterioration.  
 B= Probably faces risk of significant deterioration.  
 C= Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #3- Integration and Follow up**

**Spontaneously Reported Side Effects During and Post Session**

Please record the maximum intensity of any spontaneously reported side effects the day of the experimental session and for 7 days after experimental session. Record any reaction still ongoing at day 7 on the Adverse Events Page. If no reactions are present for an entire day, check the “none” box. Only use as many spaces as needed for a given day. For example, if only two reactions are present for a given day, complete two columns and leave the remaining columns blank. Use codes below.

Days Post Exp. Session #3	Check if None	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code
Day of Session #3 (V14)	<input type="checkbox"/>										
Day 1- Day of Integrative session (V15)	<input type="checkbox"/>										
Day 2	<input type="checkbox"/>										
Day 3	<input type="checkbox"/>										
Day 4	<input type="checkbox"/>										
Day 5	<input type="checkbox"/>										
Day 6	<input type="checkbox"/>										
Day 7	<input type="checkbox"/>										

**Reaction Codes-**

- A- Anxiety
- B- Diarrhea
- C- Difficulty concentrating
- D- Dizziness
- E- Drowsiness
- F- Dry Mouth
- G- Fatigue
- H- Headache
- I- Impaired Judgment
- J- Impaired Gait/balance
- K- Increased Irritability
- L- Insomnia
- M- Jaw clenching, tight jaw

- N- Lack of appetite
- O- Low Mood
- P- Muscle tension
- Q- Nausea
- R- Nystagmus
- S- Parasthesias
- T Perspiration
- U- Restlessness
- V- Ruminations
- W- Sensitivity to Cold
- X- Thirst
- Y- Unusual Somatic Sensations
- Z- Weakness

**Intensity Codes-**

- 1= Mild
  - 2= Moderate
  - 3= Severe
- Mild:** no limitation in normal daily activity
- Moderate:** some limitation in normal daily activity
- Severe:** unable to perform normal daily activity

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #3- Integration and Follow up**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**2 Days Post Experimental Session #3 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**7 Days Post Experimental Session #3 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 17 Integrative Session Post Experimental Session #3**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 18- Follow up 2 Months Post Experimental Session #3**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Experimental Session #3- Integration and Follow up**

**General Well Being**

	<b>Date</b> dd-mmm-yyyy	<b>Subject Demeanor and State of Mind</b> enter code 1-6	<b>Subject currently</b> enter code A-C
<b>Visit 16</b>	<input type="checkbox"/> NA if done during 7 days of contact		
<b>Visit 17</b>			
<b>Visit 18</b>			

- 1= Very stable and calm
- 2= Stable and calm
- 3= Slightly stable and calm
- 4= Slightly distressed
- 5= Distressed
- 6= Very distressed

- A**= Does not face risk of significant deterioration.
- B**= Probably faces risk of significant deterioration.
- C**= Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Follow up- 2 Months Post Experimental Session #3**

**Visit 18**

**Date of Evaluation** \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
dd mmm yyyy

**CAPS Scoring**

Criterion A met (traumatic event)			Frequency	Intensity
B (re-experiencing) sx ( $\geq 1$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
C (Avoidance) ( $\geq 3$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
D (Hyperarousal) ( $\geq 2$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
E (duration in months and is duration $\geq 1$ month)?	Total Months	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
F (Distress/impairment)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>CURRENT PTSD (Criteria A-F)</b>		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
PTSD Global	Score			

**Global Functioning Scale**

GAF	
-----	--

**Beck Depression Inventory (BDI)**

BDI Score	
-----------	--

**PTGI**

PTGI Score	
------------	--

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 1 CRF

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**Stage 1- Follow up- 2 Months Post Experimental Session 3**

**Independent Reviewer belief of condition assignment**

- MDMA Active Placebo Dose 30mg
- MDMA 75 mg
- MDMA 125 mg

- Not at all certain
- Somewhat certain
- Certain
- Very certain

**Visit 18 Complete Unblinding**

**Condition assignment:**     MDMA 30 mg     MDMA 75 mg     MDMA 125 mg

***If the subject received active placebo dose, subject is eligible for stage 2. Complete questions below.***

**Will subject continue onto stage 2?**

- Yes    If yes, Enroll Subject in Stage 2;complete CRFs series 200
- No    If no, Complete Long Term Follow up CRF series 300 and then CRFs series 500 as appropriate

If subject **received active placebo**, and is **NOT** moving on to stage 2, please provide a reason Stage 2 is not being completed:

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Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Preparatory Sessions**

Subject received Active Placebo in Stage 1 and is eligible for Stage 2. Ensure subject continues to meet eligibility.

**Start Date for Stage 2** \_\_\_\_\_  
dd mmm yyyy

**Complete Optional Stage 2 Baseline for CAPS and GAF if more then 30 days elapsed since the Start of Stage 2 and the outcome assessment at Visit 18. If less then 30 days complete ONLY Visit 19 preparatory session activities, general well being, and CSSRS.**

**General Well Being**

	<b>Visit Date</b>	<b>Subject Demeanor and State of Mind</b> enter code 1-6	<b>Subject currently</b> enter code A-C
<b>Visit 19</b>			

- 1= Very stable and calm
- 2= Stable and calm
- 3= Slightly stable and calm
- 4= Slightly distressed
- 5= Distressed
- 6= Very distressed

- A=** Does not face risk of significant deterioration.
- B=** Probably faces risk of significant deterioration.
- C=** Faces risk of significant deterioration.

**Columbia Suicide Severity Rating Scale (CSSRS)**

**Visit 19 Preparatory Session CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Preparatory Sessions**

**Optional Baseline Stage 2**

**Date of Evaluation** \_\_\_\_-\_\_\_\_-\_\_\_\_ or  **None**  
 dd mmm yyyy

**CAPS/GAF/BDI/PTGI**

Record score if more than 30 days have elapsed since Visit 19 evaluation. If a new score is not needed check the None box above.

Criterion A met (traumatic event)			Frequency	Intensity
B (re-experiencing) sx ( $\geq 1$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
C (Avoidance) ( $\geq 3$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
D (Hyperarousal) ( $\geq 2$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
E (duration in months and is duration $\geq 1$ month)?	Total Months	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
F (Distress/impairment)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>CURRENT PTSD (Criteria A-F)</b>		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
PTSD Global	Score			

**Global Functioning Scale**

GAF	
-----	--

**Beck Depression Inventory (BDI)**

BDI Score	
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**PTGI**

PTGI Score	
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Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session # 1**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**Visit 20 Pre Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 20 Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 21 Integrative Session 1 Day Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session # 1**

**Urine Pregnancy Test**

- Positive
- Negative
- Not Applicable

(Subject is Male, or there is Non-child bearing potential,  
if non childbearing potential clarify in Medical history)

**Dosing Visit 20**

Date of Dose

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
dd        mmm        yyyy

Dose administered, record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Supplemental Administered?

Yes     No

If yes, Record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session #1**

**Physiological measures, body temperature and SUDS**

Record result and time of measurement. Body temperature should be recorded in Centigrade.

	Baseline Value (pre-dose)  (____:____) time 24 hr clock	Mid Point (3 hrs +/- 30 Minutes)  (____:____) time 24 hr clock	End Point (7 hrs /+ 30 Minutes)  (____:____) time 24 hr clock
Blood Pressure (mm/Hg)	/		
Pulse (BPM)			
Body Temperature C°			
SUDS			

	Record Time of Highest Value  time 24 hr clock	Record Highest Value	Was Value ever over:	If yes, how long? If < than 1 hr record min. only.
Blood Pressure reading where Systolic is highest (mm/Hg)	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Blood Pressure reading where Diastolic is highest (mm/Hg)	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Pulse (BPM)	(____:____)		110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Body Temperature C°	(____:____)		1 degree C° above baseline? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
SUDS	(____:____)			

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session #1- Integration and Follow up**

**General Well Being- Measured for 7 days post Experimental Session, Complete Visit # if the contact is overlapping a scheduled integrative visit.**

Days Post Experimental Session #1	Date dd-mmm-yyyy	Subject Demeanor and State of Mind enter code 1-6	Subject currently enter code A-C
Day of Experimental Session #1 Post Session (V20)			
Day 1- Day of Integrative Session (V19)			
Day 2 <input type="checkbox"/> Phone <input type="checkbox"/> Visit ____			
Day 3 <input type="checkbox"/> Phone <input type="checkbox"/> Visit ____			
Day 4 <input type="checkbox"/> Phone <input type="checkbox"/> Visit ____			
Day 5 <input type="checkbox"/> Phone <input type="checkbox"/> Visit ____			
Day 6 <input type="checkbox"/> Phone <input type="checkbox"/> Visit ____			
Day 7 <input type="checkbox"/> Phone <input type="checkbox"/> Visit ____			

1= Very stable and calm  
 2= Stable and calm  
 3= Slightly stable and calm  
 4= Slightly distressed  
 5= Distressed  
 6= Very distressed

A= Does not face risk of significant deterioration.  
 B= Probably faces risk of significant deterioration.  
 C= Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session #1- Integration and Follow up**

**Spontaneously Reported Side Effects During and Post Session**

Please record the maximum intensity of any spontaneously reported side effects the day of the experimental session and for 7 days after experimental session. Record any reaction still ongoing at day 7 on the Adverse Events Page. If no reactions are present for an entire day, check the "none" box. Only use as many spaces as needed for a given day. For example, if only two reactions are present for a given day, complete two columns and leave the remaining columns blank. Use codes below.

Days Post Exp. Session #1	Check if None	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code
Day of Session #1 (V20)	<input type="checkbox"/>										
Day 1- Day of Integrative session (V19)	<input type="checkbox"/>										
Day 2	<input type="checkbox"/>										
Day 3	<input type="checkbox"/>										
Day 4	<input type="checkbox"/>										
Day 5	<input type="checkbox"/>										
Day 6	<input type="checkbox"/>										
Day 7	<input type="checkbox"/>										

**Reaction Codes-**

- A- Anxiety
- B- Diarrhea
- C- Difficulty concentrating
- D- Dizziness
- E- Drowsiness
- F- Dry Mouth
- G- Fatigue
- H- Headache
- I- Impaired Judgment
- J- Impaired Gait/balance
- K- Increased Irritability
- L- Insomnia
- M- Jaw clenching, tight jaw

- N- Lack of appetite
- O- Low Mood
- P- Muscle tension
- Q- Nausea
- R- Nystagmus
- S- Parasthesias
- T Perspiration
- U- Restlessness
- V- Ruminations
- W- Sensitivity to Cold
- X- Thirst
- Y- Unusual Somatic Sensations
- Z- Weakness

**Intensity Codes-**

- 1= Mild
- 2= Moderate
- 3= Severe
- Mild:** no limitation in normal daily activity
- Moderate:** some limitation in normal daily activity
- Severe:** unable to perform normal daily activity

**Stage 2- Experimental Session #1- Integration and Follow up**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**2 Days Post Experimental Session #1 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**7 Days Post Experimental Session #1 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 23 Integrative session post Experimental Session #1 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session #1- Integrative Sessions**

**General Well Being:** Complete optional visits if additional integrative sessions are scheduled.

	<b>Date</b> dd-mmm-yyyy	<b>Subject Demeanor and State of Mind</b> enter code 1-6	<b>Subject currently</b> enter code A-C
<b>Visit 22</b>	<input type="checkbox"/> NA if done during 7 days of contact		
<b>Visit 23</b>			
<b>Visit 23.1 Optional</b>	<input type="checkbox"/> NA		
<b>Visit 23.2 Optional</b>	<input type="checkbox"/> NA		

1= Very stable and calm  
 2= Stable and calm  
 3= Slightly stable and calm  
 4= Slightly distressed  
 5= Distressed  
 6= Very distressed

**A=** Does not face risk of significant deterioration.  
**B=** Probably faces risk of significant deterioration.  
**C=** Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session # 2**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**Visit 24 Pre Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 24 Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 25 Integrative Session 1 Day Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session # 2**

**Urine Pregnancy Test**

- Positive
- Negative
- Not Applicable

(Subject is Male or there is Non-child bearing potential,  
if non childbearing potential clarify in Medical history)

**Dosing Visit 24**

Date of Dose

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
dd                  mmm                  yyyy

Dose administered, record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Supplemental Administered?

Yes     No

If yes, Record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session # 2**

**Physiological measures, body temperature and SUDS**

Record each measure and time of measurement. Body temperature should be recorded in Centigrade.

	<b>Baseline Value (pre-dose)</b>  (____:____) time 24 hr clock	<b>Mid Point (3 hrs +/- 30 Minutes)</b>  (____:____) time 24 hr clock	<b>End Point (7 hrs /+ 30 Minutes)</b>  (____:____) time 24 hr clock
<b>Blood Pressure (mm/Hg)</b>	/		
<b>Pulse (BPM)</b>			
<b>Body Temperature C°</b>			
<b>SUDS</b>			

	<b>Record Time of Highest Value</b> time 24 hr clock	<b>Record Highest Value</b>	<b>Was Value ever over:</b>	<b>If yes, how long? If &lt; than 1 hr record min. only.</b>
<b>Blood Pressure reading where Systolic is highest (mm/Hg)</b>	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Blood Pressure reading where Diastolic is highest (mm/Hg)</b>	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Pulse (BPM)</b>	(____:____)		110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>Body Temperature C°</b>	(____:____)		1 degree C° above baseline? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
<b>SUDS</b>	(____:____)			

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session #2- Integration and Follow up**

**General Well Being- Measured for 7 days post Experimental Session, Complete Visit # if the contact is overlapping a scheduled integrative visit.**

Days Post Experimental Session #2	Date dd-mmm-yyyy	Subject Demeanor and State of Mind enter code 1-6	Subject currently enter code A-C
Day of Experimental Session #2 Post Session (V24)			
Day 1- Day of Integrative Session (V25)			
Day 2 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 3 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 4 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 5 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 6 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 7 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			

1= Very stable and calm  
 2= Stable and calm  
 3= Slightly stable and calm  
 4= Slightly distressed  
 5= Distressed  
 6= Very distressed

**A**= Does not face risk of significant deterioration.  
**B**= Probably faces risk of significant deterioration.  
**C**= Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

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**Stage 2- Experimental Session #2- Integration and Follow up**

**Spontaneously Reported Side Effects During and Post Session**

Please record the maximum intensity of any spontaneously reported side effects the day of the experimental session and for 7 days after experimental session. Record any reaction still ongoing at day 7 on the Adverse Events Page. If no reactions are present for an entire day, check the “none” box. Only use as many spaces as needed for a given day. For example, if only two reactions are present for a given day, complete two columns and leave the remaining columns blank. Use codes below.

Days Post Exp. Session #2	Check if None	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code
Day of Session #1 (V24)	<input type="checkbox"/>										
Day 1- Day of Integrative session (V25)	<input type="checkbox"/>										
Day 2	<input type="checkbox"/>										
Day 3	<input type="checkbox"/>										
Day 4	<input type="checkbox"/>										
Day 5	<input type="checkbox"/>										
Day 6	<input type="checkbox"/>										
Day 7	<input type="checkbox"/>										

**Reaction Codes-**

- A- Anxiety
- B- Diarrhea
- C- Difficulty concentrating
- D- Dizziness
- E- Drowsiness
- F- Dry Mouth
- G- Fatigue
- H- Headache
- I- Impaired Judgment
- J- Impaired Gait/balance
- K- Increased Irritability
- L- Insomnia
- M- Jaw clenching, tight jaw

- N- Lack of appetite
- O- Low Mood
- P- Muscle tension
- Q- Nausea
- R- Nystagmus
- S- Parasthesias
- T Perspiration
- U- Restlessness
- V- Ruminations
- W- Sensitivity to Cold
- X- Thirst
- Y- Unusual Somatic Sensations
- Z- Weakness

**Intensity Codes-**

- 1= Mild
- 2= Moderate
- 3= Severe
- Mild:** no limitation in normal daily activity
- Moderate:** some limitation in normal daily activity
- Severe:** unable to perform normal daily activity

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 215

**Stage 2- Experimental Session #2 -Integration and Follow up**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**2 Days Post Experimental Session #2 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**7 Days Post Experimental Session #2 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 27 Integrative Session Post Experimental Session #2**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 216

**Stage 2- Experimental Session #2- Integration and Follow up**

**General Well Being:** Complete optional visits if additional integrative sessions are scheduled.

	<b>Date</b> dd-mmm-yyyy	<b>Subject Demeanor and State of Mind</b> enter code 1-6	<b>Subject currently</b> enter code A-C
<b>Visit 26</b>	<input type="checkbox"/> NA if done during 7 days of contact		
<b>Visit 27</b>			
<b>Visit 27.1 Optional</b>	<input type="checkbox"/> NA		
<b>Visit 27.2 Optional</b>	<input type="checkbox"/> NA		

- 1= Very stable and calm
- 2= Stable and calm
- 3= Slightly stable and calm
- 4= Slightly distressed
- 5= Distressed
- 6= Very distressed

- A=** Does not face risk of significant deterioration.
- B=** Probably faces risk of significant deterioration.
- C=** Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 217

**Stage 2- Follow up- 1 Month Post Experimental Session #2**

**Visit 28**

**CAPS Scoring**

**Date of Evaluation** \_\_\_\_\_  
 dd mmm yyyy

Criterion A met (traumatic event)			Frequency	Intensity
B (re-experiencing) sx ( $\geq 1$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
C (Avoidance) ( $\geq 3$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
D (Hyperarousal) ( $\geq 2$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
E (duration in months and is duration $\geq 1$ month)?	Total Months	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
F (Distress/impairment)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>CURRENT PTSD (Criteria A-F)</b>		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
PTSD Global	Score			

**Global Functioning Scale**

GAF	
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**Beck Depression Inventory (BDI)**

BDI Score	
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**PTGI**

PTGI Score	
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Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 218

**Stage 2- Experimental Session # 3**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**Visit 29 Pre Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 29 Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 30 Integrative Session 1 Day Post Drug Administration CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 219

**Stage 2- Experimental Session # 3**

**Urine Pregnancy Test**

- Positive
- Negative
- Not Applicable

(Subject is Male or there is Non-child bearing potential,  
if non childbearing potential clarify in Medical history)

**Dosing Visit 29**

Date of Dose

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
dd          mmm          yyyy

Dose administered, record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Supplemental Administered?

Yes    No

If yes, Record time:

\_\_\_\_ : \_\_\_\_  
(24 hr clock)

Record bottle number

\_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

**Stage 2- Experimental Session # 3**

**Physiological measures, body temperature and SUDS**

Record each measure and time of measurement. Body temperature should be recorded in Centigrade.

	Baseline Value (pre-dose) (____:____) time 24 hr clock	Mid Point (3 hrs +/- 30 Minutes) (____:____) time 24 hr clock	End Point (7 hrs +/- 30 Minutes) (____:____) time 24 hr clock
Blood Pressure (mm/Hg)	/		
Pulse (BPM)			
Body Temperature C°			
SUDS			

	Record Time of Highest Value time 24 hr clock	Record Highest Value	Was Value ever over:	If yes, how long? If < than 1 hr record min. only.
Blood Pressure reading where Systolic is highest (mm/Hg)	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Blood Pressure reading where Diastolic is highest (mm/Hg)	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Pulse (BPM)	(____:____)		110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Body Temperature C°	(____:____)		1 degree C° above baseline? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
SUDS	(____:____)			

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 221

**Stage 2- Experimental Session #3- Integration and Follow up**

**General Well Being- Measured for 7 days post Experimental Session, Complete Visit # if the contact is overlapping a scheduled integrative visit.**

Days Post Experimental Session #3	Date dd-mmm-yyyy	Subject Demeanor and State of Mind enter code 1-6	Subject currently enter code A-C
Day of Experimental Session #3 Post Session (V29)			
Day 1- Day of Integrative Session (V30)			
Day 2 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 3 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 4 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 5 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 6 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			
Day 7 <input type="checkbox"/> Phone <input type="checkbox"/> Visit _____			

1= Very stable and calm  
 2= Stable and calm  
 3= Slightly stable and calm  
 4= Slightly distressed  
 5= Distressed  
 6= Very distressed

**A=** Does not face risk of significant deterioration.  
**B=** Probably faces risk of significant deterioration.  
**C=** Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 222

**Stage 2- Experimental Session #3- Integration and Follow up**

**Spontaneously Reported Side Effects During and Post Session**

Please record the maximum intensity of any spontaneously reported side effects the day of the experimental session and for 7 days after experimental session. Record any reaction still ongoing at day 7 on the Adverse Events Page. If no reactions are present for an entire day, check the “none” box. Only use as many spaces as needed for a given day. For example, if only two reactions are present for a given day, complete two columns and leave the remaining columns blank. Use codes below.

Days Post Exp. Session #3	Check if None	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code
Day of Session #1 (V29)	<input type="checkbox"/>										
Day 1- Day of Integrative session (V30)	<input type="checkbox"/>										
Day 2	<input type="checkbox"/>										
Day 3	<input type="checkbox"/>										
Day 4	<input type="checkbox"/>										
Day 5	<input type="checkbox"/>										
Day 6	<input type="checkbox"/>										
Day 7	<input type="checkbox"/>										

**Reaction Codes-**

- A- Anxiety
- B- Diarrhea
- C- Difficulty concentrating
- D- Dizziness
- E- Drowsiness
- F- Dry Mouth
- G- Fatigue
- H- Headache
- I- Impaired Judgment
- J- Impaired Gait/balance
- K- Increased Irritability
- L- Insomnia
- M- Jaw clenching, tight jaw

- N- Lack of appetite
- O- Low Mood
- P- Muscle tension
- Q- Nausea
- R- Nystagmus
- S- Parasthesias
- T Perspiration
- U- Restlessness
- V- Ruminations
- W- Sensitivity to Cold
- X- Thirst
- Y- Unusual Somatic Sensations
- Z- Weakness

**Intensity Codes-**

- 1= Mild
- 2= Moderate
- 3= Severe
- Mild:** no limitation in normal daily activity
- Moderate:** some limitation in normal daily activity
- Severe:** unable to perform normal daily activity

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 223

**Stage 2- Experimental Session #3- Integration and Follow up**

**Columbia Suicide Severity Rating Scale (CSSRS)**

**2 Days Post Experimental Session #3 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**7 Days Post Experimental Session #3 CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 32 Integrative Session Post Experimental Session #3**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Visit 33- Follow up 2 Months Post Experimental Session #3**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 224

**Stage 2- Experimental Session #3- Integration and Follow up**

**General Well Being**

	<b>Date</b> dd-mmm-yyyy	<b>Subject Demeanor and State of Mind</b> enter code 1-6	<b>Subject currently</b> enter code A-C
<b>Visit 31</b>	<input type="checkbox"/> NA if done during 7 days of contact		
<b>Visit 32</b>			
<b>Visit 33</b>			

1= Very stable and calm  
 2= Stable and calm  
 3= Slightly stable and calm  
 4= Slightly distressed  
 5= Distressed  
 6= Very distressed

**A=** Does not face risk of significant deterioration.  
**B=** Probably faces risk of significant deterioration.  
**C=** Faces risk of significant deterioration.

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Stage 2 CRF

Page 225

**Stage 2- Follow up- 2 Months Post Experimental Session #3**

**Visit 33**

**CAPS Scoring**

**Date of Evaluation** \_\_\_\_\_  
 dd mmm yyyy

Criterion A met (traumatic event)			Frequency	Intensity
B (re-experiencing) sx ( $\geq 1$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
C (Avoidance) ( $\geq 3$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
D (Hyperarousal) ( $\geq 2$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
E (duration in months and is duration $\geq 1$ month)?	Total Months	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
F (Distress/impairment)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>CURRENT PTSD (Criteria A-F)</b>		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
PTSD Global	Score			

**Global Functioning Scale**

GAF	
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**Beck Depression Inventory (BDI)**

BDI Score	
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**PTGI**

PTGI Score	
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**Stage 2 is complete. Complete Long Term Follow up CRF Series 300 and CRF series 500**

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Follow up CRF

Page 301

**Follow up Phase -12 Months Post Last Experimental Session**

Physical Exam Date	Weight	Body Temperature	Blood Pressure (mmHg)	Heart Rate (BPM)
____ - ____ - ____ dd mmm yyyy	_____ kg	_____ °C	____ / ____	_____

**Follow up Phase -12 Months CSSRS**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Follow up CRF

Page 302

**Follow up Phase -12 Months Post Last Experimental Session**

**12 Months**

**Date of Evaluation** \_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
dd mmm yyyy

**CAPS Scoring**

Criterion A met (traumatic event)			Frequency	Intensity
B (re-experiencing) sx ( $\geq 1$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
C (Avoidance) ( $\geq 3$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
D (Hyperarousal) ( $\geq 2$ )?	Score	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
E (duration in months and is duration $\geq 1$ month)?	Total Months	Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
F(Distress/impairment)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
CURRENT PTSD (Criteria A-F)		Criterion met? <input type="checkbox"/> Yes <input type="checkbox"/> No		
PTSD Global	Score			

**Global Functioning Scale**

GAF	
-----	--

**Beck Depression Inventory (BDI)**

BDI Score	
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**PTGI**

PTGI Score	
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**Long Term Follow up is complete. Complete CRF Series 500 through Termination**

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

Con Med CRF

Page Series 500.  if last page

**Concomitant Medications- Baseline and Study Duration**

- Record psychotropic medications previously used/tapered **and** psychotropic and other prescription and non-prescriptions medications subject is taking at baseline. For past and baseline Meds check the Prestudy box (include start date if known) and provide Medical History Diagnosis and Prestudy Diagnosis number if applicable. Provide route and stop date/continuing for all medications, tapered medications require a stop date.
- Record **all new medications** taken after visit 1 through termination visit. Provide route and start date. Provide AE# (from AE page) or complete Other Reason for Treatment. Check the Continuing box if continuing at study termination.

CHECK IF NONE

Medication	Route <sup>a</sup> code 1-10	Start Date (dd-mmm-yyyy)	Stop Date (dd-mmm-yyyy)	Reason for Treatment Complete at least one column			
				Medical History Diag #	Prestudy Disorder Code <sup>b</sup>	AE#	Other
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				

<sup>a</sup> Codes for Route; 1=oral , 2= IV, 3= injection, 4=topical, 5=transdermal, 6=intranasal, 7=inhalaional, 8=intravitreal, 9=vaginal, 10=rectal

<sup>b</sup> Code for prestudy disorders; 1= Depression, 2 = Panic Disorder, 3 = General Anxiety Disorder (GAD), 4 = Insomnia / sleeping difficulty, 5 = Obsessive compulsive disorder (OCD), 6 = PTSD

Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Protocol MP8

AE CRF

Page Series 501. \_\_\_\_\_ ✓ if last page

**Adverse Events**

CHECK IF NONE

Record all Adverse Events through 7 days post experimental session 3 in Stage 1 and 2. Record only AEs requiring a Dr Visit from the 7 days follow up after the last experimental session through the final follow up visit in Stage 1 and Stage 2. Record all SAEs through the entire study. Record any exacerbations of a Medical History Diagnosis. Record side effects on the Side Effects CRF unless the reactions are still present at day 7.

AE #	Adverse event Diagnosis	Serious <sup>a</sup>	Onset date (dd/mmm/yyyy)	Resolution date (dd/mmm/yyyy)	Severity <sup>b</sup>	Frequency <sup>c</sup>	Action taken for Study <sup>d</sup>	Action taken-treatment <sup>e</sup>	Action Taken Other Specify	Outcome <sup>f</sup>	Relationship to Drug <sup>g</sup>

**a**  
**Serious?**  
1 = Serious\*  
2 = Not serious

\* Serious = Fatal, life-threatening, requires prolonged hospitalization, results in persistent or significant disability, or requires medical or surgical intervention to prevent one of the outcomes defined as "serious" listed above.

**b**  
**Severity**  
1= Mild  
2 = Moderate  
3 = Severe

**c**  
**Frequency**  
1 = Single/Intermittent  
2 = Continuous

**d**  
**Action Taken: Study**  
1 = None  
2 = Interrupted session  
3 = Delayed experimental session  
4 = Discontinued experimental session

**e**  
**Action Taken: Treatment**  
1 = None  
2 = Procedure or therapy  
3 = Blood or Blood products  
4 = Withdrawn from study due to AE  
5 = Prescription Med  
6 = Non Prescription Med  
7 = Hospitalization  
8 = IV Fluids  
9 = Other specify

**f**  
**Outcome**  
1 = Full recovery/return to baseline  
2 = Persists, diminishing  
3 = Persists, worsening  
4 = Persists, the same  
5 = Alive with sequelae  
6 = Death

**g**  
**Relationship to Drug**  
1 = Not related  
2 = Possibly related  
3 = Probably related





Subject Number \_\_\_\_\_

Initials \_\_\_\_\_

MAPS Study \_\_\_\_\_

CRF –Optional

Page 900. \_\_\_\_\_  ✓ if last page

**Columbia Suicide Severity Rating Scale (CSSRS)-Additional Time Points**

Complete Header including Study Number. For page # enter .1 for the first page and .2 for the next, ✓ the box if it is the last optional CSSRS page completed for the study.

**If additional CSSRS are completed fill in data below for each additional time point.**

**Date \_\_\_\_\_ Associated Visit # \_\_\_\_\_ or Call \_\_\_\_\_ (if applicable)**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Date \_\_\_\_\_ Associated Visit # \_\_\_\_\_ or Call \_\_\_\_\_ (if applicable)**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_

**Date \_\_\_\_\_ Associated Visit # \_\_\_\_\_ or Call \_\_\_\_\_ (if applicable)**

Suicidal Ideation \_\_\_\_\_

Ideation Intensity \_\_\_\_\_

Suicidal Behavior \_\_\_\_\_