



24000

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -     Protocol #  N  I  D  A -  M  D  S -  A  R  I  P  I  P -  0  0  0  1

site #                      subject #

Not Done

### ARCI

Study Day:  -7 (Infusion 1)                       10 (Infusion 4)  
 -5 (Infusion 2)                                       12 (Infusion 5)  
 -3 (Infusion 3)                                       15 (Infusion 6)

Time:  -15 min pre                      Actual Time Performed  
 30 min post                                        :    
(00:00-23:59)

- True  False 1. Speech is slurred
  - True  False 2. Not as active as usual
  - True  False 3. Feeling of dragging
  - True  False 4. Feel sluggish
  - True  False 5. Head feels heavy
  - True  False 6. Feel like avoiding
  - True  False 7. Feel dizzy
  - True  False 8. Harder to move around
  - True  False 9. I am moody
  - True  False 10. I am a little dull
  - True  False 11. I feel drowsy
  - True  False 12. I am full of energy
  - True  False 13. Say things easiest
  - True  False 14. Things more pleasing
  - True  False 15. Pleasant feelings
  - True  False 16. Lose contentment
  - True  False 17. Complete harmony
  - True  False 18. Appreciate saying
  - True  False 19. Happy all the time
  - True  False 20. So good others know
  - True  False 21. Something pleasant
  - True  False 22. Be happy all the time
  - True  False 23. More clear headed
  - True  False 24. More popular
- Completed by (initials):

- True  False 25. Pleasant emptiness
- True  False 26. Thoughts come easier
- True  False 27. Less discouraged
- True  False 28. Mood to talk
- True  False 29. More excited
- True  False 30. Answering was easy
- True  False 31. Memory sharper
- True  False 32. Could write for hours
- True  False 33. Very patient
- True  False 34. Body is tingling
- True  False 35. Have weird feeling
- True  False 36. Movements faster
- True  False 37. Movements slower
- True  False 38. Better control
- True  False 39. Mind on task
- True  False 40. Don't like reading
- True  False 41. Spending longer
- True  False 42. Hands feel clumsy
- True  False 43. Hands shake
- True  False 44. Disturbed stomach
- True  False 45. Bodily sensations
- True  False 46. Anxious and upset
- True  False 47. Weakness of muscles
- True  False 48. Thrill through me
- True  False 49. Movements are free



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## Aripiprazole for Methamphetamine Dependence

Subject ID      -     Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
site # subject #

Not Done **ADDICTION SEVERITY INDEX(ASI): LITE**

Study Day:  Intake Screening Assessment Date  /  / 20    
mm / dd / yyyy

### MEDICAL STATUS

- 1. How many times in your life have you been hospitalized for medical problems? (Include overdoses and delirium tremens (DTs) but exclude detox.)
- 2. Do you have any chronic medical problem(s) which continue to interfere with your life?  Yes  No  
If yes to #2, specify:
- 3. Are you taking any prescribed medication on a regular basis for a physical problem?  Yes  No
- 4. Do you receive a pension for a physical disability? (Exclude psychiatric disabilities.)  Yes  No
- 5. If yes to #4, specify:
- 6. How many days have you experienced medical problems in the past 30 days?

### FOR QUESTIONS 7 AND 8 PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE.

- 7. How troubled or bothered have you been by these medical problems in the past 30 days?  
 0 = Not at all  1 = Slightly  2 = Moderately  3 = Considerably  4 = Extremely
- 8. How important to you now is treatment for these medical problems?  
 0 = Not at all  1 = Slightly  2 = Moderately  3 = Considerably  4 = Extremely

### CONFIDENCE RATINGS

Is the above information significantly distorted by:

- 9. Subject's misrepresentation?  Yes  No
- 10. Subject's inability to understand?  Yes  No

11. Comments:



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# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -      Protocol #       -       -

site #                      subject #

### ADDICTION SEVERITY INDEX: LITE

#### EMPLOYMENT/SUPPORT STATUS

1. Education completed (GED = 12 years):   years   months
2. Training or technical education completed:   months
3. Do you have a valid driver's license?  Yes  No
4. Do you have an automobile available?  
(Answer "no" if no valid driver's license.)  Yes  No
5. How long was your longest full-time job?   years   months
- 6a. Usual (or last) occupation:
- 6b. Hollingshead occupational category:  1  2  3  4  5  6  7  8  9

- 1 = Higher executive, doctoral level professional, owner of large business
- 2 = Business manager, owner of medium business, other professional
- 3 = Administrative personnel, manager, owner/proprietor of small business
- 4 = Clerical and sales, technician
- 5 = Skilled manual
- 6 = Semi-skilled
- 7 = Unskilled
- 8 = Homemaker
- 9 = Student, disabled, no occupation

7. Does someone contribute the majority of your support?  Yes  No

8. Usual employment pattern, past 3 years.

- 1 = full time (35+ hrs/week)
- 2 = part time (regular hours)
- 3 = part time (irregular)
- 4 = student
- 5 = military service
- 6 = retired/disabled
- 7 = unemployed
- 8 = in controlled environment



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### ADDICTION SEVERITY INDEX: LITE

9. How many days were you paid for working in the past 30 days?

How much money did you receive from the following sources in the past 30 days?

10. Employment (net income)

\$

11. Unemployment compensation

\$

12. Public assistance (welfare)

\$

13. Pension, benefits or social security

\$

14. Mate, family or friends (money for personal expenses)

\$

15. Illegal

\$

16. How many people depend on you for the majority of their food, shelter, etc.?

17. How many days have you experienced employment problems in the past 30 days?

### FOR QUESTIONS 18 AND 19 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

18. How troubled or bothered have you been by these employment problems in the past 30 days?

- 0 = Not at all     1 = Slightly     2 = Moderately     3 = Considerably     4 = Extremely

19. How important to you now is counseling for these employment problems?

- 0 = Not at all     1 = Slightly     2 = Moderately     3 = Considerably     4 = Extremely

### CONFIDENCE RATINGS

Is the above information significantly distorted by:

20. Subject's misrepresentation?

- Yes     No

21. Subject's inability to understand?

- Yes     No

22. Comments:



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-	M	D	S
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-	A	R	I	P	I	P
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-	0	0	0	1
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### ADDICTION SEVERITY INDEX: LITE

#### DRUG/ALCOHOL USE

	Days in Past 30 Days	Lifetime (Years)	Route of Administration					
			oral	nasal	smoking	non-iv inj.	iv inj.	
1. Alcohol - any use at all	<input type="text"/>	<input type="text"/>	<input type="radio"/>					
2. Alcohol - to intoxication	<input type="text"/>	<input type="text"/>	<input type="radio"/>					
3. Heroin	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Methadone	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Other opiates/analgesics	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Barbiturates	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Sedatives/hypnotics/tranquilizers	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Cocaine	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Amphetamines	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Cannabis	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			
11. Hallucinogens	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Inhalants	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>				
13. More than one substance per day (including alcohol)	<input type="text"/>	<input type="text"/>						



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A	R	I	P	I	P
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0	0	0	1
---	---	---	---

### ADDICTION SEVERITY INDEX: LITE

14. How many times have you had alcohol DTs?

--	--

How many times in your life have you been treated for:

15. Alcohol abuse

--	--

16. Drug abuse

--	--

How many of these were detox only?

17. Alcohol

--	--

18. Drug

--	--

How much money have you spent during the past 30 days on:

19. Alcohol

\$ 

--	--	--	--

20. Drugs

\$ 

--	--	--	--

21. How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days? (Include NA, AA.)

--	--

How many days in the past 30 days have you experienced:

22. Alcohol problems

--	--

23. Drug problems

--	--

### FOR QUESTIONS 24 - 27 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

How troubled or bothered have you been in the past 30 days by these:

24. Alcohol problems

- 0 = Not at all     1 = Slightly     2 = Moderately     3 = Considerably     4 = Extremely

25. Drug problems

- 0 = Not at all     1 = Slightly     2 = Moderately     3 = Considerably     4 = Extremely

How important to you now is treatment for these:

26. Alcohol problems

- 0 = Not at all     1 = Slightly     2 = Moderately     3 = Considerably     4 = Extremely

27. Drug problems

- 0 = Not at all     1 = Slightly     2 = Moderately     3 = Considerably     4 = Extremely



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M	D	S
---	---	---

A	R	I	P	I	P
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0	0	0	1
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### ADDICTION SEVERITY INDEX: LITE

#### CONFIDENCE RATINGS

Is the above information significantly distorted by:

28. Subject's misrepresentation?  Yes  No

29. Subject's inability to understand?  Yes  No

30. Comments:

--

#### LEGAL STATUS

1. Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)?  Yes  No

2. Are you on probation or parole?  Yes  No

How many times in your life have you been arrested and charged with the following:

3. Shoplifting/vandalism

--	--

4. Parole/probation violation(s)

--	--

5. Drug charge(s)

--	--

6. Forgery

--	--

7. Weapons offense

--	--

8. Burglary, larceny, breaking and entering

--	--

9. Robbery

--	--

10. Assault

--	--

11. Arson

--	--

12. Rape

--	--

13. Homicide, manslaughter

--	--



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### ADDICTION SEVERITY INDEX: LITE

14. Prostitution

--	--

15. Contempt of court

--	--

16. Other, specify:

--

--	--

17. How many of these charges resulted in conviction?

--	--

**How many times in your life have you been charged with the following:**

18. Disorderly conduct, vagrancy, public intoxication?

--	--

19. Driving while intoxicated?

--	--

20. Major driving violations (reckless driving, speeding, no license, etc.)?

--	--

21. How many months were you incarcerated in your life?

--	--	--

months

22. Are you presently awaiting charges, trial or sentence?

Yes  No

23. What for?

(if multiple charges use most severe from codes for 3 through 16 above)

--	--

24. How many days in the past 30 were you detained or incarcerated?

--	--

days

25. How many days in the past 30 have you engaged in illegal activities for profit?

--	--

days

### FOR QUESTIONS 26 - 27 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

26. How serious do you feel your present legal problems are?

0 = None at all    1 = Slightly    2 = Moderately    3 = Considerably    4 = Extremely

27. How important to you now is counseling or referral for these legal problems?

0 = None at all    1 = Slightly    2 = Moderately    3 = Considerably    4 = Extremely



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### ADDICTION SEVERITY INDEX: LITE

#### CONFIDENCE RATINGS

Is the above information significantly distorted by:

28. Subject's misrepresentation?  Yes  No

29. Subject's inability to understand?  Yes  No

30. Comments:

#### FAMILY/SOCIAL RELATIONSHIPS

1. Marital status:

- 1= married
- 2= remarried
- 3= widowed
- 4= separated
- 5= divorced
- 6= never married

2. Are you satisfied with this situation?  Yes  No  Indifferent

3. Usual living arrangements (past three years):

- 1 = with sexual partner and children
- 2 = with sexual partner alone
- 3 = with children alone
- 4 = with parents
- 5 = with family
- 6 = with friends
- 7 = alone
- 8 = controlled environment
- 9 = no stable arrangements



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### ADDICTION SEVERITY INDEX: LITE

4. Are you satisfied with these living arrangements?       Yes    No    Indifferent

**Do you live with anyone who:**

5. Has a current alcohol problem?       Yes    No

6. Uses non-prescribed drugs?       Yes    No

7. With whom do you spend most of your free time?       Family    Friends    Alone

8. Are you satisfied with spending your free time this way?       Yes    No    Indifferent

**Have you had any significant periods in which you have experienced serious problems getting along with:**

	In the past 30 days				Lifetime			
	Yes	No	I don't know	Not applicable	Yes	No	I don't know	Not applicable
9. Mother	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Father	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Siblings	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Sexual partner/spouse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Children	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Other significant family	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. If 14 is yes, specify:	<input style="width: 100%; height: 20px;" type="text"/>							
16. Close Friends	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. Neighbors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Co-workers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



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### ADDICTION SEVERITY INDEX: LITE

Did any of these people (#'s 9 - 18 above) abuse you?

In the past 30 days

Lifetime

19. Physically (caused you physical harm)

Yes  No

Yes  No

20. Sexually (forced sexual advances or sexual acts)

Yes  No

Yes  No

How many days in the past 30 have you had serious conflicts?

21. With your family:

--	--

22. With other people excluding family:

--	--

### FOR QUESTIONS 23 - 26 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

How troubled or bothered have you been in the past 30 days by these:

23. Family problems

0 = Not at all    1 = Slightly    2 = Moderately    3 = Considerably    4 = Extremely

24. Social problems

0 = Not at all    1 = Slightly    2 = Moderately    3 = Considerably    4 = Extremely

How important to you now is treatment or counseling for these:

25. Family problems

0 = Not at all    1 = Slightly    2 = Moderately    3 = Considerably    4 = Extremely

26. Social problems

0 = Not at all    1 = Slightly    2 = Moderately    3 = Considerably    4 = Extremely

### CONFIDENCE RATINGS

Is the above information significantly distorted by:

27. Subject's misrepresentation?

Yes  No

28. Subject's inability to understand?

Yes  No

29. Comments:

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# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -      Protocol #       -       -

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### ADDICTION SEVERITY INDEX: LITE

#### PSYCHIATRIC STATUS

How many times have you been treated for any psychological or emotional problem(s)?

- 1. In a hospital
- 2. As an outpatient or private patient
- 3. Do you receive a pension for a psychiatric disability?  Yes  No

Have you had a significant period (that was not a direct result of drug/alcohol use) in which you have:

- |  | In the past 30 days                                | Lifetime   |
|--|--|--|
| 4. Experienced serious depression?   | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> Yes <input type="radio"/> No |
| 5. Experienced serious anxiety or tension?   | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> Yes <input type="radio"/> No |
| 6. Experienced hallucinations?   | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> Yes <input type="radio"/> No |
| 7. Experienced trouble understanding, concentrating, or remembering?                       | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> Yes <input type="radio"/> No |
| 8. Experienced trouble controlling violent behavior?                                       | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> Yes <input type="radio"/> No |
| 9. Experienced serious thoughts of suicide?  | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> Yes <input type="radio"/> No |
| 10. Attempted suicide?   | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> Yes <input type="radio"/> No |
| 11. Been prescribed medication for any psychological or emotional problem?                 | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> Yes <input type="radio"/> No |
| 12. How many days in the last 30 have you experienced psychological or emotional problems? | <input type="text"/> <input type="text"/>          |  |

#### FOR QUESTIONS 13 - 14 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

- 13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?  
 0 = Not at all     1 = Slightly     2 = Moderately     3 = Considerably     4 = Extremely
- 14. How important to you now is treatment for these psychological problems?  
 0 = Not at all     1 = Slightly     2 = Moderately     3 = Considerably     4 = Extremely



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-	0	0	0	1
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### ADDICTION SEVERITY INDEX: LITE

#### CONFIDENCE RATINGS

Is the above information significantly distorted by:

15. Subject's misrepresentation?

Yes  No

16. Subject's inability to understand?

Yes  No

17. Comments:

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Completed by (initials):

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# National Institute on Drug Abuse

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### ADVERSE EVENTS (AE)

**INSTRUCTIONS:** Complete CRF at intake and every 7 days following until the end of inpatient portion of the study. Also, complete CRF at discharge, follow-up week 1 follow-up week 4, and in the event of an SAE.

Are any AEs reported on this page?  YES  NO

If yes, list below using the provided legend:

A. SEVERITY	B. STUDY DRUG RELATIONSHIP	C. ACTION TAKEN REGARDING INVESTIGATIONAL AGENT	D. OTHER ACTION TAKEN	E. OUTCOME OF AE
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely 2 = Probably 3 = Possibly 4 = Remotely 5 = Definitely Not 6 = Unknown	1 = None 2 = Discontinued Perm. 3 = Discontinued Temp. 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = None 2 = Remedial therapy - Pharm. 3 = Remedial therapy - Nonpharm. 4 = Hospitalization	1 = Resolved, No Sequelae 2 = AE Still Present - No Tx. 3 = AE Still Present - Tx. 4 = Residual Effects Present - No Tx. 5 = Residual Effects Present - Tx. 6 = Death 7 = Unknown

Adverse Event	Onset Date (mm/dd/yyyy)	End Date (mm/dd/yyyy)	A.	B.	C.	D.	E.	Serious?
<input style="width: 100%; height: 20px;" type="text"/>	<input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> / <input style="width: 40px;" type="text"/>	<input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> / <input style="width: 40px;" type="text"/>	<input style="width: 20px;" type="text"/>	<input type="radio"/> yes* <input type="radio"/> no				
<input style="width: 100%; height: 20px;" type="text"/>	<input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> / <input style="width: 40px;" type="text"/>	<input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> / <input style="width: 40px;" type="text"/>	<input style="width: 20px;" type="text"/>	<input type="radio"/> yes* <input type="radio"/> no				
<input style="width: 100%; height: 20px;" type="text"/>	<input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> / <input style="width: 40px;" type="text"/>	<input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> / <input style="width: 40px;" type="text"/>	<input style="width: 20px;" type="text"/>	<input type="radio"/> yes* <input type="radio"/> no				
<input style="width: 100%; height: 20px;" type="text"/>	<input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> / <input style="width: 40px;" type="text"/>	<input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> / <input style="width: 40px;" type="text"/>	<input style="width: 20px;" type="text"/>	<input type="radio"/> yes* <input type="radio"/> no				
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\*If yes, complete SAE form.

49101

Completed by (initials):

Date completed

 /  / 

mm / dd / yyyy

Page

 OF





# Aripiprazole for Methamphetamine Dependence

<b>Subject ID</b>		<b>Protocol #</b>		<b>Assessment Date</b>																																	
<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> - <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table>										<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;">N</td><td style="width: 20px; height: 20px;">I</td><td style="width: 20px; height: 20px;">D</td><td style="width: 20px; height: 20px;">A</td></tr> </table> - <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;">M</td><td style="width: 20px; height: 20px;">D</td><td style="width: 20px; height: 20px;">S</td></tr> </table> - <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;">A</td><td style="width: 20px; height: 20px;">R</td><td style="width: 20px; height: 20px;">I</td><td style="width: 20px; height: 20px;">P</td><td style="width: 20px; height: 20px;">I</td><td style="width: 20px; height: 20px;">P</td></tr> </table> - <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;">0</td><td style="width: 20px; height: 20px;">0</td><td style="width: 20px; height: 20px;">0</td><td style="width: 20px; height: 20px;">1</td></tr> </table>	N	I	D	A	M	D	S	A	R	I	P	I	P	0	0	0	1	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> / <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> / <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;">2</td><td style="width: 20px; height: 20px;">0</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table>					2	0			
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0	0	0	1																																		
2	0																																				
site #	subject #			mm	dd	yyyy																															

## ATTENTION-DEFICIT DISORDER (ADD) ASSESSMENT

Hyperactivity		If so, how old were you when this problem started?	Did/does this cause you trouble at home?	Did/does this cause you trouble at school/work?	
10. Did/do you fidget with your hands or feet or squirm in your seat...	...as a child?	<input type="radio"/> yes <input type="radio"/> no	<table border="1" style="width: 40px; height: 20px; margin: auto;"></table>	<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
	...currently?	<input type="radio"/> yes <input type="radio"/> no		<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
11. Did/do you leave your seat in classrooms or in other situations in which remaining seated is expected...	...as a child?	<input type="radio"/> yes <input type="radio"/> no	<table border="1" style="width: 40px; height: 20px; margin: auto;"></table>	<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
	...currently?	<input type="radio"/> yes <input type="radio"/> no		<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
12. Did/do you run about or climb excessively in situations in which it was inappropriate... (In adults, this may be limited to subjective feelings of restlessness.)	...as a child?	<input type="radio"/> yes <input type="radio"/> no	<table border="1" style="width: 40px; height: 20px; margin: auto;"></table>	<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
	...currently?	<input type="radio"/> yes <input type="radio"/> no		<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
13. Did/do you have difficulty playing or engaging in leisure activities quietly...	...as a child?	<input type="radio"/> yes <input type="radio"/> no	<table border="1" style="width: 40px; height: 20px; margin: auto;"></table>	<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
	...currently?	<input type="radio"/> yes <input type="radio"/> no		<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
14. Did/do you tend to be 'on the go' or act as if you were 'driven by a motor'...	...as a child?	<input type="radio"/> yes <input type="radio"/> no	<table border="1" style="width: 40px; height: 20px; margin: auto;"></table>	<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
	...currently?	<input type="radio"/> yes <input type="radio"/> no		<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no



## Aripiprazole for Methamphetamine Dependence

<b>Subject ID</b>		<b>Protocol #</b>		<b>Assessment Date</b>																																								
<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> - <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table>												<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;">N</td><td style="width: 20px; height: 20px;">I</td><td style="width: 20px; height: 20px;">D</td><td style="width: 20px; height: 20px;">A</td><td style="width: 20px; height: 20px;">-</td><td style="width: 20px; height: 20px;">M</td><td style="width: 20px; height: 20px;">D</td><td style="width: 20px; height: 20px;">S</td><td style="width: 20px; height: 20px;">-</td><td style="width: 20px; height: 20px;">A</td><td style="width: 20px; height: 20px;">R</td><td style="width: 20px; height: 20px;">I</td><td style="width: 20px; height: 20px;">P</td><td style="width: 20px; height: 20px;">I</td><td style="width: 20px; height: 20px;">P</td><td style="width: 20px; height: 20px;">-</td><td style="width: 20px; height: 20px;">0</td><td style="width: 20px; height: 20px;">0</td><td style="width: 20px; height: 20px;">0</td><td style="width: 20px; height: 20px;">1</td></tr> </table>	N	I	D	A	-	M	D	S	-	A	R	I	P	I	P	-	0	0	0	1	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;">/</td><td style="width: 20px; height: 20px;">2</td><td style="width: 20px; height: 20px;">0</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table>			/			/	2	0			
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		/			/	2	0																																					
site #	subject #			mm	dd	yyyy																																						

### ATTENTION-DEFICIT DISORDER (ADD) ASSESSMENT

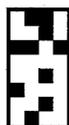
		If so, how old were you when this problem started?	Did/does this cause you trouble at home?	Did/does this cause you trouble at school/work?		
15. Did/do you talk excessively...	...as a child? <input type="radio"/> yes <input type="radio"/> no	<table border="1" style="width: 40px; height: 20px; margin: auto;"> <tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr> </table>			<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
...currently? <input type="radio"/> yes <input type="radio"/> no						
<b>Impulsivity</b> 16. Did/do you blurt out answers before questions are completed...	...as a child? <input type="radio"/> yes <input type="radio"/> no	<table border="1" style="width: 40px; height: 20px; margin: auto;"> <tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr> </table>			<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
...currently? <input type="radio"/> yes <input type="radio"/> no						
17. Did/do you have difficulty awaiting your turn...	...as a child? <input type="radio"/> yes <input type="radio"/> no	<table border="1" style="width: 40px; height: 20px; margin: auto;"> <tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr> </table>			<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
...currently? <input type="radio"/> yes <input type="radio"/> no						
18. Did/do you interrupt or intrude on others (e.g. butt into conversations or games)...	...as a child? <input type="radio"/> yes <input type="radio"/> no	<table border="1" style="width: 40px; height: 20px; margin: auto;"> <tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr> </table>			<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no
...currently? <input type="radio"/> yes <input type="radio"/> no						

19. Does the subject have a diagnosis of childhood ADHD?  yes  no

20. Does the subject have a diagnosis of adult ADD?  yes  no

Completed by (initials):

--	--	--



34131



26134

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

  
site #  
subject #

Protocol #

  
NIDA  
MDS  
ARIPIP  
0001

Not Done

### BARNES AKATHISIA SCALE

Study Day:  1

5

12

Unscheduled

Assessment Date

 /  / 20

mm / dd / yyyy

Objective Signs of Restlessness

0     1     2     3

Subjective - Awareness of Restlessness

0     1     2     3

Subjective - Distress Related to Restlessness

0     1     2     3

Global Clinical Assessment of Akathisia

0     1     2     3     4     5

Completed by (initials):





55514

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -      Protocol #  N  I  D  A -  M  D  S -  A  R  I  P  I  P -  0  0  0  1

site #                      subject #

Not Done

### BLOOD PK (INFUSION 4)

Study Day:  10 (Infusion 4)

Time Relative to Infusion	Aripiprazole (Gray Top) Draw Time (00:00-23:59)
------------------------------	--

6:55 AM	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
---------	---

-5 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
--------	---

120 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
---------	---

Completed by (initials):



40596

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -      Protocol #       -       -

site #

subject #

Not Done

### BLOOD PK (INFUSIONS 2 AND 3)

Study Day:  -5 (Infusion 2)     -3 (Infusion 3)

**Meth PK  
(Green Top)  
Draw Time  
(00:00-23:59)**

-5 min	<input type="text"/>	:	<input type="text"/>
+5 min	<input type="text"/>	:	<input type="text"/>
15 min	<input type="text"/>	:	<input type="text"/>
30 min	<input type="text"/>	:	<input type="text"/>
60 min	<input type="text"/>	:	<input type="text"/>
90 min	<input type="text"/>	:	<input type="text"/>
120 min	<input type="text"/>	:	<input type="text"/>
240 min	<input type="text"/>	:	<input type="text"/>
360 min	<input type="text"/>	:	<input type="text"/>
480 min	<input type="text"/>	:	<input type="text"/>
12 hr	<input type="text"/>	:	<input type="text"/>
20 hr	<input type="text"/>	:	<input type="text"/>
24 hr	<input type="text"/>	:	<input type="text"/>
36 hr	<input type="text"/>	:	<input type="text"/>
48 hr	<input type="text"/>	:	<input type="text"/>

Completed by (initials):



63915

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID      -      Protocol #       -       -

site #                      subject #

Not Done

### BLOOD PK (INFUSIONS 5 AND 6)

Study Day:  12 (Infusion 5)     15 (Infusion 6)

Time Relative to Infusion	Meth PK (Green Top) Draw Time (00:00-23:59)	Aripiprazole (Gray Top) Draw Time (00:00-23:59)
6:55 AM	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
-5 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
+5 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
15 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
30 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
60 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
90 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
120 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
240 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
360 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
480 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
12 hr	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
20 hr	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
24 hr	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
36 hr	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
48 hr	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	

Completed by (initials):



11124

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

     
     
       
     
 Not Done

### BRIEF PSYCHIATRIC RATING SCALE (BPRS)

Study Day:  -7 (Infusion 1) 10 (Infusion 4)

Assessment Date

  /   / 20  
 -5 (Infusion 2) 12 (Infusion 5)

mm / dd / yyyy

 -3 (Infusion 3) 15 (Infusion 6)

Time Performed

  :   (00:00-23:59)

(60 min. post infusion)

**Instructions:** Transcribe from BPRS source document the number selected. Mark 0 for symptoms not assessed.

1. Somatic Concern

13. Self-neglect

2. Anxiety

14. Disorientation

3. Depression

15. Conceptual Disorganization

4. Suicidality

16. Blunted Affect

5. Guilt

17. Emotional Withdrawal

6. Hostility

18. Motor Retardation

7. Elevated Mood

19. Tension

8. Grandiosity

20. Uncooperativeness

9. Suspiciousness

21. Excitement

10. Hallucinations

22. Distractibility

11. Unusual Thought Content

23. Motor Hyperactivity

12. Bizarre Behavior

24. Mannerisms and Posturing

Completed by (initials):





10009

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

Not Done **BRIEF SUBSTANCE CRAVING SCALE (BSCS) - Inpatient**

**INSTRUCTIONS:** Fill in inpatient study day and complete assessment date in mm/dd/yyy format. Transcribe responses from the BSCS source document. BSCS should be completed every other day following intake.

Inpatient study day:

Assessment Date

mm / dd / yyyy

1. Meth Intensity

2. Meth frequency

3. Meth length

4. Number

5. Hours Craved

Minutes Craved

6. Worst Day Craving
- Sunday
  - Monday
  - Tuesday
  - Wednesday
  - Thursday
  - Friday
  - Saturday
  - All days were the same

7. Date Worst Craving  /  /

8. Intensity Worst Day

Completed by (initials):

9. Second drug craved

If other circled, specify

10. Second drug intensity

11. Second drug frequency

12. Second drug length

13. Third drug craved

If other circled, specify

14. Third drug intensity

15. Third drug frequency

16. Third drug length



6801

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

Not Done

### BRIEF SUBSTANCE CRAVING SCALE (BSCS)

**INSTRUCTIONS:** Bubble in study day and complete assessment date in mm/dd/yyyy format. Transcribe responses from the BSCS source document.

Study day:  Intake Screening

19 (Discharge)

Assessment Date

mm / dd / yyyy

1. Meth Intensity

2. Meth frequency

3. Meth length

4. Number

5. Hours Craved

Minutes Craved

6. Worst Day Craving

Sunday

Monday

Tuesday

Wednesday

Thursday

Friday

Saturday

All days were the same

7. Date Worst Craving

8. Intensity Worst Day

9. Second drug craved

If other circled, specify

10. Second drug intensity

11. Second drug frequency

12. Second drug length

13. Third drug craved

If other circled, specify

14. Third drug intensity

15. Third drug frequency

16. Third drug length

Completed by (initials):



38541

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID      -      Protocol # N I D A - M D S - A R I P I P - 0 0 0 1

site #                      subject #

Not Done                      **BRIEF SYMPTOM INVENTORY (BSI)**

Study Day:  Intake Screening  
 10  
 19 (Discharge)

Assessment Date   /   / 20

mm / dd / yyyy

**Instructions:** Transcribe from BSI source document the number circled for each response.

- |  |   |
|--|---|
| <input type="checkbox"/> 1. Nervous          | <input type="checkbox"/> 17. Blue           |
| <input type="checkbox"/> 2. Faint            | <input type="checkbox"/> 18. No interest    |
| <input type="checkbox"/> 3. Controlled       | <input type="checkbox"/> 19. Fearful        |
| <input type="checkbox"/> 4. Blaming          | <input type="checkbox"/> 20. Easily hurt    |
| <input type="checkbox"/> 5. Remembering      | <input type="checkbox"/> 21. Disliked       |
| <input type="checkbox"/> 6. Annoyed          | <input type="checkbox"/> 22. Inferior       |
| <input type="checkbox"/> 7. Pains            | <input type="checkbox"/> 23. Nausea         |
| <input type="checkbox"/> 8. Afraid           | <input type="checkbox"/> 24. Watched        |
| <input type="checkbox"/> 9. Suicide          | <input type="checkbox"/> 25. Falling asleep |
| <input type="checkbox"/> 10. No Trust        | <input type="checkbox"/> 26. Double check   |
| <input type="checkbox"/> 11. No appetite     | <input type="checkbox"/> 27. Decisions      |
| <input type="checkbox"/> 12. Scared          | <input type="checkbox"/> 28. Afraid travel  |
| <input type="checkbox"/> 13. Temper          | <input type="checkbox"/> 29. Getting breath |
| <input type="checkbox"/> 14. Lonely w/others | <input type="checkbox"/> 30. Hot/Cold       |
| <input type="checkbox"/> 15. Blocked         | <input type="checkbox"/> 31. Frightened     |
| <input type="checkbox"/> 16. Lonely          | <input type="checkbox"/> 32. Blank          |



38541

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -     Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
site # subject #

### BRIEF SYMPTOM INVENTORY (BSI)

33. Numbness

43. Uneasy

34. Punished

44. Close

35. Hopeless

45. Terror

36. Concentrate

46. Arguments

37. Weak

47. Nervous

38. Tense

48. No credit

39. Dying

49. Restless

40. Harm

50. Worthless

41. Break

51. Take advantage

42. Self Conscious

52. Guilt

53. Wrong

Completed by (initials):



37624

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

 Not Done

### CHEMISTRIES

Study Day:  Pre-Intake Screening 14 19 (Discharge) Unscheduled

Test Date

mm / dd / yyyy

**INSTRUCTIONS:** Lab data can be transcribed either by using standard quantity and unit listed at left, **OR** by using other quantity and other unit (specify) text box at right. **You do not need to list lab data twice.**

**NORMAL:** within lab normal limits, **ABNORMAL:** outside of normal limits but not clinically significant,

**ABNORMAL SIGNIFICANT:** significant during screening means subject is ineligible for study; significant while on study means it should be reported as an adverse event.

Analyte	Std. Quantity	Unit	or Other Quantity	Other Unit (specify)	normal	abnormal	abnormal significant	not done
Sodium (NA)	<input type="text"/>	mEq/L*	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Potassium (K)	<input type="text"/>	mEq/L*	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chloride (Cl)	<input type="text"/>	mEq/L*	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bicarbonate (HCO <sub>3</sub> )	<input type="text"/>	mEq/L*	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Glucose	<input type="text"/>	mg/dL	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Creatinine	<input type="text"/>	mg/dL	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
SGOT/AST	<input type="text"/>	U/L	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
SGPT/ALT	<input type="text"/>	U/L	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
GGT	<input type="text"/>	U/L	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Total Bilirubin	<input type="text"/>	mg/dL	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
LDH	<input type="text"/>	U/L	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
CPK	<input type="text"/>	U/L	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Alkaline phosphatase	<input type="text"/>	U/L	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
BUN	<input type="text"/>	mg/dL	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Provide comments for any abnormal value(s):

Completed by (initials):

\* mEq/L = mmol/L



42516

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

     
   
     
   
 Not Done

### CHILD BEARING POTENTIAL

Study Day:  Pre-Intake Screening

Assessment Date

  /   / 20  

mm / dd / yyyy

**INSTRUCTIONS:** Complete this CRF for female participants only.

Is the female subject post menopausal, had a hysterectomy, or been surgically sterilized?  
(if yes, skip down to completed by)

 yes  no

If no, is the subject using an acceptable method of birth control?

 yes  no (if no, subject is not eligible to participate in study)

If yes, what method of birth control?

- oral contraceptives ("The Pill")  
 Patch  
 barrier (diaphragm or condom)  
 intrauterine contraceptive system (IUD)  
 lovenorgestrel implant (Norplant)  
 medroxyprogesterone acetate contraceptive injection  
 complete abstinence from sexual intercourse  
 hormonal vaginal contraceptive ring

Was a urine pregnancy test performed?

 yes  no

Urine Pregnancy Test Date

  /   /     mm / dd / yyyy

Pregnancy test result:

- Positive  
 Negative  
 Unknown

Pregnancy test comments:

Is the subject lactating?

 yes  no

Completed by (initials):

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

34648



### CONCOMITANT MEDICATIONS

**INSTRUCTIONS:** Complete CRF at intake and then every 7 days after until the end of inpatient portion of the study. Also complete for an SAE.

Are any Con Meds reported on this page?  YES  NO

If yes, list below using the provided legend:

DOSE	UNIT OF MEDICATION	FREQUENCY	ROUTE OF ADMINISTRATION
Number (e.g. 0.4, 1, 81)  UNK = unknown	CAP = capsule      PUF = puff g = gram              SPY = spray/squirt GR = grain            SUP = suppository GTT = drop            TSP = teaspoon ug = microgram      TBS = tablespoon uL = microliter      TAB = tablet mg = milligram      UNK = unknown mL = milliliter      OTH = other OZ = ounce	ONCE = one time only QD = once daily BID = twice daily TID = three times a day QID = four times a day QOD = every other day PRN = as needed UNK = unknown OTH = other	PO = oral              AUR = auricular TD = transdermal    IA = intra-articular INH = inhaled        IO = intraocular IM = intramuscular   UNK = unknown IV = intravenous     OTH = other REC = rectal VAG = vaginal SQ = subcutaneous SL = sublingual

Medication Name	Reason	Dose	Unit	Freq.	Route	Start Date (mm/dd/yyyy)	Stop Date (mm/dd/yyyy)
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>						
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>						
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>						
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>						
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>						
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>						
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>						

Completed by (initials):

Date completed:

 /  / 

mm / dd / yyyy

Page

 OF



24362

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -      Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
site # subject #

Not Done

### CUE MONITORING

Study Day:  1  
 9

Assessment Date  /  / 20    
mm / dd / yyyy

Time Interval	Actual Time (00:00-23:59)	Blood Pressure (sys/dias)	Heart Rate (beats/min)
-10 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
-5 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

CUE PRESENTATION (0-15 MIN.)  Neutral  Methamphetamine

0 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
5 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
10 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
15 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

CUE PRESENTATION ENDED

20 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
25 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
30 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

PARTICIPANT AT REST (30-50 MIN.)

55 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
60 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

CUE PRESENTATION (65-80 MIN.)  Neutral  Methamphetamine

65 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
70 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
75 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
80 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

CUE PRESENTATION ENDED

85 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
90 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
95 min	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

Completed by (initials):



58936

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

### DEATH REPORT

**INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.**

Subject date of death

 /  / 20

mm / dd / yyyy

Was autopsy performed?

 yes     no     unknown

If yes, is autopsy report available?

 yes\*     no

Is cause of death known?

 yes     no

If yes, in the investigator's clinical judgment, what was the primary cause of death?

Narrative description of death (include information about why cause of death is unknown, if applicable.)

\* Insert a copy of the autopsy report in source document binder behind Death Report.

Completed by (initials):

Date completed

 /  / 20

mm / dd / yyyy

Investigator's signature

Date



50172

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID      -     Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
 site # subject #

Not Done **DEMOGRAPHICS**

Study Day:  Pre-Intake Screening Assessment Date  /  / 20    
 mm / dd / yyyy

1. Gender:  Male  Female
2. Date of Birth  
 /  /     mm / dd / yyyy
3. Do you identify yourself as Spanish, Hispanic, or Latino?  
 No (If no, skip to question 4)  
 Yes, I see myself as (mark any that apply):  
 Mexican, Mexican American or Chicano  
 Puerto Rican  
 Cuban  
 Other Spanish, Hispanic or Latino (specify)

4. Ethnicity/Race :  
 For each of the following, answer Yes to all that apply and No to those that do not. If you mark yes, specify subgroup by marking all that apply.

- Yes  No American Indian or Alaskan Native  
 Yes  No Asian (mark all that apply)  
 Asian Indian  
 Chinese  
 Filipino  
 Japanese  
 Korean  
 Vietnamese  
 Other (specify)   
 Yes  No Black or African American  
 Yes  No Native Hawaiian or Pacific Islander (mark all that apply)  
 Native Hawaiian  
 Guamanian or Chamorro  
 Samoan  
 Other (specify)   
 Yes  No White  
 Yes  No Other (specify)   
 Participant chooses not to answer  
 Unknown

Completed by (initials):



# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID      -     Protocol #     -

site #                      subject #

Not Done    **12 LEAD ELECTROCARDIOGRAM (ECG) - INFUSION**

Study Day:  -7 (Infusion 1)                       10 (Infusion 4)                       -15 min pre                       45 min post  
 -5 (Infusion 2)                       12 (Infusion 5)                      Schd Time:  15 min post                       60 min post  
 -3 (Infusion 3)                       15 (Infusion 6)                       30 min post  
Actual Time   :   (00:00-23:59)

A. ECG overall results were:     Normal     Abnormal

If ECG was normal, skip to question C; otherwise indicate if any result was **ABNORMAL** but does not exclude the subject from participation in the study, or **ABNORMAL SIGNIFICANT** and does preclude (continued) participation in the study.

B. Abnormal results were:

- |                                   | abnormal              | abnormal significant  |  | abnormal              | abnormal significant  |
|-----------------------------------|-----------------------|-----------------------|--|-----------------------|-----------------------|
| 1. Increased QRS Voltage          | <input type="radio"/> | <input type="radio"/> | 17. Supraventricular Premature Beat        | <input type="radio"/> | <input type="radio"/> |
| 2. QTc Prolongation               | <input type="radio"/> | <input type="radio"/> | 18. Ventricular Premature Beat             | <input type="radio"/> | <input type="radio"/> |
| 3. Left Atrial Hypertrophy        | <input type="radio"/> | <input type="radio"/> | 19. Supraventricular Tachycardia           | <input type="radio"/> | <input type="radio"/> |
| 4. Right Atrial Hypertrophy       | <input type="radio"/> | <input type="radio"/> | 20. Ventricular Tachycardia                | <input type="radio"/> | <input type="radio"/> |
| 5. Left Ventricular Hypertrophy   | <input type="radio"/> | <input type="radio"/> | 21. Atrial Fibrillation                    | <input type="radio"/> | <input type="radio"/> |
| 6. Right Ventricular Hypertrophy  | <input type="radio"/> | <input type="radio"/> | 22. Atrial Flutter                         | <input type="radio"/> | <input type="radio"/> |
| 7. Acute Infarction               | <input type="radio"/> | <input type="radio"/> | 23. Other Rhythm Abnormalities             | <input type="radio"/> | <input type="radio"/> |
| 8. Subacute Infarction            | <input type="radio"/> | <input type="radio"/> | 24. Implanted Pacemaker                    | <input type="radio"/> | <input type="radio"/> |
| 9. Old Infarction                 | <input type="radio"/> | <input type="radio"/> | 25. 1st Degree A-V Block                   | <input type="radio"/> | <input type="radio"/> |
| 10. Myocardial Ischemia           | <input type="radio"/> | <input type="radio"/> | 26. 2nd Degree A-V Block                   | <input type="radio"/> | <input type="radio"/> |
| 11. Digitalis Effect              | <input type="radio"/> | <input type="radio"/> | 27. 3rd Degree A-V Block                   | <input type="radio"/> | <input type="radio"/> |
| 12. Symmetrical T-Wave Inversions | <input type="radio"/> | <input type="radio"/> | 28. LBB Block                              | <input type="radio"/> | <input type="radio"/> |
| 13. Poor R-Wave Progression       | <input type="radio"/> | <input type="radio"/> | 29. RBB Block                              | <input type="radio"/> | <input type="radio"/> |
| 14. Other Nonspecific ST/T        | <input type="radio"/> | <input type="radio"/> | 30. Pre-excitation Syndrome                | <input type="radio"/> | <input type="radio"/> |
| 15. Sinus Tachycardia             | <input type="radio"/> | <input type="radio"/> | 31. Other Intraventricular Condition Block | <input type="radio"/> | <input type="radio"/> |
| 16. Sinus Bradycardia             | <input type="radio"/> | <input type="radio"/> | 32. Other, specify:                        | <input type="radio"/> | <input type="radio"/> |

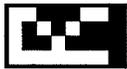
C. Ventricular rate (bpm):

E. QRS (ms)

D. PR (ms):

F. QTc (ms):

Completed by (initials):



22383

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -     Protocol #     -     -     -

site #                      subject #

Not Done                      **12 LEAD ELECTROCARDIOGRAM (ECG)**

Study Day:  Pre-Intake Screening  
 Intake Screening  
 19 (Discharge)  
 Unscheduled

Test Date   /   / 20    
mm / dd / yyyy

Time   :   (00:00-23:59)

A. ECG overall results were:                       Normal    Abnormal

If ECG was normal, skip to question C; otherwise indicate if any result was **ABNORMAL** but does not exclude the subject from participation in the study, or **ABNORMAL SIGNIFICANT** and does preclude (continued) participation in the study.

B. Abnormal results were:

	abnormal	abnormal significant		abnormal	abnormal significant
1. Increased QRS Voltage	<input type="radio"/>	<input type="radio"/>	17. Supraventricular Premature Beat	<input type="radio"/>	<input type="radio"/>
2. QTc Prolongation	<input type="radio"/>	<input type="radio"/>	18. Ventricular Premature Beat	<input type="radio"/>	<input type="radio"/>
3. Left Atrial Hypertrophy	<input type="radio"/>	<input type="radio"/>	19. Supraventricular Tachycardia	<input type="radio"/>	<input type="radio"/>
4. Right Atrial Hypertrophy	<input type="radio"/>	<input type="radio"/>	20. Ventricular Tachycardia	<input type="radio"/>	<input type="radio"/>
5. Left Ventricular Hypertrophy	<input type="radio"/>	<input type="radio"/>	21. Atrial Fibrillation	<input type="radio"/>	<input type="radio"/>
6. Right Ventricular Hypertrophy	<input type="radio"/>	<input type="radio"/>	22. Atrial Flutter	<input type="radio"/>	<input type="radio"/>
7. Acute Infarction	<input type="radio"/>	<input type="radio"/>	23. Other Rhythm Abnormalities	<input type="radio"/>	<input type="radio"/>
8. Subacute Infarction	<input type="radio"/>	<input type="radio"/>	24. Implanted Pacemaker	<input type="radio"/>	<input type="radio"/>
9. Old Infarction	<input type="radio"/>	<input type="radio"/>	25. 1st Degree A-V Block	<input type="radio"/>	<input type="radio"/>
10. Myocardial Ischemia	<input type="radio"/>	<input type="radio"/>	26. 2nd Degree A-V Block	<input type="radio"/>	<input type="radio"/>
11. Digitalis Effect	<input type="radio"/>	<input type="radio"/>	27. 3rd Degree A-V Block	<input type="radio"/>	<input type="radio"/>
12. Symmetrical T-Wave Inversions	<input type="radio"/>	<input type="radio"/>	28. LBB Block	<input type="radio"/>	<input type="radio"/>
13. Poor R-Wave Progression	<input type="radio"/>	<input type="radio"/>	29. RBB Block	<input type="radio"/>	<input type="radio"/>
14. Other Nonspecific ST/T	<input type="radio"/>	<input type="radio"/>	30. Pre-excitation Syndrome	<input type="radio"/>	<input type="radio"/>
15. Sinus Tachycardia	<input type="radio"/>	<input type="radio"/>	31. Other Intraventricular Condition Block	<input type="radio"/>	<input type="radio"/>
16. Sinus Bradycardia	<input type="radio"/>	<input type="radio"/>	32. Other, specify:	<input type="radio"/>	<input type="radio"/>

C. Ventricular rate (bpm):

E. QRS (ms)

D. PR (ms):

F. QTc (ms):

Completed by (initials):



58111

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID      -     Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
site # subject #

### END OF TRIAL

**INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.**

1. Date of discharge or last visit   /   / 2 0   mm / dd / yyyy

a. Study day of discharge/last visit  (i.e -4, 3, 23)

2. Was the subject terminated early from the trial?  Yes  No

3. Provide reason subject ended participation in study (select only one):

- Subject completed study.
- Subject was determined after enrollment to be ineligible. (Provide comments.)
- Subject requested to withdraw. (Provide comments.)
- Subject experienced intercurrent illness, unrelated medical condition, or clinically significant adverse events which, in the judgment of the investigator, prompted early termination. (If subject experienced adverse event(s), an Adverse Event Case Report Form(s) must be completed.) (Provide comments.)
- Subject terminated for administrative reasons. (Provide comments; include protocol non-compliance in this category.)
- Subject transferred to another treatment program (indicate type).
  - Methadone
  - Drug Free
  - Inpatient Detox or Treatment
  - LAAM
  - Therapeutic Community
  - Other, specify
- Subject was incarcerated.
- Subject became pregnant.
- Subject developed sensitivity to study agent.
- Subject was lost to follow-up.
- Subject moved from area.
- Subject died. (If subject died, a Death Report Case Report Form must be completed.)
- Subject can no longer attend clinic.
- Subject no longer attends clinic.
- Subject is in a controlled environment.
- Subject is a screen failure
- Other (Provide comments.)

b. If requested, provide additional comments:

Completed by (initials):    Date form completed   /   / 2 0   mm / dd / yyyy



52819

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

### ENROLLMENT

**INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.**

Is subject eligible for participation based on the Eligibility Criteria?(required field)  yes  no\*

\*if no, skip to completed by field and complete End of Trial CRF marking Screen Failure

If yes, was subject enrolled into the study?  yes  no

If yes, date enrolled:  /  /  mm / dd / yyyy

If no,(subject was eligible but not enrolled), indicate reason:

(Complete End of Trial CRF marking Other and specify in text box exact reason)

- failed to return to clinic
- declined study participation
- other, specify:

Completed by (initials):

Date completed

 /  / 

mm / dd / yyyy



5775

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

						-				
site #					subject #					

Protocol #

N	I	D	A	-	M	D	S	-	A	R	I	P	I	P	-	0	0	0	1
---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

 Not Done

### HEMATOLOGY

Study Day:  Pre-Intake Screening 14 19 (Discharge) Unscheduled

Test Date

		/			/	2	0		
mm			dd			yyyy			

**INSTRUCTIONS:** Lab data can be transcribed either by using standard quantity and unit listed at left, **OR** by using other quantity and other unit (specify) text box at right. **You do not need to list lab data twice.**

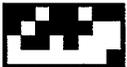
Indicate whether the laboratory value is **NORMAL:** within lab normal limits, **ABNORMAL:** outside of normal limits but not clinically significant, **ABNORMAL SIGNIFICANT:** significant during screening means subject is ineligible for study; significant while on study means it should be reported as an adverse event.

	Quantity	Unit	OR	Other Quantity	Other Unit (specify)	normal	abnormal	abnormal significant	not done
<b>CBC</b>									
Hemoglobin	<input type="text"/> <input type="text"/> . <input type="text"/>	g/dL		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hematocrit	<input type="text"/> <input type="text"/> . <input type="text"/>	%		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
RBC	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	million/uL		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Platelet count	<input type="text"/> <input type="text"/> <input type="text"/>	thousand/uL		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
WBC	<input type="text"/> <input type="text"/> . <input type="text"/>	thousand/uL		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
MCV	<input type="text"/> <input type="text"/> . <input type="text"/>	fL (mcm <sup>3</sup> )		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Differential</b>									
Neutrophils	<input type="text"/> <input type="text"/> . <input type="text"/>	%		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lymphocytes	<input type="text"/> <input type="text"/> . <input type="text"/>	%		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Monocytes	<input type="text"/> <input type="text"/> . <input type="text"/>	%		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Eosinophils	<input type="text"/> <input type="text"/> . <input type="text"/>	%		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Basophils	<input type="text"/> <input type="text"/> . <input type="text"/>	%		_____ . _____	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Provide comments for any abnormal value(s):

Completed by (initials):

--	--	--



48232

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	-	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Protocol #	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	-	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	-	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	-	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>													
	site #		subject #		N	I	D	A	-	M	D	S	-	A	R	I	P	I	P	-	0	0	0	1

Not Done **HIV RISK-TAKING BEHAVIOR SCALE (HRBS)**

Study Day:  Intake Screening      Assessment Date  /  / 20  
mm / dd / yyyy

**Drug Use**

1. How many times have you hit up (i.e. injected any drugs) in the last month?

- I haven't hit up
- Once a week or less
- More than once a week but less than once a day
- Once a day
- 2-3 times a day
- More than three times a day

*If you have not injected drugs in the last month, go to Question 7.*

2. How many times in the last month have you used a needle after someone else had already used it?

- No times
- One time
- Two times
- 3-5 times
- 6-10 times
- More than 10 times

3. How many different people have used a needle before you in the past month?

- None
- One person
- Two people
- 3-5 people
- 6-10 people
- More than 10 people

4. How many times in the last month has someone used a needle after you?

- No times
- One time
- Two times
- 3-5 times
- 6-10 times
- More than 10 times



48232

**National Institute on Drug Abuse**  
**Aripiprazole for Methamphetamine Dependence**

Subject ID

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site #

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subject #

Protocol #

N	I	D	A
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-	M	D	S
---	---	---	---

-	A	R	I	P	I	P
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-	0	0	0	1
---	---	---	---	---

**HIV RISK-TAKING BEHAVIOR SCALE (HRBS)**

5. How often, in the last month, have you cleaned needles before re-using them?

- I do not re-use
- Every time
- Often
- Sometimes
- Rarely
- Never

6. Before using needles again, how often in the past month did you use bleach to clean them?

- I do not re-use
- Every time
- Often
- Sometimes
- Rarely
- Never

**Sexual Behavior**

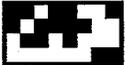
7. How many people, including clients, have you had sex with in the last month?

- None
- One
- Two
- 3-5 people
- 6-10 people
- More than 10 people

*If no sex in the last month, skip to question #12.*

8. How often have you used condoms when having sex with your regular partner(s) in the last month?

- No regular partner/no penetrative sex
- Every time
- Often
- Sometimes
- Rarely
- Never



48232

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

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site #

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subject #

Protocol #

N	I	D	A
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M	D	S
---	---	---

A	R	I	P	I	P
---	---	---	---	---	---

0	0	0	1
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### HIV RISK-TAKING BEHAVIOR SCALE (HRBS)

9. How often have you used condoms when you had sex with casual partners?

- No casual partners/no penetrative sex
- Every time
- Often
- Sometimes
- Rarely
- Never

10. How often have you used condoms when you have been paid for sex in the last month?

- No paid sex/no penetrative sex
- Every time
- Often
- Sometimes
- Rarely
- Never

11. How many times have you had anal sex in the last month?

- No times
- One time
- Two times
- 3-5 times
- 6-10 times
- More than 10 times

12. Have you ever been diagnosed with AIDS?

- Yes
- No
- Don't Know

Completed by (initials):

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(Source: Darke S et al., The reliability and validity of a scale to measure HIV risk-taking behaviour among intravenous drug users. *AIDS*, Feb 1991)



8371

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

     
   
     
   
 Not Done
**HIV TEST**Study Day:  Intake Screening Unscheduled

Test Date

  /   / 20  

mm / dd / yyyy

HIV test type:

- ELISA  
 Western Blot  
 PCR  
 other (specify)   
 unknown

HIV test result:

- positive  
 negative  
 unknown

 If HIV result is positive,  
 was confirmatory test  
 performed?

- yes  
 no  
 unknown

If confirmatory test was done:

Date blood was drawn

  /   /     mm / dd / yyyy

Confirmatory test type:

- ELISA  
 Western Blot  
 PCR  
 other (specify)   
 unknown

Confirmatory test result:

- positive  
 negative  
 unknown

Comments:

Completed by (initials):



15299

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

### INCLUSION/EXCLUSION CRITERIA

Study Day:  Intake Screening

Assessment Date

  /   / 20  

mm / dd / yyyy

**Inclusion Criteria:** All responses must be YES for participant to be eligible. The participant must:

1. Meet DSM-IV criteria for methamphetamine abuse or dependence and is not seeking treatment at time of study.  yes  no
2. Be between 18 - 45 years of age.  yes  no
3. Be within 20% of ideal body weight according to Metropolitan Height and Weight Standards, and weigh at least 45kg ( 99 lbs).  yes  no
4. Demonstrate understanding of consent form, be able to provide written consent and verbalize willingness to complete study procedures.  yes  no
5. Have used methamphetamine, as assessed by self-report and a positive urine test, within 2 weeks of entering the study.  yes  no
6. Have a history and physical exam that demonstrates no clinically significant contraindication for participating in this study, in the judgment of the admitting physician and site investigator.  yes  no
7. Be male or, if female, have a negative pregnancy test within 72 hours prior to receiving the first dose of Aripiprazole or placebo. If patient is not postmenopausal, has had a hysterectomy or has not been sterilized, must agree to follow a birth control method specified in protocol (page 21).  yes  no
8. Have vital signs as follows: resting pulse between 50 and 90 bpm, BP below 150 mm Hg systolic and 90 mm Hg diastolic.  yes  no
9. Have electrolytes (Na, K, Cl, HCO<sub>3</sub>) and hematocrit that are clinically normal (+/- 10% of laboratory limits).  yes  no
10. Have liver function tests (total bilirubin, ALT, AST, GGT and alk phos) within normal limits.  yes  no
11. Have kidney function tests (creatinine and BUN) within normal limits.  yes  no
12. Have an ECG performed that demonstrates normal sinus rhythm, normal conduction, and no clinically significant arrhythmias.  yes  no



15299

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

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site #

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subject #

Protocol #

N	I	D	A
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M	D	S
---	---	---

A	R	I	P	I	P
---	---	---	---	---	---

0	0	0	1
---	---	---	---

### INCLUSION/EXCLUSION CRITERIA

**Exclusion Criteria:** All responses must be NO for participant to be eligible. The participant must NOT:

- |   |                           |                          |
|---|---------------------------|--------------------------|
| 1. Meet DSM-IV criteria for dependence on drugs or ETOH (excluding methamphetamine or nicotine)   | <input type="radio"/> yes | <input type="radio"/> no |
| 2. Have any previous medically adverse reaction to methamphetamine, including loss of consciousness, chest pain, or seizure.  | <input type="radio"/> yes | <input type="radio"/> no |
| 3. According to DSM-IV criteria as determined by structured clinical interview (SCID), have any history of major psychiatric illness other than drug dependence or disorders secondary to drug use. Included in this exclusion are Axis I psychiatric disorders as specified by the protocol (page 22, #3). | <input type="radio"/> yes | <input type="radio"/> no |
| 4. Have any evidence of clinically significant heart disease, hypertension or significant medical illness, condition, and/or use of medications that in the opinion of the site investigator and the admitting physician, would preclude safe and/or successful completion of the study.                    | <input type="radio"/> yes | <input type="radio"/> no |
| 5. Be pregnant or nursing.  | <input type="radio"/> yes | <input type="radio"/> no |
| 6. Have a significant family history of early cardiovascular morbidity or mortality.  | <input type="radio"/> yes | <input type="radio"/> no |
| 7. Have a diagnosis of adult onset asthma (> 21 years or older), or chronic obstructive pulmonary disease (COPD), including those with a history of acute asthma within the past 2 years, and those with current or recent (past 2 years) treatment with inhaled or oral beta-agonist or steroid therapy.   | <input type="radio"/> yes | <input type="radio"/> no |
| 8. Have active syphilis that has not been treated or refuses treatment for syphilis (see protocol, pg 23 for exception to having a positive RPR test).  | <input type="radio"/> yes | <input type="radio"/> no |
| 9. Be undergoing HIV treatment with antiviral and/or non-antiviral therapy or treatment for HIV-related opportunistic infection. A positive antibody titer to HIV is not exclusionary.  | <input type="radio"/> yes | <input type="radio"/> no |
| 10. Have AIDS according to the current CDC criteria for AIDS - MMWR 1999; 48 (no. RR-13:29-31).   | <input type="radio"/> yes | <input type="radio"/> no |
| 11. Have received investigational drug in the last 30 days prior to signing the informed consent.   | <input type="radio"/> yes | <input type="radio"/> no |
| 12. Be using Aripiprazole or any medication that could interact adversely with Aripiprazole, within the following times of beginning of administration of Aripiprazole based on the longest time interval of A, B, or C below:  | <input type="radio"/> yes | <input type="radio"/> no |
| A) 5 half lives of other medication or active metabolite(s), whichever is longer  |                           |                          |
| B) 2 weeks  |                           |                          |
| C) Interval recommended by other medication's product labeling.   |                           |                          |

Completed by (initials):

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56986

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -     Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
site # subject #

Not Done

### INFECTIOUS DISEASE PANEL

Study Day:  Intake Screening  
 Unscheduled

Test Date  /  / 20    
mm / dd / yyyy

Indicate whether the laboratory value is **NEGATIVE**: negative test result, **POSITIVE**: but **DOES NOT EXCLUDE** subject from participation or continued study participation, **POSITIVE SIGNIFICANT**: significant during screening means subject is ineligible for study; significant while on study means it should be reported as an adverse event, **INDETERMINANT**: result was not interpretable.

negative  
positive  
positive significant  
indeterminant  
not done

Provide comments for any abnormal value.

Hepatitis B surface antigen result

Hepatitis B surface antibody result

Hepatitis B core antibody result

Hepatitis C virus antibody result

Date PPD test administered  /  / 20   mm / dd / yyyy

Time PPD test administered  :  24 hour clock

Date PPD test read  /  / 20   mm / dd / yyyy

Time PPD test read  :  24 hour clock

PPD test result  PPD Previously Positive  
\*(Test not done, chest X-ray required)  
 negative  
 positive\* \*If positive, chest X-ray is required.  
 unknown

If PPD test not done, state reason.

Provide comments for any positive value.



56986

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

### INFECTIOUS DISEASE PANEL

Date chest X-ray performed

mm / dd / yyyy

Results of chest X-ray

- normal
- abnormal
- abnormal significant
- indeterminant
- not done

If chest x-ray not done, state reason.

Provide comments for any abnormal finding.

Completed by (initials):





22581

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

Not Done

### INFUSION RANDOMIZATION

**INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.**

Date of Infusion Randomization:

mm / dd / yyyy

Randomization #

Completed by (initials):

Date completed

mm / dd / yyyy



59112

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

						-				
site #					subject #					

Protocol #

N	I	D	A	-	M	D	S	-	A	R	I	P	I	P	-	0	0	0	1
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Not Done

### INVESTIGATIONAL AGENT ADMINISTRATION

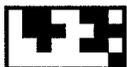
STUDY DAY	DATE (mm/dd/yyyy)	Number of tablets administered	Time administered (00:00-23:59)	Administered by (initials)
-----------	-------------------	--------------------------------	---------------------------------	----------------------------

1	/ / 20		:	
2	/ / 20		:	
3	/ / 20		:	
4	/ / 20		:	
5	/ / 20		:	
6	/ / 20		:	
7	/ / 20		:	
8	/ / 20		:	
9	/ / 20		:	
10	/ / 20		:	
11	/ / 20		:	
12	/ / 20		:	
13	/ / 20		:	
14	/ / 20		:	
15	/ / 20		:	

Completed by (initials):

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29478

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

Not Done

### MEDICAL HISTORY

Study Day:  Pre-Intake Screening

Assessment Date

mm / dd / yyyy

Mark one answer for each disorder. Mark "Yes excludes" if subject has condition that excludes him/her from study participation. Mark "Yes doesn't exclude" if subject has condition that does not exclude him/her from study participation. Mark "No history of disorder" if subject has not ever had condition. Mark "Not evaluated" if not evaluated or unknown.

Disorder:	*Yes		No	Not evaluated	*If Yes, specify or describe
	excludes	doesn't exclude	history of disorder		
1. allergies: drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
2. allergies: other, specify <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
3. sensitivity to investigational agent or related compounds	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
4. history of asthma	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
5. head, ears, eyes, nose, throat (HEENT)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
6. cardiovascular	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
7. renal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
8. hepatic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
9. pulmonary	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
10. gastrointestinal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
11. musculoskeletal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
12. neurologic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
13. psychiatric	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
14. dermatologic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
15. metabolic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
16. hematologic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>



29478

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

Site # [ ][ ][ ][ ][ ][ ]

site #

subject # [ ][ ][ ][ ][ ]

subject #

Protocol #

NIDA

MDS

ARIPIP

0001

### MEDICAL HISTORY

Disorder:	*Yes excludes	*Yes doesn't exclude	No history of disorder	Not evaluated	*If Yes, specify or describe
17. endocrine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	[ ]
18. genitourinary	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	[ ]
19. reproductive system	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	[ ]
20. seizure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	[ ]
21. infectious disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	[ ]
22. other1, specify [ ]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		[ ]
23. other2, specify [ ]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		[ ]

24. Was major surgery ever performed?  Yes  No  
If Yes, list surgeries:

	Type of Surgery	Date of Surgery			Yes excludes	Yes doesn't exclude	No
		mm	dd	yyyy			
25.	[ ]	[ ][ ]	[ ][ ]	[ ][ ][ ][ ]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26.	[ ]	[ ][ ]	[ ][ ]	[ ][ ][ ][ ]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27.	[ ]	[ ][ ]	[ ][ ]	[ ][ ][ ][ ]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### Tobacco History

28. Has subject used any tobacco product (e.g. cigarettes, cigars, pipe, chewing tobacco) in the past week?  Yes  No
29. Has subject ever used any tobacco product for at least one year?  Yes  No
30. If yes, number of years tobacco used? [ ][ ]

#### Cardiovascular Family History:

31. Does subject have a significant family history of early cardiovascular morbidity or mortality?  Yes  No

Additional Comments (optional):

[ ]

Completed by (initials):

[ ][ ][ ]



59438

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

						-					
site #							subject #				

Protocol #

N	I	D	A	-	M	D	S	-	A	R	I	P	I	P	-	0	0	0	1
---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

 Not Done

### PHYSICAL EXAM

 Study Day:  Pre-intake Screening  
 Unscheduled

Exam Date

		/			/	2	0		
mm / dd / yyyy									

Height

--	--	--

inches

Weight

--	--	--

pounds

Indicate whether the physical exam reveals a body system is **NORMAL**: no physical problems, **ABNORMAL**: but does not affect enrollment or continued study participation, **ABNORMAL SIGNIFICANT**: significant during screening means subject is ineligible for study.

	normal	abnormal	abnormal significant	not done	Provide comments for any abnormal finding.
Oral (mouth)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Head and neck	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Eyes, ears, nose/throat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Cardiovascular	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Chest	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Lungs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Abdomen (include liver/spleen)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Extremities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Skin, hair, nails	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Neuropsychiatric mental status	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Neuropsychiatric sensory/motor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Musculoskeletal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
General appearance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Other (specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="text"/>
Other (specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="text"/>

Completed by (initials):

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9835

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -     Protocol #       -       -

site #                      subject #

Not Done **PREGNANCY TEST**

Study Day:  Intake Screening  
 Within 72 hrs of Study Drug dosing  
 19 (Discharge)  
 Follow Up (Week 4)  
 Unscheduled

Test Date   /   / 20

mm / dd / yyyy

Urine pregnancy test result:  Positive  
 Negative  
 Unknown

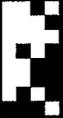
Pregnancy test comments:

Completed by (initials):

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

36115



Subject ID

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site #

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subject #

Protocol #

N	I	D	A	-	M	D	S	-	A	R	I	P	I	P	-	0	0	0	1
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Not Done

### PRIOR MEDICATIONS

**INSTRUCTIONS: COMPLETE PRIOR MEDICATIONS CRF AT SIGNING OF INFORMED CONSENT.**

Are any Prior Meds reported on this page?  YES  NO

If yes, list below using the provided legend:

DOSE	UNIT OF MEDICATION	FREQUENCY	ROUTE OF ADMINISTRATION
Number (e.g. 0.4, 1, 81)  UNK = unknown	CAP = capsule g = gram GR = grain GTT = drop ug = microgram uL = microliter mg = milligram mL = milliliter OZ = ounce  PUF = puff SPY = spray/squirt SUP = suppository TSP = teaspoon TBS = tablespoon TAB = tablet UNK = unknown OTH = other	ONCE = one time only QD = once daily BID = twice daily TID = three times a day QID = four times a day QOD = every other day PRN = as needed UNK = unknown OTH = other	PO = oral TD = transdermal INH = inhaled IM = intramuscular IV = intravenous REC = rectal VAG = vaginal SQ = subcutaneous SL = sublingual  AUR = auricular IA = intra-articular IO = intraocular UNK = unknown OTH = other

Medication Name	Reason	Dose	Unit	Freq.	Route	Start Date (mm/dd/yyyy)	Stop Date (mm/dd/yyyy)																		
						<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> / <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> / <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> </table>										<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> / <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> / <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> </table>									
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Completed by (initials):

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Date completed:

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mm / dd / yyyy

Page

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8827

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

     
   
       
   
 Not Done

### PROFILE OF MOOD STATUS (POMS)

Study Day:  Intake Screening 10 19 (Discharge)

Assessment Date

  /   / 20  

mm / dd / yyyy

**Instructions:** Transcribe from POMS source document the number circled for each adjective.

1. Friendly

17. Grouchy

33. Resentful

2. Tense

18. Blue

34. Nervous

3. Angry

19. Energetic

35. Lonely

4. Worn out

20. Panicky

36. Miserable

5. Unhappy

21. Hopeless

37. Muddled

6. Clear-headed

22. Relaxed

38. Cheerful

7. Lively

23. Unworthy

39. Bitter

8. Confused

24. Spiteful

40. Exhausted

9. Sorry for things

25. Sympathetic

41. Anxious

10. Shaky

26. Uneasy

42. Ready to fight

11. Listless

27. Restless

43. Good natured

12. Peeved

28. Unable to concentrate

44. Gloomy

13. Considerate

29. Fatigued

45. Desperate

14. Sad

30. Helpful

46. Sluggish

15. Active

31. Annoyed

47. Rebellious

16. On edge

32. Discouraged

48. Helpless



8827

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

-

site #

subject #

Protocol #

-      -       -

### PROFILE OF MOOD STATUS (POMS)

49. Weary

50. Bewildered

51. Alert

52. Deceived

53. Furious

54. Efficient

55. Trusting

56. Full of pep

57. Bad-tempered

58. Worthless

59. Forgetful

60. Carefree

61. Terrified

62. Guilty

63. Vigorous

64. Uncertain about things

65. Bushed

Completed by (initials):



43743

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #						subject #					

Protocol #

N	I	D	A	-	M	D	S	-	A	R	I	P	I	P	-	0	0	0	1
---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

 Not Done**SCID**Study Day:  Intake Screening

Assessment Date

		/			/	2	0		
mm / dd / yyyy									

**INSTRUCTIONS:** Please list all CURRENT and PAST Substance abuse or Dependence Diagnoses, other current and other past diagnoses (include DSM-IV code).

Axis 1 Diagnoses Type
-----------------------

- |  |
|--|
| 1= Current Diagnoses Substance Abuse or Dependence<br>2= Past Diagnoses Substance Abuse or Dependence<br>3= Other Current Diagnoses<br>4= Other Past Diagnoses |
|--|

Line #	Axis 1 Diagnoses Type (use legend above)	DSM-IV Code	Diagnosis
1	<input style="width: 20px; height: 20px;" type="checkbox"/>		
2	<input style="width: 20px; height: 20px;" type="checkbox"/>		
3	<input style="width: 20px; height: 20px;" type="checkbox"/>		
4	<input style="width: 20px; height: 20px;" type="checkbox"/>		

Completed by (initials):

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15026

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

### SERIOUS ADVERSE EVENT

Reason(s) adverse event is reported as serious

- Death\*
- Life-threatening
- Hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Other, specify

\*If outcome was death, a Death Report Case Report Form must be completed.

Severity grade  mild  moderate  severe

Was SAE related to investigational agent?

- definitely
- probably
- possibly
- remotely
- definitely not
- unknown

Action taken regarding investigational agent

- none
- discontinued permanently
- discontinued temporarily
- reduced dose
- increased dose
- delayed dose

Other action(s) taken

- none
- remedial therapy - pharmacologic
- remedial therapy - nonpharmacologic
- hospitalization (new or prolonged)

Relevant tests/laboratory data, including dates

Relevant history including pre-existing medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)



15026

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID      -     Protocol #       -       -

site #

subject #

### SERIOUS ADVERSE EVENT

#### INVESTIGATIONAL AGENT ADMINISTRATION

Has participant been dosed with study agent/placebo?  yes  no (if no, skip down to completed by)

Date of Last Dose:   /   / 20   Time of last dose:  :    
(00:00-23:59)

Additional Comments (if needed):

Completed by (initials):    Date Completed:   /   / 20    
mm / dd / yyyy

Principal Investigator:                       
(Last Name, First Name)

Name of Institution

Investigator's signature

Date



30692

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID      -    Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
site # subject #

Not Done

### SIMPSON-ANGUS SCALE

- Study Day:  1  
 5  
 12  
 Unscheduled

Assessment Date  
  /   / 2 0    
 mm / dd / yyyy

- |                   |                         |                         |                         |                         |                         |
|-------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Gait              | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |
| Arm Dropping      | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |
| Shoulder Shaking  | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |
| Elbow Rigidity    | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |
| Wrist Rigidity    | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |
| Leg Pendulousness | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |
| Head Rotation     | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |
| Glabellar Tap     | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |
| Tremor            | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |
| Salivation        | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 |

Completed by (initials):



3174

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

Not Done

### STUDY DRUG RANDOMIZATION

**INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.**

Is participant still eligible for participation based on the Eligibility Criteria? (required field)

yes

no

Date of study drug randomization:

mm / dd / yyyy

Randomization #

Completed by (initials):

Date completed

mm / dd / yyyy



38170

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID       -     Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
site # subject #

Not Done **SYPHILIS TEST**

Study Day:  Intake screening  
 Unscheduled

Test Date  /  / 20    
mm / dd / yyyy

**INSTRUCTIONS:** Indicate the laboratory value.

negative  
positive\*  
indeterminant\*\*  
not done

If RPR test is not done, state reason.

Rapid plasma reagin (RPR) test result

\*If positive, fluorescent treponemal antibody absorbent assay (FTP-abs) or microhemagglutinin assay-Treponema pallidum (MHA-TP) confirmatory test is required.

\*\*If RPR test is indeterminant, it must be repeated.

Date FTP-abs test administered  /  / 20   mm / dd / yyyy

FTP-abs test result  negative  
 positive†  
 indeterminant  
 not done  
If test not done, state reason.

†If FTP-abs result is positive, is subject willing to undergo treatment for syphilis?

Yes  
 No

If treated, date of written proof of treatment:  /  / 20

If subject is unwilling to undergo treatment for active syphilis, s/he is ineligible to participate in research study.

Comments:

Completed by (initials):



59990

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID      -     Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
site # subject #

Not Done **TIMELINE FOLLOW BACK-Intake**

Study Day:  Intake

Assessment Date  /  / 2 0    
mm / dd / yyyy

**INSTRUCTIONS:** Transcribe responses from Timeline follow back source document. Treat Day 1 as the day of Pre-Intake. Use as many lines as needed to document from Day 1 (Pre-Intake) to yesterday.

Day 1 (Pre-Intake)   /   / 2 0

Yesterday   /   / 2 0

Day 1  yes  no

Day 8  yes  no

Day 2  yes  no

Day 9  yes  no

Day 3  yes  no

Day 10  yes  no

Day 4  yes  no

Day 11  yes  no

Day 5  yes  no

Day 12  yes  no

Day 6  yes  no

Day 13  yes  no

Day 7  yes  no

Day 14  yes  no

Completed by (initials):



30778

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

Not Done

### TIMELINE FOLLOW BACK- Pre-Intake

Study Day:  Pre-Intake Screening

Assessment Date

mm / dd / yyyy

**INSTRUCTIONS:** Transcribe responses from Timeline follow back source document. Treat Day 30 as yesterday.

Day 1 (30 days ago)  /  /

Day 30 (yesterday)  /  /

Day 1  yes  no

Day 15  yes  no

Day 29  yes  no

Day 2  yes  no

Day 16  yes  no

Day 30 (yesterday)  yes  no

Day 3  yes  no

Day 17  yes  no

Day 4  yes  no

Day 18  yes  no

Day 5  yes  no

Day 19  yes  no

Day 6  yes  no

Day 20  yes  no

Day 7  yes  no

Day 21  yes  no

Day 8  yes  no

Day 22  yes  no

Day 9  yes  no

Day 23  yes  no

Day 10  yes  no

Day 24  yes  no

Day 11  yes  no

Day 25  yes  no

Day 12  yes  no

Day 26  yes  no

Day 13  yes  no

Day 27  yes  no

Day 14  yes  no

Day 28  yes  no

Completed by (initials):







47805

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

Not Done

### URINE PK (INFUSIONS 3 AND 6)

Study Day:  -3 (Infusion 3)     15 (Infusion 6)

Sample #	Time Relative to Infusion	Collection Volume (mL)
1	-2 to 0 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
2	0 to 6 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3	6 to 12 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4	12 to 21 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
5	21 to 24 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
6	24 to 30 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
7	30 to 36 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
8	36 to 48 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
9	48 to 54 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
10	54 to 60 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
11	60 to 72 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
12	72 to 84 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
13	84 to 96 hrs	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Completed by (initials):



20520

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

 Not Done

### URINE TOXICOLOGY - Inpatient

**INSTRUCTIONS:** Complete study day and assessment date in mm/dd/yyyy format.

Inpatient study day:

(i.e -4, 3, 23)

Test Date

mm / dd / yyyy

Urine temperature within expected range?  Yes  No  Unknown  
(96.4  $\geq$  T  $\leq$  100.4 °F)

	Positive	Negative	Not done
Amphetamines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Barbiturates	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Benzodiazepines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cannabinoids (THC)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cocaine metabolites	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methadone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methamphetamine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methaqualone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opiates	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Phencyclidine (PCP)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Propoxyphene	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Completed by (initials):



# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

						-				
--	--	--	--	--	--	---	--	--	--	--

site #

subject #

Protocol #

N	I	D	A	-	M	D	S	-	A	R	I	P	I	P	-	0	0	0	1
---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

Not Done

### VISUAL ANALOG SCALE(VAS)-Cue Reactivity

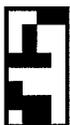
Study Day:  1  
 9

**Instructions:** Transcribe responses from VAS-Cue Reactivity Source Document. Complete actual time assessment administered. For each question, measure response using ruler printed on transparent film. Lay film over bar to calculate corresponding numerical value. Calculate response to subsequent questions using ruler provided.

Time Interval	Actual Time (00:00-23:59)	Any meth-like effect?	Desire for Drug?	Depressed?	Anxious?	Nervous?	Irritable?	Stimulated?	Likely to Use?
-10 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
+15 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
25 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
55 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
80 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
90 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Completed by (initials):

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52937

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

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site #

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subject #

Protocol #

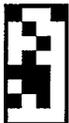
N	I	D	A	-	M	D	S	-	A	R	I	P	I	P	-	0	0	0	1
---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

Not Done

### VISUAL ANALOG SCALE(VAS)-Infusion

Study Day:  -7 (Infusion 1)                       10 (Infusion 4)  
 -5 (Infusion 2)                                       12 (Infusion 5)  
 -3 (Infusion 3)     15 (Infusion 6)

Time Interval	Actual Time (00:00-23:59)	Any drug effect?	High?	Good effects?	Bad effects?	Liking?	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
-15 min												
+3 min												
6 min												
10 min												
15 min												
30 min												
45 min												
60 min												
90 min												
180 min												
210 min												
240 min												
300 min												
360 min												
420 min												
480 min												



14964

Completed by (initials):

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21720

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID  -  Protocol # N I D A - M D S - A R I P I P - 0 0 0 1  
site # subject #

Not Done

### VITAL SIGNS - Inpatient

**INSTRUCTIONS:** Fill in study day and complete assessment date in mm/dd/yyyy format.

Inpatient study day:  (i.e -4, 3, 23) Assessment Date  /  / 20   
mm / dd / yyyy

Time vital signs taken  :  (24 hr clock)

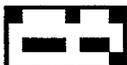
Temperature (oral)  .  °F  Not done

Respiratory rate  breaths/minute  Not done

Blood pressure- sitting (systolic / diastolic)  /  mm Hg  Not done

Pulse rate-sitting  beats/minute  Not done

Completed by (initials):



118

# National Institute on Drug Abuse

## Aripiprazole for Methamphetamine Dependence

Subject ID

site #

subject #

Protocol #

 Not Done**VITAL SIGNS****INSTRUCTIONS:** Bubble in study day and complete assessment date in mm/dd/yyyy format.Study Day:  Pre-Intake Screening Intake Screening 19 (Discharge) Unscheduled

Assessment Date

mm / dd / yyyy

Time vital signs taken

(24 hr clock)

Temperature (oral)

°F

 Not done

Respiratory rate

breaths/minute

 Not doneBlood pressure- sitting  
(systolic / diastolic)

mm Hg

 Not done

Pulse rate-sitting

beats/minute

 Not done

Completed by (initials):