

All items must be completed. Use U if information is Unavailable. Use N if information is Not Applicable.

WEEK NUMBER  week

SUBJECT NUMBER  PAT

EVALUATION DATE  demodate  
(MM/DD/YY)

NAME/DOB CODE   
(1st 3 letters of last name, 1st initial, year of birth)

SITE NUMBER  demohosp

demoNDOB

1. Date of Birth

demo01 1.   
MM DD YY

2. Gender (1 = Male, 2 = Female)

demo02 2.

3. Ethnicity

- 1 = Caucasian
- 2 = Black
- 3 = Hispanic
- 4 = Asian
- 5 = American Indian
- 6 = Other \_\_\_\_\_

demo03 3.

4. Was subject hospitalized in the past? (1 = Yes, 2 = No)

demo04 4.

5. Has the subject ever had a significant disorder, disease or surgery of the following systems?:

0 = None      1 = Current      2 = Past      (Specify disorder, duration, hospitalization)  
[if PAST, specify TIME]

5a. Pulmonary disorder \_\_\_\_\_ demo05a 5a.

5b. Cardiovascular disorder \_\_\_\_\_ demo05b 5b.

5c. Hepatobiliary disorder \_\_\_\_\_ 5c.

5d. Gastrointestinal disorder \_\_\_\_\_ 5d.

5e. Hemato-Lymphatic disorder \_\_\_\_\_ 5e.

5f. Dermatological disorder \_\_\_\_\_ 5f.

5g. Renal disorder \_\_\_\_\_ 5g.

5h. Genito-Urinary disorder \_\_\_\_\_ 5h.

5i. Ophthalmic disorder \_\_\_\_\_ 5i.

5j. Ear, Nose, Throat disorder \_\_\_\_\_ 5j.

5k. Musculoskeletal disorder \_\_\_\_\_ 5k.

5l. Metabolic/Endocrine disorder \_\_\_\_\_ 5l.

5m. Neurological disorder (excl.-PD) \_\_\_\_\_ 5m.

5n. Psychiatric disorder \_\_\_\_\_ 5n.

5o. Allergy/Immunological disorder \_\_\_\_\_ 5o.

5p. Other (specify) \_\_\_\_\_ demo05p 5p.

**HABITS:**

6. Drug abuse? (1 = Yes, 2 = No) *demo06* 6.
7. Alcohol consumption? (1 = Yes, 2 = No) *demo07* 7.
8. If Yes in item 7, how many glasses per day (if NO enter NN in boxes)? *demo08* 8.
9. Smoking? 0 = None 1 = Current 2 = Past *demo09* 9.
10. If past or current in item 9, please specify how many 'pack years'  
(No. of packs per day X No. of smoking years): *demo10* 10.
11. If past in item 9, when did the subject quit smoking? *demo11* 11.    
YEAR

**PARKINSON'S DISEASE HISTORY**

12. Date of Parkinson's disease diagnosis: *demo12* 12.      
MONTH YEAR

13. What were the symptoms at the time of diagnosis?

1 = YES 2 = NO 3 = UNKOWN

- 13a. Tremor *demo13a* 13a.
- 13b. Rigidity 13b.
- 13c. Bradykinesia 13c.
- 13d. Postural disturbances 13d.
- 13e. Other, please specify: \_\_\_\_\_ *demo13e* 13e.

14. Site personnel responsible for information entered: *demo14* 14.      
Staff Code



**EXCLUSION CRITERIA**

YES NO

- 9. Does the subject have any unstable systemic medical problems or clinically significant malignancy and/or clinically significant or unstable vascular disease? *inex09* 9.
- 10. Does the subject have clinically significant arrhythmia, valvular heart disease, or congestive heart failure (NYHA class 2 or greater) as judged by investigator? *inex10* 10.
- 11. Does the subject have significant ischemic heart or cerebrovascular disease, severe hypertension, clinically significant orthostatic hypotension, or clinically significant syncope associated with hypotension (in the past 2 years)? *inex11* 11.
- 12. Does the subject have dementia as defined by MMSE score  $\leq 23$ ? *inex12* 12.
- 13. Does the subject have clinically significant psychiatric illness which compromises their ability to provide consent or participate fully in the study? *inex13* 13.
- 14. Does the subject have major/severe depression? *inex14* 14.
- 15. Does the subject have clinically significant abnormal laboratory test results that make him/her ineligible for this study? *inex15* 15.
- 16. Does the subject abuse substances or drugs? *inex16* 16.
- 17. Has the subject participated in a clinical trial during the previous 60 days or been taking any experimental drug within the past 90 days? *inex17* 17.
- 18. Has the subject ever experienced any serious adverse reaction to selegiline (deprenyl)? *inex18* 18.
- 19. Has the subject ever had any adverse reaction associated with ingestion of tyramine-containing food (i.e., cheese, red wine)? *inex19* 19.

- 20. Has the subject signed an informed consent? *inex20* 20.
- 21. Does the subject meet all the inclusion/exclusion criteria for this study? *inex21* 21.
- 22. Completed by (Investigator only): *inex22* 22.      
Staff Code

TEMPO

TEVA Pharmaceuticals  
Protocol No.: TVP-1012/232

INCLUSION/EXCLUSION CRITERIA (INEX)

Form 1400  
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All items must be completed. Use U if information is Unavailable. Use N if information is Not Applicable.

WEEK NUMBER  SUBJECT NUMBER  FAT

EVALUATION DATE  in ex date NAME/DOB CODE  in ex DOB  
(MM/DD/YY) (1st 3 letters of last name, 1st initial, year of birth)

SITE NUMBER  in ex hosp SCREENING NUMBER  in ex 21

**INCLUSION CRITERIA**

YES NO NA

1. Has the subject been diagnosed as having idiopathic Parkinson's disease (PD) confirmed by at least two of the cardinal signs (resting tremor, bradykinesia, rigidity) being present? 1.
2. If female, is the subject postmenopausal, surgically-sterilized, or adequate birth control (barrier methods not adequate)? 2.
3. If female and of childbearing potential was the pregnancy test (Plasma beta-HCG test) negative at screening? 3.
4. Is the subject 35 years or older? 4.
5. Is the modified Hoehn and Yahr stage ≤ 3.0? 5.
- 6a. If the subject was previously on levodopa, amantadine, or dopamine agonists, have they been off these drugs and stable for at least 42 days at the time of baseline visit? 6a.
- 6b. Has the subject been on a stable dose of anticholinergics or specified antidepressants (amitriptyline or trazadone) for at least 60 days, if taking one of these medicines? 6b.
- 6c. Has subject been withdrawn from selective serotonin reuptake inhibitors (SSRI), antidepressants (with the exception of amitriptyline and trazadone), meperidine (pethidine) for at least 42 days prior to baseline, if previously taking one of these medicines? 6c.
7. Has subject been stable for at least 90 days off of selegiline at the time of the baseline visit, if previously taking selegiline? 7.
8. Has the subject been withdrawn from sympathomimetics (including over the counter (OTC) cold remedies-oral or nasal) for at least 7 days prior to baseline? 8.

6/9/98 ← revised

**EXCLUSION CRITERIA**

YES NO

- 9. Does the subject have any unstable systemic medical problems or clinically significant malignancy and/or clinically significant or unstable vascular disease? 9.
- 10. Does the subject have clinically significant arrhythmia, valvular heart disease, or congestive heart failure (NYHA class 2 or greater) as judged by investigator? 10.
- 11. Does the subject have significant ischemic heart or cerebrovascular disease, severe hypertension, clinically significant orthostatic hypotension, or clinically significant syncope associated with hypotension (in the past 2 years)? 11.
- 12. Does the subject have dementia as defined by MMSE score  $\leq 23$ ? 12.
- 13. Does the subject have clinically significant psychiatric illness which compromises their ability to provide consent or participate fully in the study? 13.
- 14. Does the subject have major/severe depression? 14.
- 15. Does the subject have clinically significant abnormal laboratory test results that make him/her ineligible for this study? 15.
- 16. Does the subject abuse substances or drugs? 16.
- 17. Has the subject participated in a clinical trial during the previous 60 days or been taking any experimental drug within the past 90 days? 17.
- 18. Has the subject ever experienced any serious adverse reaction to selegiline (deprenyl)? 18.
- 19. Has the subject ever had any adverse reaction associated with ingestion of tyramine-containing food (i.e., cheese, red wine)? 19.

- 20. Has the subject signed an informed consent? 20.
- 21. Does the subject meet all the inclusion/exclusion criteria for this study? 21.
- 22. Completed by (Investigator only): 22.     
Staff Code

Conditions of Amendment I should not be incorporated into the protocol until your site has IRB approval

YES NO NA

23. Has the subject been withdrawn from dextromethorphan (DM) for at least 7 days prior to baseline?    *inex23*

24. Has the subject been withdrawn from gentamicin for at least 14 days prior to baseline?    *inex24*

25. Has the subject been withdrawn from St. John's Wort for at least 14 days prior to baseline?    *inex25*

26. Has the subject participated at any time in an earlier trial of rasagiline?   *inex26*

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WEEK NUMBER   week SUBJECT NUMBER      PAT

EVALUATION DATE (MM/DD/YY)       disphate NAME/DOB CODE       (1st 3 letters of last name, 1st initial, year of birth) dispndob

SITE NUMBER    disphosp

1. Subject Disposition: dispo1 1.

1 = subject qualifies for this clinical trial

2 = subject does not meet inclusion/exclusion criteria

3 = subject deceased

4 = subject decided to withdraw

If Yes, give reason:

\_\_\_\_\_

5 = subject lost to follow-up during screening

If Yes, explain:

\_\_\_\_\_

6. Other

If Yes, specify:

\_\_\_\_\_

2. Completed by (Investigator or Coordinator): dispo2 2.    Staff Code

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WEEK NUMBER   week

SUBJECT NUMBER      PAT

EVALUATION DATE       physdate  
(MM/DD/YY)

NAME/DOB CODE        
(1st 3 letters of last name, 1st initial, year of birth)

SITE NUMBER    physhosp

Phys N DOB

**ORGAN SYSTEM ABNORMALITIES BY EXAMINATION (check appropriate response)**

1 = Normal  
2 = Abnormal

If **Abnormal**, describe abnormality briefly in as quantitative terms as possible.  
[If not examined, enter N in box, i.e., subject refused]

1. Skin \_\_\_\_\_ *Phys01* 1.

2. Head/Neck \_\_\_\_\_ *Phys02* 2.

3. Ears/Nose-Throat \_\_\_\_\_ 3.

4. Lungs-Chest \_\_\_\_\_ 4.

5. Breasts \_\_\_\_\_ 5.

6. Cardiovascular (heart) \_\_\_\_\_ 6.

7. Abdomen \_\_\_\_\_ 7.

8. Musculoskeletal \_\_\_\_\_ 8.

9. Lymphatic \_\_\_\_\_ 9.

10. Peripheral Vascular \_\_\_\_\_ 10.

11. Other \_\_\_\_\_ *Phys11* 11.

<p><b>12. MOOD</b>      12. <input type="checkbox"/> <i>phys12</i></p> <p>1 = depression 2 = sadness 3 = normal 4 = euphoria 5 = mania psychosis</p>	<p><b>13. SPEECH</b>      <i>phys13</i>      13. <input type="checkbox"/></p> <p>1 = normal 2 = abnormal</p>
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**14. CRANIAL NERVES**      KEY: 1 = normal, 2 = abnormal

Describe Abnormality:

14a. I _____	14a. <input type="checkbox"/>	<i>phys14a</i> ↓ <i>phys14i</i>
14b. II _____	14b. <input type="checkbox"/>	
14c. III, IV, VI _____	14c. <input type="checkbox"/>	
14d. V _____	14d. <input type="checkbox"/>	
14e. VII _____	14e. <input type="checkbox"/>	
14f. VIII _____	14f. <input type="checkbox"/>	
14g. IX, X _____	14g. <input type="checkbox"/>	
14h. XI _____	14h. <input type="checkbox"/>	
14i. XII _____	14i. <input type="checkbox"/>	

**15. MUSCLE STRENGTH and TONE**      KEY: 1 = normal, 2 = abnormal

**Muscle Strength**

15a. Upper Extremities		15b. Lower Extremities	
15al. Left <input type="checkbox"/>	15ar. Right <input type="checkbox"/>	15bl. Left <input type="checkbox"/>	15br. Right <input type="checkbox"/>
<i>phys15al</i> <i>phys15ar</i> <b>Muscle Tone</b> <i>phys15bl</i> <i>phys15br</i>			
15c. Upper Extremities		15d. Lower Extremities	
15cl. Left <input type="checkbox"/>	15cr. Right <input type="checkbox"/>	15dl. Left <input type="checkbox"/>	15dr. Right <input type="checkbox"/>
<i>phys15cl</i> <i>phys15cr</i> <i>phys15dl</i> <i>phys15dr</i>			

<p><b>16. COORDINATION</b>      KEY: 1 = normal, 2 = abnormal</p> <p>16a. Rapid alternating movements</p> <p>16b. Finger to nose</p> <p>16al. Left <input type="checkbox"/>      16ar. Right <input type="checkbox"/>      16bl. Left <input type="checkbox"/>      16br. Right <input type="checkbox"/></p>	<p><b>17. GAIT</b>      KEY: 1 = normal, 2 = abnormal</p> <p>17a. Gait</p> <p>17al. Left <input type="checkbox"/>      17ar. Right <input type="checkbox"/></p>
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*phys16al*   *phys16ar*   *phys16bl*   *phys16br*   *phys17al*   *phys17ar*

**18. REFLEXES**

Indicate if reflexes are Normal or Abnormal (18a-18b) KEY: 1 = normal, 2 = abnormal

18a. Upper Extremities		18b. Lower Extremities	
18a. Left <input type="checkbox"/>	18a. Right <input type="checkbox"/>	18b. Left <input type="checkbox"/>	18b. Right <input type="checkbox"/>

*phys18a*

*phys18a*

*phys18b*

*phys18b*

(18c) KEY: 3 = absent, 4 = present

18c. Babinski	
18c. Left <input type="checkbox"/>	18c. Right <input type="checkbox"/>

*phys18c*

*phys18c*

**19. SENSATION**

Indicate if the following sensations are Normal, Abnormal, or Untestable.

KEY: 1 = normal, 2 = abnormal, 3 = untestable

	Left	Right	
<i>phys19a</i> 19a. Pain	<input type="checkbox"/>	19aa. <input type="checkbox"/>	<i>phys19aa</i>
<i>phys19b</i> 19b. Light Touch	<input type="checkbox"/>	19bb. <input type="checkbox"/>	<i>phys19bb</i>
<i>phys19c</i> 19c. Position	<input type="checkbox"/>	19cc. <input type="checkbox"/>	<i>phys19cc</i>
<i>phys19d</i> 19d. Vibration	<input type="checkbox"/>	19dd. <input type="checkbox"/>	<i>phys19dd</i>

20. Completed by (Investigator or Coordinator):

20.     
 Staff Code

TEVA Pharmaceuticals  
Protocol No.: TVP-1012/232

UNIFIED PARKINSON'S DISEASE  
RATING SCALE (UPDR)

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WEEK NUMBER   week SUBJECT NUMBER      PAT

EVALUATION DATE     updrdate NAME/DOB CODE        
(MM/DD/YY) (1st 3 letters of last name, 1st initial, year of birth)

SITE NUMBER    updr hosp updrndob

**PART I MENTATION, BEHAVIOR AND MOOD**

(RATE ITEMS 1 TO 4 BY INTERVIEW)

**1. Intellectual Impairment:**

updr01 1.

- 0 = None
- 1 = Mild. Consistent forgetfulness with partial recollection of events and no other difficulties.
- 2 = Moderate memory loss, with disorientation and moderate difficulty handling complex problems.  
Mild but definite impairment of function at home with need of occasional prompting.
- 3 = Severe memory loss with disorientation for time and often to place. Severe impairment in handling problems.
- 4 = Severe memory loss with orientation preserved to person only. Unable to make judgements or solve problems. Requires much help with personal care. Cannot be left alone at all.

**2. Thought Disorder (Due to dementia or drug intoxication):**

updr02 2.

- 0 = None.
- 1 = Vivid dreaming.
- 2 = "Benign" hallucinations with insight retained.
- 3 = Occasional to frequent hallucinations or delusions; without insight; could interfere with daily activities.
- 4 = Persistent hallucinations, delusions, or florid psychosis. Not able to care for self.

**3. Depression:**

updr03 3.

- 0 = Not present.
- 1 = Periods of sadness or guilt greater than normal, never sustained for days or weeks.
- 2 = Sustained depression (1 week or more).
- 3 = Sustained depression with vegetative symptoms (insomnia, anorexia, weight loss, loss of interest).
- 4 = Sustained depression with vegetative symptoms and suicidal thoughts or intent.

**4. Motivation/Initiative:**

updr04 4.

- 0 = Normal.
- 1 = Less assertive than usual; more passive.
- 2 = Loss of initiative or disinterest in elective (non-routine) activities.
- 3 = Loss of initiative or disinterest in day-to-day (routine) activities.
- 4 = Withdrawn, complete loss of motivation.

