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# ICCTG PROTOCOL #1

## Run-in Dosage Record (Administrative )

Patient ID: \_\_\_\_\_  
Patient Initials: \_\_\_\_\_  
Clinical Center: \_\_\_\_\_  
RC ID: \_\_\_\_\_

(RC completed during the run-in period (weeks 1 through 3). To record telephone conversation between the Research Coordinator and the patient, and to record variation of dosage, if applicable, of the green capsules.)

The left side of the slash ( " x / \_ " ) indicates the column number (dose #1, #2, #3) of the blister packet from which the patient is scheduled to take the capsules.

The Research Coordinator should record on the right side of the slash ( " \_ / x " ) the actual column number/s from which the patient is taking the capsules.

There must be a documented conversation between the Research Coordinator and the patient if the patient requests to take capsules from a different column than the scheduled column. This must be documented in the lines below.

Date patient started study medication: _____ / _____ / _____ month day year								
<u>GREEN CAPSULES:</u>  scheduled / actual (column) (column)	Run-in Period	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1 / ?	Week #1	1 / _	1 / _	1 / _	1 / _	1 / _	1 / _	1 / _
2 / ?	Week #2	2 / _	2 / _	2 / _	2 / _	2 / _	2 / _	2 / _
2&3 / ??	Week #3	2&3 / _	2&3 / _	2&3 / _	2&3 / _	2&3 / _	2&3 / _	2&3 / _
_ / _	Week #4	_ / _	_ / _	_ / _	_ / _	_ / _	_ / _	_ / _

If **extra dose** is used, explain here:

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Use this area to record comments and document patient contacts that resulted in a change in dosage. Indicate the changed dose, the reason for the change (complete an Adverse Event report, if necessary), and the date the change became effective.