



**TN20 IMMUNE EFFECTS OF ORAL INSULIN TRIAL
STUDY DRUG ADMINISTRATION, DISPENSATION AND
RETURN FORM**

Form IE04
15JAN16
Version 2.0
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Site Number: _____ Participant ID: _____ Participant Letters: _____

A. STUDY DRUG ADMINISTRATION

1. Pre-Dose glucose (per clinic meter):* _____ mg/dl not done

2. Was the participant given their study drug dose in clinic?*

Y N

If YES,

2a. Enter the dose of study drug given:
_____ mg

2b. Enter the time the dose was given:
____:____

3. Were there any signs or symptoms of hypoglycemia during the observation period?*

Y N

If YES,

3a. Describe Symptoms:

3b. Glucose Value (per clinic meter): _____ mg/dl not done

4. Were there any other problems during the observation period?*

Y N

If YES,

4a. Describe problem:

B. RETURN OF STUDY DRUG

1. Was study drug returned? *

Y N

2. Date study drug returned:

____/____/____
DAY MONTH YEAR

3. Number of capsules returned (including full medication packs):

_____ capsule(s)



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C. DISPENSATION OF STUDY DRUG

1. Was study drug dispensed? * Y N

2. Date study drug dispensed: _____ / _____ / _____
DAY MONTH YEAR

a. Number of capsules dispensed (including medication packs that were returned): _____ capsule(s)

b. How did the participant receive the study drug?
 ₁ At Clinical Center ₂ By Courier

3. Record the Randomization Number used for study drug dispensation: _____ - _____

4. Study drug dispensed to the participant:

Medication Pack Number	Lot Number	Date Dispersed
		____ / ____ / ____ DAY MONTH YEAR
		____ / ____ / ____ DAY MONTH YEAR

C. ADDITIONAL INFORMATION

1. Were there any unusual circumstances? Y N

If YES,

a. Describe:
