

Section A: General Study Information for Office Use Only:

A1. Study ID#:

Label

A2. Visit # Randomization RAND

A3. Date Form Completed:

____ / ____ / ____
Month Day Year

A4. Study Staff Initials: ____

SECTION B: ELIGIBILITY VERIFICATION FOR MEDICATION AND BLADDER DIARY

B1. Upon review with the patient of her **current medication status**, did she report any changes or additions that affect eligibility (e.g. use of anticholinergics, tricyclic antidepressants, duloxetine, or cholinergic agonists, OR a change in diuretic dose)?

YES..... 1 → **INELIGIBLE**

NO 2 → **SKIP TO B2**

B1a. Specify the medication change or addition that rendered the patient ineligible:

B1b. Code: _____ → **SKIP TO END OF FORM**

B2. Is the patient's **7 Day Baseline Bladder Diary** valid?

YES..... 1

NO 2 → **INELIGIBLE**

B2a. Is the patient **eligible by diary**, i.e., incontinence frequency of at least 7 times per week?

YES..... 1

NO 2 → **INELIGIBLE**

B2ai. Please Complete the Following:

a. MESA Stress Symptoms Score (F201, field D10)	b. Did Patient Report Any “Stress” or “Other” Type Accidents on the Bladder Diary?	c. Number of Total Accidents Reported on the Bladder Diary	d. Number of Valid Diary Days from the Bladder Diary
_____	YES..... 1 NO.....2	_____	_____
If MESA Stress Score >0, Type = Mixed	If YES, Type = Mixed		

B2b. What is the patient’s **incontinence frequency**?

LOWER (<14 episodes of UI/week)..... 1

HIGHER (≥14 episodes of UI/week) 2

B2c. Upon review of the MESA and the diary, what **type of incontinence** does the patient have, i.e., mixed (at least one stress or “other” type accident on the diary OR one affirmative response to a stress symptom on the MESA) or urge only?

MIXED..... 1

URGE ONLY 2

SECTION C: ELIGIBILITY VERIFICATION AND CURRENCY OF OTHER BASELINE MEASURES

Is the patient eligible by...

		Eligible	Ineligible	
C1.	...F201 (G1)?	Y	N	Date F201 Completed (A3): _____ / _____ / _____ Month Day Year
C2.	...F202 (D1)?	Y	N	Date F202 Completed (A3): _____ / _____ / _____ Month Day Year
C3.	...F203 (B11)?	Y	N	Date F203 Completed (A3): _____ / _____ / _____ Month Day Year
C4.	...F204 (J1)?	Y	N	Date F204 Completed (J4): _____ / _____ / _____ Month Day Year

C5. Date F205 Completed (A3): _____ / _____ / _____
(Use the date from “RAND” F205) Month Day Year

C6. Date F206a Started (“Day 1”): _____ / _____ / _____
Month Day Year

C7. Date F207 Completed (A7): _____ / _____ / _____
Month Day Year

C8. Date F208 Completed (A6): _____ / _____ / _____
Month Day Year

SECTION D: SIGNATURE

D1. BE-DRI Staff Member’s initials: _____

BE-DRI Staff Member's Signature: _____

Attachment

Current Medication Status Exclusion Codes (Eligibility questions from F203)

B4	Recent change in diuretic dose (within last 3 months)
B5	Current or recent (within last 4 weeks) use of anticholinergics
B6	Current use of a cholinergic agonist
B7	Current or recent (within last 4 weeks) use of tricyclic antidepressants
B8	Current or recent (within last 4 weeks) use of duloxetine

BE-DRI