

Participant Disposition [Complete when participant is exiting study]

01	Status of participant	<input type="checkbox"/> Did not enroll <input type="checkbox"/> Enrolled but did not complete study (answer 01a) <input type="checkbox"/> Enrolled and completed all study visits (answer 01a)
02	Date of Study exit:	___ / ___ / _____ (dd/mm/yyyy)
03	Primary reason for completion/discontinuation:	<input type="checkbox"/> Scheduled exit visit/end of study <input type="checkbox"/> Participant did not meet all eligibility criteria (answer 03a) <input type="checkbox"/> Participant did not enroll within 45 days of screening <input type="checkbox"/> Participant refused further participation/Participant is unwilling or unable to comply with required study procedures <input type="checkbox"/> Participant refused further study product use <input type="checkbox"/> Lost to follow-up <input type="checkbox"/> Investigator decision <input type="checkbox"/> Early study closure <input type="checkbox"/> Study terminated by sponsor <input type="checkbox"/> Protocol deviation <input type="checkbox"/> AE/SAE (answer 03c) <input type="checkbox"/> Product Hold/Discontinuation (Complete Product Hold/Discontinuation form) <input type="checkbox"/> Other (answer 03d)

01a. Complete if participant enrolled in study, regardless of completion status:

Is this participant evaluable? ⓘ Per protocol, "evaluable" is defined as having completed V5.	<input type="checkbox"/> Yes <input type="checkbox"/> No
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03a. Complete if primary reason for completion/discontinuation is "Participant did not meet all eligibility criteria":

Which eligibility criteria prevented the participant from enrolling? ⓘ Mark all that apply.	<input type="checkbox"/> Inclusion criteria (answer 03b-1) <input type="checkbox"/> Exclusion criteria (answer 03b-2)
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03b-1. Complete if the eligibility criteria that prevented the participant from enrolling was "Inclusion criteria":

Mark one primary reason the participant did not meet the inclusion criteria: ⓘ Based on Protocol v1.0 dated 29JUN2023..	
<input type="checkbox"/> Not aged 18-45 y/o <input type="checkbox"/> Not assigned female sex at birth <input type="checkbox"/> Did not provide consent <input type="checkbox"/> Inadequate locator information <input type="checkbox"/> Not able/willing to comply with protocol requirement: sex and vaginal product restrictions <input type="checkbox"/> Not able/willing to refrain from participation in other research studies for the duration of the study <input type="checkbox"/> Not able/wiling to respond to scheduled phone/short message service contacts, or attend all clinic follow-up visits. <input type="checkbox"/> Not HIV-uninfected <input type="checkbox"/> Not abstinent nor in monogamous relationship, or has a partner with HIV or STI <input type="checkbox"/> Positive urine pregnancy test <input type="checkbox"/> Could not provide documentation of a Grade 0 Pap smear within the past 3 years (if over age 21), or required treatment for pap smear at screening <input type="checkbox"/> Not protected from pregnancy, or not on an effective contraceptive method	
If there is a secondary reason the participant did not meet inclusion criteria, specify:	_____

Participant Disposition (continued)

03b-2. Complete if the eligibility criteria that prevented the participant from enrolling was "Exclusion criteria":

Mark one primary reason the participant did not meet the exclusion criteria:

Based on Protocol v1.0 dated 29JUN2023.

- Participant intends to become pregnant
- Participant intends to breastfeed
- Participant intends to relocate from study site
- Participant intends to travel during study period and would interfere with participation
- HIV + at screen or enrollment
- STI at screening AND past 12 months
- UTI, PID, or RTI at enrollment
- Grade 2 or higher pelvic exam finding at enrollment
- Known study product adverse reaction
- Hysterectomy
- Pelvic surgical procedures within 21 days of enrollment
- Use of diaphragm, NuvaRing, or spermicide in two weeks prior to screening
- Antibiotic, steroid, or antifungal (oral or intravaginal) therapy within 14 days of Enrollment
- Prior use of PEP or PrEP in the 4 weeks, or any prior use of long-acting systemic PrEP ever
- Use of non-therapeutic drugs in past 12 months as defined in the protocol
- Significant uncontrolled active or chronic issue at screening or enrollment as determined by IoR/Designeer
- Grade 2 or higher AST
- Grade 2 or higher ALT
- Grade 2 or higher Creatinine
- Grade 2 or higher hemoglobin
- Any other condition per IoR precluding informed consent or safe study participation

If there is a secondary reason the participant did not meet exclusion criteria, specify: _____

03c. Complete if primary reason for completion/discontinuation is "AE/SAE":

If "AE/SAE" indicate applicable adverse event term/description: _____

03d. Complete if primary reason for completion/discontinuation is "Other":

If "Other" specify: _____

04	Document additional relevant details: <div style="border: 1px solid black; border-radius: 15px; height: 100px; margin-top: 10px;"></div>
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CRF Completed By: _____ (initials)

CRF Completion Date: ___ / ___ / _____ (dd/mm/yyyy)