|  |  |
| --- | --- |
| **Inclusion Criteria**  |  ***Yes No* *NA*** |
| **I1** | Born Female (including participants who were female at birth, who now identify as male)*Source: Physical Exam CRF, Pelvic Exam Diagrams CRF and Pelvic Exam CRF* |  |
| **I2** | Age of 18 to 45 (inclusive) at ScreeningSour*ce: copy of identification card or other document as specified in the site SOP* |  |
| **I3** | Able and willing to provide written informed consent to screen for and participate in MTN-027*Source: signed/marked consent form* |  |
| **I4** | Able and willing to provide adequate locator information *Source: site specific locator forms as specified in site SOP* |  |
| **I5** | HIV uninfected*Source: site HIV rapid testing logs/lab results report* |  |
| **I6** | In general good health *Source: Baseline Medical History Questions, Physical Exam CRF, Pre-Existing Conditions CRF, Pelvic Exam Diagram CRF and Pelvic Exam CRF*  |  |
| **I7** | Willing to abstain from receptive sexual activity for the 5 days prior to enrollment and duration of study participation*Source: Screening Behavioral Eligibility Worksheet* |  |
| **I8** | Using and intends to continue using an effective method of contraception for duration of study participation*Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **I9** | Women ≥ 21 years of age with a satisfactory Pap result (Grade 0 or Grade 1 or higher with no treatment) within the past 3 years *Source: Lab results report* |  |
| **I10** | Willing to not take part in other research studies involving drugs, medical devices, or vaginal products for the duration of study participation *Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet* |  |
| **I11** | Has a regular menses (not applicable to participants using a progestin-only method of contraception or continuous combination oral contraceptive pills)  *Source: Screening Behavioral Eligibility Worksheet* |  |
| **I12** | Willing to refrain from inserting non-study vaginal products or objects into the vagina for the 5 days prior to Enrollment and for the duration of study participation*Source: Screening Behavioral Eligibility Worksheet*  |  |

Note: In order for the participant to be eligible, all of the responses to items I1—I12 above must be **'yes' or ‘n/a’**.

| **Exclusion Criteria**  | ***Yes No***  |
| --- | --- |
| **E1** | **Participant report of any of the following:** |  |
| **E1a** | Known allergy to any components of study products*Source: Screening Behavioral Eligibility Worksheet*  |  |
| **E1b** | Non-therapeutic injection drug use within past 12 months prior to Screening or Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
|  **E1c** | Use of post-exposure prophylaxis (PEP) for HIV exposure within the 6 months prior to Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **E1d** | Use of pre-exposure prophylaxis (PrEP) for HIV exposure within the 6 months prior to Enrollment  *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **E1e** | Use and/or anticipated use during the period of study participation of CYP3A inducer(s) and/or inhibitor(s) *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **E1f** | Use and/or anticipated use during the period of study participation of female-to-male transition therapy *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*  |  |
| **E1g** | Chronic and/or recurrent vaginal candidiasis *Source: Screening Behavioral Eligibility Worksheet, Baseline Medical History Questions* |  |
| **E1h** | Gonorrhea, chlamydia and/or syphilis diagnosis in the 6 months prior Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **E1i** | Last pregnancy outcome within 90 days prior to Screening*Source: Screening Behavioral Eligibility Worksheet* |  |
| **E1j** | Currently breastfeeding *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **E1k** | Has had a hysterectomy*Source: Screening Behavioral Eligibility Worksheet, Baseline Medical History Questions, Pelvic Exam Diagrams CRF and Pelvic Exam CRF* |  |
| **E1l** | Intends to become pregnant within next 3 months*Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **E1m** | Intends to relocate away from study site within the next 3 months *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **E1n** | Known HIV positive sexual partner Source: *Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **E2** | Participation in any other research study involving drugs, medical devices, or vaginal products, in the 60 days prior to Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet* |  |
| **E3** | Has any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease*Source: Baseline Medical History Questions, Physical Exam CRF, Pre-Existing Conditions CRF, Pelvic Exam Diagrams CRF and Pelvic Exam CRF* |  |
| **E4** | **Has any of the following laboratory abnormalities at Screening:** |  |
| **E4a** | Grade 1\* or higher Alanine transaminase (ALT) and/or aspartate aminotransferase (AST)*Source: Lab results report* |  |
| **E4b** | Calculated creatinine clearance less than 60 mL/min *Source: Creatinine Clearance calculation worksheet*  |  |
| **E4c** | Grade 1\* or higher Hemoglobin *Source: Lab results report*  |  |
| **E4d** | Grade 1\* or higher Platelet count *Source: Lab results report* |  |
| **E4e** | Grade 2\* or higher white blood cell count *Source: Lab results report* |  |
| **E4f** | Positive for hepatitis B surface antigen*Source: Lab results report* |  |
| **E4g** | Positive for hepatitis C antibody*Source: Lab results report* |  |
| **E4h** | International normalized ratio (INR) > 1.5 x the site laboratory upper limit of normal*Source: Lab results report* |  |
| **E5** | Currently pregnant*Source: Lab results report*  |  |
| **E6** | Diagnosed with urinary tract infection and has not completed treatment or symptoms have not resolved  *Source: Urine culture if done, Baseline Medical History Questions Sheet, Pre-existing Conditions CRF*  |  |
| **E7** | Diagnosed with pelvic inflammatory disease, reproductive tract infection (RTI) or a sexually transmitted infection (STI) requiring treatment per current CDC guidelines. (Note GC, CT, Syphilis are exclusionary; other STIs are exclusionary only if treatment has not been completed or symptoms have not resolved) *Source: Baseline Medical History Questions Sheet, Pelvic Exam Diagrams CRF, Pelvic Exam CRF, Pre-Existing Conditions CRF and local site specific testing log and/or local lab results report* |  |
| **E8** | At enrollment, has a clinically apparent Grade 1 or higher pelvic exam finding\*\*, observed by study clinician or designee  *Source: Pelvic Exam Diagrams CRF, Pelvic Exam CRF and Pre-Existing Conditions CRF* |  |
| **E9** | Severe pelvic relaxation such that either the vaginal walls or the uterine cervix descend beyond the vaginal introitus with valsalva maneuver or has pelvic anatomy that compromises the ability to adequately assess vaginal safety*Source: Pelvic Exam Diagrams CRF, Pelvic Exam CRF and Pre-Existing Conditions CRF* |  |
| **E10** | Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives*Source: chart notes or this checklist* |  |

\*As per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 1.0, December, 2004 (Clarification dated August 2009)

\*\*As per the Female Genital Grading Table for Use in Microbicide Studies Addendum 1 to the Division of AIDS (DAIDS) Table for Grading Adult and Pediatric Adverse Events, Version 1.0, December 2004 (Clarification dated August 2009)

Note: In order for the participant to be eligible, all of the responses to items E1-E10 above must be **'no'**.

Complete Eligibility Criteria CRF for each participant screened for the study, regardless of enrollment.