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| **Screening Date** | | **Screening Attempt** | **PTID** | | | **Staff Initials/Date** | **Enrollment Date  (or N/A if not enrolled)** | | **Screen Failure Date (or N/A if enrolled)** | **Screening Failure/ Discontinuation Codes (or N/A if enrolled)** | | | | **Staff Initials/Date** |
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| **Screening Failure/Discontinuation Codes** | | | | | | | | | | | | |
| **I1** | Not 18 or older  Not born female | | | **I8** | Intention to provide breastmilk | | **E1a** | Known adverse reaction to study product | | | **E5** | Positive pregnancy test | | |
| **I2** | Not 6 weeks post-partum | | | **I9** | Not willing to express breastmilk | | **E1b** | Participation in drug/device trial | | | **E6** | Diagnosed with UTI | | |
| **I3** | No informed consent | | | **I10** | Non-effective contraception | | **E1c** | Use of vaginal medication | | | **E7** | Diagnosed with STI/RTI | | |
| **I4** | Inadequate locator | | | **I11** | ≥21 y.o: unsatisfactory Pap | | **E1d** | Complication of lactation | | | **E8a** | Incomplete involution of uterus | | |
| **I5** | Non-English speaking | | | **I12** | Not willing to abstain from sexual activity | | **E2** | Milk supply <1 ounce | | | **E8b** | Pelvic finding grade 2 or higher | | |
| **I6** | HIV-positive | | | **I13** | Not willing to abstain from vaginal products | | **E3** | Uncontrolled/chronic condition | | | **E9** | Use of antibiotic/antifungal medication | | |
| **I7** | Breastfeeding | | | **I14** | Not willing to refrain from other studies | | **E4** | AST or ALT grade 2 or higher | | | **E10** | Any other condition (IoR/designee) | | |