

PHARMACISTS' ROLE IN ASPIRE – MUJHU Considerations.

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Study drug order and receipt

- Avoid study drug stock out by doing monthly stock counts of study drug.
- Timely ordering and proper processing of shipment documents by liaising with the National Drug Authority.
- Proper receipt and documentation of study drug.

Proper storage

- Study product is stored in a temperature monitored room at a range of 15 – 30 Oc.
- Min-max thermometers are used to record the temperature daily on the temperature log.
- Temperature range is maintained with the use of airconditioner and there is a sensaphone which calls the pharmacist incase of excursions.

Dispensing

- Dispensing of study product to the authorised clinic staff without unblinding them.
- Proper documentation during dispense.
- Providing non study medications from the pharmacy and condoms for the ASPIRE participants.

Counseling

- Provide information/education during participant meetings or group education sessions about study product when called upon.
- Pharmacist will be referred to in case a participant has specific questions about the study product.

Destruction of Study product.

- Liase with National Drug Authority for study product destruction both for the clinic and the pharmacy returns.
- Thank You!!

Destruction of used rings.

- Used ring is placed in a white return zip lock bag and then placed in the biohazard waste container, whose access is restricted by use of a padlock, placed in designated rooms within the study clinic.
- Contents of bin containers are destroyed every 6 months or earlier when bins are full.
- The study pharmacist is contacted by the clinic staff after the rings have been weighed to initiate the destruction process with National Drug Authority.

BIOHAZARDOUS CONTAINER



Used ring destruction cont.

- The clinic study product accountability log cover page will be completed everytime contents of the bin are destroyed.
- Destruction of the biohazard container is documented by the party responsible for destruction at NDA.
- NDA will provide destruction certificate which will be sent to the site pharmacist who will send it to the regulatory office for filing.

THANK YOU