PELLET QUALITY CONTROL

General Appearance

- Inspect the organoleptic properties of pellet.
- Each pellet is inspected a minimum of four (4) times.

Potency/Sterility

- Random sampling of each lot of pellets produced
- Testing outsourced to Analytical Research Laboratories

Rigidity

- Determine the force required to break a pellet in a diametric compression test
- Each batch of pellets is randomly sampled; minimum of six (6) pellets per batch. Each pellet sampled must pass proprietary standard for batch to be used as end product
- Parameters (proprietary standard) for hardness are considered proprietary and have been developed specifically for BioTE®.
- Testing is performed, in-house, utilizing industry leading technology

Friability

- Evaluate ability of pellet to withstand breakage during in-house testing, transportation and shipping/handling. Minimum of twenty (20) pellets per batch is tested.
- Weigh each pellet and run in-house testing device at 25rpm for 4 minutes
- Weigh each pellet, post-testing, to determine amount of loss. Any loss greater than 1% has failed and batch cannot be used for end product.

Weight Variation

- Measure to ensure uniformity of dosage units
- Weigh 20 pellets (individually) from each batch
- 18 of 20 pellets shall not deviate from proprietary average for batch to be used for end product

Disintegration:

- Measure the time takes for solid units to completely disintegrate

Dissolution:

- Release of drug from the pellet into solution

Temperature Tolerance

- Tests potency, sterility and hardness for shipping and handling policy