

## Pellet Information

1. Trituration should be blended by mechanical means (not mortar and pestle) EMP. Mini-Blender are good.
2. Hormone powders should all be NON-Micron zed as micronized are too fine to work with. Always put triturate thru a sieve (80 mesh or less)
3. Use Stearic Acid Powder, Triple Pressed to determine the height the vertical column needs to be set for.
 

E.g.: Estradiol 25 mg pellets	2.8 - 2.9 mm
Estradiol 50 mg pellets	5.6 - 5.8 mm
Testosterone 75 mg pellets	9.0 mm
Testosterone 50 mg	6.0 mm
Progesterone 50 mg	6.0 mm

*wettable \* 121° 15# (No filler)*
4. A permanent mark should be made on the vertical column as well as the base for each type pellet made. Caution: the vertical column has a tendency to turn in a clockwise direction, causing pellets to lengthen and lack proper compression.
6. After filling the die with triturate, the lever should be rotated forward in a single full stroke. Too much pressure can cause the punch to break - they are only sold in a matched pair with the die and costs several hundred dollars to replace.
7. If pellets produced look like 'sliced bread', this is probably due to the length being improper or triturate not blended properly.
8. As stated in Formula Number 4024, there should be no more than 2% error in weight.
9. When making Estradiol Pellets, the die should be cleaned with a brush after each pellet, after Testosterone Pellets cleaning needs to be done every 6 - 10 pellets.
10. If punch becomes difficult to remove from die, clean with 95% Ethanol and make a plain Stearic Acid Pellet which lubricated the system.
11. Never begin a stroke with the lever, pause, then complete the stroke. This causes "layering of pellet which produces a bad pellet.
12. Optimum humidity for the work area should be approximately 50%.
13. A well made pellet will emerge from the die with a nice sheen which is easily visible under light. After autoclaving, the sheen will disappear, especially the Testosterones.

14. When autoclaving, the vials holding the pellets should be hermetically sealed in a polyester autoclave bag to prevent moisture coming in contact with pellets. At present this is our only way to sterilize pellets. It is not ideal, but we are working on other methods. Dry heat sterilization at 140 degrees C melts the pellets.
15. On occasion we have received faulty punch and die sets and if customer has tried every means to make pellets without success, this should be explored.
16. This a very labor intensive process and while the pharmacist needs to be adept at making pellets. However, it would behoove the owner to have a technician master the process and not attempt to do it themselves.
17. With the powder in the die, it needs to be gently tapped before compression. Care must be taken not to let the die and die holder separate as powder will be lost. This can be heard by a click while tapping.
- \* 18. When making Progesterone Pellets, only the Wettable Progesterone should be used. These compress very easily and no Stearic Acid or other binder is necessary.
19. When first used, the punch and die will impart a grayish color to pellets. Punch and die should be cleaned with a mixture of equal parts of Acetone and 95% Ethanol. A brush should be used to clean the die. Making plain Stearic Acid pellets will help clean the punch and die and will give the operator a lot of experience in using the equipment.
20. Most problems seen are a result of pellets of improper length. This cannot be stressed too much. The fact that the vertical column will turn clockwise, causing a pellet that is too long and not properly compressed is usually the problem. A difference of 0.2 mm in length is significant and a problem. THIS CANNOT BE STRESSED TOO MUCH.
21. In areas with extremely low humidity, a humidifier can be used to increase the humidity, allowing the powders to be worked with more easily.

\* - melting

$\downarrow T$   
5°

$\uparrow P$   
5# - 10#

Placebo Pellets

Stearic Acid or  
Magnesium Stearate or  
Cholesterol (148.5°)