

Instituto Bioclón's Concepts of Process Validation (PV) for Anascorp Drug Product

Research & Development Scale Validation

1. ----- (b) (4) -----
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2. ----- (b) (4) -----
 - i. ----- (b) (4) -----
 - b. ----- (b) (4) -----
 - i. ----- (b) (4) -----

 - ii. ----- (b) (4) -----
 - iii. ----- (b) (4) -----

 - c. ----- (b) (4) -----
 - i. ----- (b) (4) -----
 - ii. ----- (b) (4) -----.
 - d. -- (b) (4) --
 - i. ----- (b) (4) -----.
 1. ----- (b) (4) -----

 - ii. ----- (b) (4) -----
 1. (b) (4)
 2. ----- (b) (4) -----
 3. -- (b) (4) --
 4. -- (b) (4) --
 5. ----- (b) (4) -----
 - e. -- (b) (4) --
 - i. ----- (b) (4) -----
 - ii. ----- (b) (4) -----
 - iii. ----- (b) (4) -----
 - f. ---- (b) (4) -----
 - i. ----- (b) (4) -----
 - g. ----- (b) (4) -----
 - i. ----- (b) (4) -----
 - ii. ----- (b) (4) ------ 3. ----- (b) (4) ----- :
 - a. ----- (b) (4) -----
 - b. ---- (b) (4) -----

