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(15) Quality control unit

ICH 20.35, Quality unit(s)

(17) Theoretical yield

ICH 20.50, Yield, Theoretical

(18) Actual yield

ICH 20.49, Yield, Expected

(19) Percentage of theoretical yield

(20) Acceptance criteria

ICH 20.1, Acceptance criteria
(21) Representative sample  
(22) Gang-printed labeling  
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6. Bioburden  
7. Calibration  
8. Computer System  
9. Computerized System  
10. Contamination  
11. Contract Manufacturer  
12. Critical  
13. Cross-Contamination  
14. Deviation  
17. Expiry date (or Expiration Date)  
18. Impurity  
19. Impurity Profile  
20. In-Process Control (or Process Control)  
26. Mother Liquor  
31. Production  
32. Qualification  
33. Quality Assurance (QA)  
34. Quality Control (QC)  
38. Reference Standard, primary  
39. Reference Standard, secondary  
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44. Signed (signature)  
45. Solvent  
46. Specification  
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