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Lowest Measured Solubility Over The . 61 . PH Range  
Of 1.2 – 6.8 Will Be Used To Classify The Drug

Substance. 62 . 63 . A Minimum Of Three Replicate  
Determinations At Each Solubility Condition/pH Is  
Necessary To . 64 . Demonstrate Solubility Using A  
Validated -indicating Method, With Appropriate ... Feb

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SYSTEM-BASED BIOWAIVERSSolubility Should Be  
Evaluated By A Method Appropriate To The Properties  
Of The Drug Substance. Equilibrium Solubility

Experiments May Be Performed, Using A Shake-flask  
Technique Or An Alternative Method, If Justified. Small  
Volumes Of Solubility Media May Be Employed If The  
Available Experimental Apparatus Will Permit It. Jun  
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M9 BIOPHARMACEUTICS CLASSIFICATION SYSTEM-

BASED BIOAVALIERSDrug Solutions Should 113 Be  
 Incubated At 37°C For A Period That Is Representative  
 Of The In Vivo Contact Of The Drug 114 Substance  
 With These Fluids, I.e., One Hour In Gastric Fluid And  
 Three ... Feb 3th, 2024Biopharmaceutics Practical  
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