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The PH Should Be Adjusted If Necessary. The 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 ... Apr 16th, 2024

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Solubility 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. Mar 5th, 2024

M9 BIOPHARMACEUTICS CLASSIFICATION SYSTEM-BASED BIOWAIVERS

Drug 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

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