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BIOPHARMACEUTICS CLASSIFICATION SYSTEM BASED

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 ... Jan 6th, 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. Apr 5th, 2024

M9 BIOPHARMACEUTICS CLASSIFICATION

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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 In Gastric Fluid And Three ... Feb 8th, 2024

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