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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 ... 1th, 2024BIOPHARMACEUTICS CLASSIFICATION 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. 1th, 2024M9 BIOPHARMACEUTICS CLASSIFICATION SYSTEM-BASED BIOWAIVERSDrug 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 ... 4th, 2024.

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FF Q Column (GE Healthcare). The Column Was Washed With 5 ML Of 10 MM TEOA HCl, PH 7.0, Containing 0, 50, 100, 150 And 500 MM NaCl, with The Product eluting With 150 MM NaCl. The Product Was Exchanged Into 10 MM NaOAc, PH 5.0, By Repeated Concentration And Dilution Using A 10 KDa MWCO Spin Concentrator (Millipore). 1th, 2024 Development And Biopharmaceutics Of Long-Acting Injectables Simulations Plus, Inc. Viera@simulations-plus.com Dr. Lukacova Is Chief Scientist At Simulations Plus, Inc. Over The Last Decade She Has Been Contributing To The Research In The Area Of Mechanistic Absorption And PBPK Modeling And Th 3th, 2024.

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