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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 ... Feb 3th, 2024

### **BIOPHARMACEUTICS CLASSIFICATION SYSTEM-BASED BIOWAIVERS**

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 3th, 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 In Gastric Fluid And Three ... Feb 2th, 2024

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Onto A Pre-equilibrated 5 ML HiTrap 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). Jan 4th, 2024

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