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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 elut-ing 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). Feb 1th, 2024.

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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 ...

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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. Jan 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 In Gastric Fluid And Three ...

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