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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 ... 1th, 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. 1th, 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 ... 4th, 2024.

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