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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. Jun 8th, 2024

M9 BIOPHARMACEUTICS CLASSIFICATION

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Drug Solutions Should Be Incubated At 37°C For A Period That Is Representative Of The In Vivo Contact Of The Drug Substance With These Fluids, I.e., One Hour In Gastric Fluid And Three ... Feb 22th, 2024

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