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FIP/AAPS Guidelines for Dissolution/In Vitro Release Testing of Novel/Special Dosage Forms* Martin Siewert,¹ Jennifer Dressman,² Cynthia Brown,³ Vinod Shah⁴ Contributors Je a n - M a r c A i a c h e ,⁵ Nobuo Aoya g i , ⁶ Dennis Ba s h a w,⁴ Cynthia Brow n , ³ William Brow n , ⁷ Diane Bu rg e s s ,⁸ John Cri s o n , ⁹ Pa t r i c k De Lu ca , ^{1 0} Ru ...

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in vitro dissolution testing guides the optimization of drug release from formulations. Over the past 50 years, dissolution testing has also been employed as a quality control (QC) procedure, in R&D to detect the influence of critical manufacturing variables and in comparative studies for in vitro-in vivo correlation (IVIVC).²

In Vitro Dissolution Testing for Solid Oral Dosage Forms

Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms U.S. Department of Health and Human Services Food and Drug Administration

Guidance for Industry - Food and Drug Administration

Dissolution Technologies | FEBRUARY 2007 15 In Vitro-In Vivo Correlation: Importance of Dissolution in IVIVC J-M. Cardot¹, E. Beyssac, and M. Alric Univ. Clermont 1, Biopharmaceutical Department, UFR Pharmacie, 28 Place Henri Dunant, B.P. 38,

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FIP/AAPS guidelines to dissolution/in vitro release ...

Guidance on Waiver of In vivo Bioequivalence Requirements 7 4.1.3. Dissolution In this guidance, a multisource product is considered to be Rapidly dissolving when no less than 85% of the labelled amount of the API dissolves in 30 minutes using a paddle apparatus at 75 rpm or a basket apparatus at 100 rpm in a

GUIDANCE ON WAIVER OF IN VIVO BIOEQUIVALENCE REQUIREMENTS

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Several slight pricks and cuts were made on both his hands, and the matter was thoroughly rubbed into them. No de... tectable illness followed. The decisive experiment, the climax of the idea, was a success. As a result of a safe inoculation the little Fipps became non-susceptible to one of the most terrible diseases, to smallpox.

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