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24 Dissolution Technologies | AUGUST 2010 e-mail: sachin_pharma06@yahoo.co.in Dissolution Testing for Poorly Soluble Drugs: A Continuing Perspective K. Gowthamarajan¹ and Sachin Kumar Singh^{2,*} ¹Department of Pharmaceutics, J. S. S. College of Pharmacy, Post Box No. 20, Rocklands, Ooty-643001 dist. Nilgiris, Tamilnadu, India

Dissolution Testing for Poorly Soluble Drugs: A Continuing ...

February 2019 volume 26 issue 1 The Critical Role of the USP Performance Verification Test in Dissolution Testing and Qualification of the Paddle Apparatus. Performance qualification of the United States Pharmacopeia (USP) paddle apparatus (USP apparatus 2), as described in USP General Chapter <711> Dissolution, requires a demonstration of the dissolution behavior of a standard material as ...

Dissolution Technologies

In vivo methods for drug absorption – Comparative physiologies, model selection, correlations with in vitro methods (IVIVC), and applications for formulation/API ...

In vivo methods for drug absorption - Comparative ...

1. Introduction. The focus of this paper is to describe specific regulatory and scientific considerations for drug-device combination products 2 which are submitted under an Abbreviated New Drug Application (ANDA). 3 The types of combination products within the scope of this article are those combination products that consist of a drug constituent part and a device constituent part; where the ...

Generic drug device combination products: Regulatory and ...

A Decade in the MIST: Learnings from Investigations of Drug Metabolites in Drug Development under the "Metabolites in Safety Testing" Regulatory Guidance.

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