



Memoires Sur La Vie Privee de Marie- Antoinette, Reine de France Et de Navarre MIS En Ordre Et Pulies Par M. Barriere (1)

By -

RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 32 pages. Original publisher: Rockville, Md. : Center for Drug Evaluation and Research, 1995 OCLC Number: (OCoLC)586037897 Subject: Solid dosage forms -- Testing -- Documentation -- United States. Excerpt: . . . C. Level 3 Changes 1. Definition of Level Level 3 changes are those that are likely to have a significant impact on formulation quality and performance. Tests and filing documentation vary depending on the following three factors: therapeutic range, solubility, and permeability. Examples: a. Any qualitative and quantitative excipient changes to a narrow therapeutic drug beyond the ranges noted in Section III. A. 1. b. b. All other drugs not meeting the dissolution criteria under Section III. B. 2. b. c. Changes in the excipient ranges of low solubility, low permeability drugs beyond those listed in Section III. A. 1. b. d. Changes in the excipient ranges of all drugs beyond those listed in Section III. B. 1. b. 2. Test Documentation a. Chemistry Documentation Application compendial release requirements and batch records. Significant body of information available: One batch with three months accelerated stability data reported in supplement; one batch on long-term stability data reported in...



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