
Guidance for Industry

Drug Product

Chemistry, Manufacturing, and Controls Information

DRAFT GUIDANCE

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**January 2003
CMC**

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**U.S. Department of Health and Human Services
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¹ Alphanumeric designations in parentheses that follow headings show where information should be placed in applications that are submitted in Common Technical Document (CTD) format.

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