



V??FDA???????

??DMF??DMF????????????????????DMF??????

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## 2. COMMON TECHNICAL DOCUMENTS SUMMARIES ????????

2.1. Quality Overall Summary (Expert Report)??????(????)

## 3. QUALITY ??

3.2.S Quality of the Substance ??????

3.2.S.1 General Information ?????

3.2.S. 1.1 Nomenclature[name, manufacturer ?????

3.2.S.1.2 Structure[name, manufacturer ?????

3.2.S.1.3 General Properties[name, manufacturer ???????

3.2.S.2 Manufacture ???

3.2.S.2.1 Manufacturer Information ??????

3.2.S.2.2 Description of Manufacturing Process and Process Controls ??????????????

3.2.S.2.3 Control of Materials ?????

3.2.S.2.4 Controls of Critical Steps and Intermediates ??????????????

3.2.S.2.5 Process Validation and/or Evaluation ????????

3.2.S.2.6 Manufacturing Process Development ?????

3.2.S.3 Characterization ?????

3.2.S.3.1 Elucidation of Structure and Other Characteristics ????????

3.2.S.3.2 Impurities ??



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