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| **案件基本資料表** | | | | | | | | | | | | |
| **申請商** | |  | | | | | | **填表日期** | | |  | |
| **中/英文品名** | |  | | | | | | **許可證字號(如無, 毋須填)** | | |  | |
| **主成分及含量** | |  | | | | | | **劑型** | | |  | |
| **宣稱適應症** | |  | | | | | | | | | | |
| **廠商聯絡人** | |  | | | | | | **電話** | | |  | |
| **E-MAIL** | |  | | | | | | **傳真** | | |  | |
| ◎若申請案件時未檢附本表單或表單內容嚴重缺失，本局得視情況退件退費。 | | | | | | | | | | | | |
| **國內已核准類似藥品【查驗登記案/臨床(人體)試驗計畫案/銜接性試驗評估案，請填寫】** | | | | | | | | | | | | |
| ※以主成分計。新複方藥品請說明各主成分單方/複方核准狀況；新使用途徑請說明其他投予途徑藥品上市狀況；新劑型藥品可說明已上市劑型藥品的上市狀況。學名藥請填寫市售品資訊及提供該市售品國內核准仿單。 | | | | | | | | | | | | |
| **許可證字號** | **發證/有效日期** | | **主成分** | | **中/英文品名** | **核准適應症** | | | **申請商** | | | **製造廠** |
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| **國外上市情況【查驗登記案/臨床(人體)試驗計畫案/銜接性試驗評估案，請填寫】** | | | | | | | | | | | | |
| ※以十大醫藥先進國為主；若無本品資訊，請提供對照藥品/參考藥品資訊。如有US FDA/EMA最新版核准仿單，亦請提供。 | | | | | | | | | | | | |
| **上市國家** | **上市日期** | | **主成分** | | **中/英文品名** | **核准適應症** | | | **許可証持有者** | | | **製造廠** |
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| **曾於我國執行之臨床試驗查核狀況/執行狀況【查驗登記案/銜接性試驗評估案，請填寫】** | | | | | | | | | | | | |
| **計畫書編號** | **試驗執行醫院** | | **試驗目的** | | | **GCP備查函** | | | **執行狀況** | | | **備註** |
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| **工廠資料備查【查驗登記案，請填寫】** | | | | | | | | | | | | |
| ※除填寫以下資訊，亦請提供該衛生署書函電子檔及其紙本。 | | | | | | | | | | | | |
|  | | | | **函文日期/文號** | | | **工廠核准編號** | | | **核准劑型** | | |
| **GMP核備函** | | | |  | | |  | | |  | | |
| **第一階段確效函** | | | |  | | |  | | |  | | |
| **第二階段確效函** | | | |  | | |  | | |  | | |
| **第三階段確效函** | | | |  | | |  | | |  | | |
| **PIC/S GMP核准函或送件案號** | | | |  | | |  | | |  | | |
| **其他** | | | |  | | |  | | |  | | |