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| 附件二、生物藥品封緘證明書 |
| 衛生福利部食品藥物管理署生物藥品封緘證明書 FDA研字第OOOOOOOOOO號

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| 申請廠商: | OOO |
| 製劑名稱 | OOO |
| 製造廠名 | OOO |
| 批號: | OOO |
| 有效日期: | OOO |
| 包裝: | OOO |
| 封緘數量: | OOO |
| 封緘劑量: | OOO |

上述生物藥品之封緘檢驗案，符合生物藥品檢驗封緘作業之規定，予以封緘，此證。 |
|
| 署長 ○○○ |  |
| 中華民國 年 月 日 |

附件三、外銷用生物藥品批次放行證明書

**衛生福利部食品藥物管理署**

**Food and Drug Administration, Ministry of Health and Welfare**

地址：11561臺北市南港區昆陽街161-2號 TEL：(02)2787-8000

161-2, Kunyang St. Nangang, TAIPEI, 11561, TAIWAN (R.O.C.) http://www.fda.gov.tw



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| LOT RELEASE CERTIFICATE |
| No. | TFDA-RA-XXXXXXXXXX |
|  | MMM. DD, YYYY |  |
| The lot referenced below meets the national requirements for lot release and conforms to the approved specifications. The lot has been tested on the basis of critical evaluation of the manufacture’s production and control protocols and on the basis of the evaluation of samples at the Food and Drug Administration. |
|  | Product trade name |  |  |
|  | Common name |  |  |
|  | Lot number |  |  |
|  | Expiry date |  |  |
|  | Number of containers |  |  |
|  | Number of doses per container |  |  |
|  | Type of container |  |  |
|  | Dosage form |  |  |
|  | Strength of the product |  |  |
|  | Name and address of manufacturer |  |  |
|  Signed by |  |  |
|   |  |
| Director, Division of Research and Analysis |  |  |
|  |  |  |
| Under the delegated authority of  |  |  |
|  |  |  |
| Director-GeneralFood and Drug AdministrationMinistry of Health and WelfareExecutive Yuan, Republic of China |  |  |