（様式１５別添）

***Ministry of Health, Labour and Welfare***

CERTIFICATE NUMBER:＿＿＿＿＿＿＿＿

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**

**Part 1**

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| Issued under the provisions of the Mutual Recognition Agreement between the European Union and ***Japan.***  The competent authority of Japan confirms the following:  The manufacturer :  Site address:  DUNS Number: |

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***YYYY-MM-DD*** *(Date)*, it is considered that it complies with  
The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between  
the European Union and ***Japan***.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and   
should not be relied upon to reflect the compliance status if more than three years have elapsed since the date   
of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

**Part 2**

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| Human Medicinal Products |

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| **1 MANUFACTURING OPERATIONS**  **製造所に関する情報を記載** |

Any restrictions related to the scope of this certificate:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Building | Room | Line/equipment | QC testing | Products |
|  |  |  |  | **[申請者名]**  **[品目(製品)名] [剤形]** |
|  |  |  |  | **複数品目を記載** |

Clarifying remarks (for public users)   
***[License Number: ] MHLW certifies the GMP Compliance of all manufacturing operations in the above manufacturing site for the products specified in the certificate. Due to different terminology of manufacturing operations in Japan and the EU, the items listed in Part 2 have been selected by the manufacturer and the MHLW bears no responsibility for this information.***

***YYYY-MM-DD (Date)*** Name and signature of the authorized person of the  
 Competent Authority of Japan

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（監視指導・麻薬対策課長名）

***Ministry of Health, Labour and Welfare***

Tel: ***+81 3 35952436***

Fax: ***+81 3 3501003***