【作成例　様式 14-1(英文)（外部試験検査機関の付記)】

PMDA 医薬品品質管理部作成(2024 年 11 月)

(Form No.14-1)

MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE ①

It is hereby certified that the following manufacturing site of (Name of the Manufacturer), (Address), in which the following product(s) is(are) produced is subject to our inspections at suitable intervals, and the manufacturing in the site conforms to all the requirements of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs ("Drugs/Quasi-drugs GMP Ordinance") laid down in accordance with the recommendation of the World Health Organization.

①、②
委託元製造所の情報を記載してください。
① 製造業者の名称、所在地
② 製造所の名称、所在地

② Name of Manufacturing Site:

Address:

③ Product(s): ○○（**The examination/testing of this(these) product(s) is(are) contracted to (name of the QC facility), (address)**）

③
製品名の後ろに（　）を付し、試験検査を外部委託している旨を追記してください。その際、外部試験検査機関の名称及び所在地も記載してください。

No.

TOKYO, date

様式 14-1(英文）チェックリストも併せてご確認ください。

（監視指導・麻薬対策課長名）
Director, Compliance and Narcotics Division
Pharmaceutical Safety Bureau
Ministry of Health, Labour and Welfare