様式第二十六の十（第五十三条の十二関係）
Form No.26－10 (related to Article 53－12)
第　　号

基　準　確　認　証
Certificate of GMP compliance of a manufacturing site

住所（法人にあつては、主たる事務所の所在地）
Address (In the case of a corporation, location of the head office)
氏名（法人にあつては、名称及び代表者の氏名）
Name (In the case of a corporation, its name and the name of its representative)

<table>
<tr><td>製造所の名称
Name of the manufacturing site</td><td colspan="2"></td></tr>
<tr><td>製造所の所在地
Location of the manufacturing site</td><td colspan="2"></td></tr>
<tr><td>製造業の許可区分
License or registration category of the manufacturer</td><td colspan="2"></td></tr>
<tr><td>製造業の許可番号
Number of the license or registration for the manufacturer</td><td colspan="2"></td></tr>
<tr><td>製造工程の区分
Categories of the manufacturing processes</td><td colspan="2"></td></tr>
<tr><td rowspan="2">医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第14条の２第２項の規定による調査
Investigation pursuant to Article 14-2, Paragraph 2 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices</td><td>結果
Result</td><td>調査実施者
Investigator</td></tr>
<tr><td>適合
Compliance</td><td>都道府県知事
Governor of the Prefecture</td></tr>
<tr><td rowspan="2">医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第14条の２第４項の規定による調査
Investigation pursuant to Article 14-2, Paragraph 4 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices</td><td>結果
Result</td><td>調査実施者
Investigator</td></tr>
<tr><td>適合
Compliance</td><td>独立行政法人医薬品医療機器総合機構
The Pharmaceuticals and Medical Devices Agency</td></tr>
</table>

医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第14条の２第５項の規定により、同法第14条第２項第４号の規定に基づき定められた医薬品及び医薬部外品の製造管理及び品質管理の基準に関する省令に定める基準に適合していることを証明する。

Pursuant to Article 14-2, Paragraph 5 of the Act on Securing Quality, Efficacy

and Safety of Products Including Pharmaceuticals and Medical Devices, it is hereby certified that the above manufacturing site complies with the standards prescribed in the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs (GMP Ministerial Ordinance), which were established based on Article 14, Paragraph 2, item 4 of the Act.

年　月　日
Year Month Day

都道府県知事
Governor of the Prefecture　印

有効期間　年　月　日から
Valid Period From Year Month Day
年　月　日まで
Until Year Month Day