

特定医薬品等区分適合性調査申請書

Application for specific investigation of conformity  
regarding the category of manufacturing processes of drug

|                                                                                      |  |
|--------------------------------------------------------------------------------------|--|
| 調査を受けようとする製造所の名称<br>Name of the manufacturing site to be investigated                |  |
| 調査を受けようとする製造所の所在地<br>Location of the manufacturing site to be investigated           |  |
| 製造業の許可区分<br>License or registration category of the manufacturer                     |  |
| 製造業の許可番号及び年月日<br>Number and date of the license or registration for the manufacturer |  |
| 調査を受けようとする製造工程の区分<br>Categories of the manufacturing processes to be investigated    |  |
| 製造品目数<br>Number of the product items                                                 |  |
| 製造販売業者数<br>Number of the marketing authorization holders in Japan                    |  |
| 輸出用の製造品目の有無<br>Presence of product items for export                                  |  |
| 調査手数料金額<br>Amount of the investigation fee                                           |  |
| 備考<br>Remarks                                                                        |  |

上記により、特定医薬品等区分適合性調査を申請します。

I hereby apply for specific investigation of conformity regarding the category of manufacturing processes of drug.

年 月 日  
Year Month Day

住所  
Address

（法人にあつては、主たる事務所の所在地）  
In the case of a corporation, location of the head office

氏名  
Name

（法人にあつては、名称及び代表者の氏名）  
In the case of a corporation, its name and the name of its representative

独立行政法人医薬品医療機器総合機構理事長  
To Chief Executive of the Pharmaceuticals and Medical Devices Agency 殿

(注意)

(Note)

1 用紙の大きさは、A4とすること。

Use paper of Japanese Industrial Standard Size A4.

- 2 字は、墨、インク等を用い、楷書ではつきりと書くこと。  
Fill in the form with clear writing with inks, etc.

- 3 製造業の許可区分欄については、第 25 条第 1 項各号のいずれに該当するかを記載すること。

In the “License or registration category of the manufacturer, accreditation or registration category of the foreign manufacturer” field, provide which category applies under each item of Article 25, Paragraph 1.

- 4 製造業の許可番号及び年月日欄については、法第 13 条第 1 項の許可を受けようとする者である場合は、許可申請受付番号及び申請年月日を記載すること。

In the “Number and date of the license or registration for the manufacturer, or of the accreditation or registration for the foreign manufacturer of drug, etc.” field, provide the receipt number and the date of the application for license, in case that applicant is seeking a license under Article 13, Paragraph 1 of the Act.

- 5 調査を受けようとする製造工程の区分欄については、第 53 条の 6 各号に掲げる区分のいずれに該当するかを記載すること。また、製造品目数欄に申請区分に属する製造品目の数、製造販売業者数欄に当該製造品目に係る製造販売業者の数、輸出用の製造品目の有無欄に申請区分に属する輸出用の製造品目の有無を記載すること。

In the “Categories of the manufacturing processes to be investigated” field, provide which categories of manufacturing processes apply under each item of Article 53-6. In addition, in the “Number of the product items” field, provide the number of product items that fall under the applied manufacturing category, in the “Number of the marketing authorization holders in Japan” field, provide the number of marketing authorization holders in Japan related to those product items, and in the “Presence of product items for export” field, provide whether there are product items for export that fall under the applied manufacturing category.

- 6 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関係手数料令において定める特定医薬品等区分適合性調査手数料を機構の口座に払い込んだことを証する書類の写しを裏面に貼付すること。

Affix a copy of the receipt for the remittance of investigation fee, as provided in the Government Order on the Fees Related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, to the bank account of the agency.