

**REQUEST FOR AUTHENTIC COPY OF GMP CERTIFICATES FOR PHARMACEUTICAL PRODUCTION
MANUFACTURING SITE (APIs)**

(A revenue stamp¹ to be canceled by affixing, part on the brand and part on the sheet, the subscription or the date, or by affixing a stamp

To: AIFA
Ufficio Ispezioni e Autorizzazioni
GMP Materie Prime
protocollo@pec.aifa.gov.it

Subject: Request for n. _____ copy(ies) of GMP certificate(s) of the pharmaceutical manufacturing site (name and address) _____

I _____, born in _____, on _____, in accordance with articles 46 and 47 of d.p.r. 28.12.2000, n. 445,

HEREBY DECLARE

- Of being the Legal Representative/delegate² of _____ which manufacturing site is in (full address) _____, tel. n. _____, fax _____, legal headquarters in _____ (full address) _____;
- Of being aware that false acts and declarations are punishable by law and that, if such declaration is in fact found to be false, the declarer will no longer have any benefits consequent to the false declaration act, as prescribed by articles 75 and 76 of said act;
- that the documents contained on CD/USB Drive, originally formed on analog support, comply with the originals documents according to d.lgs. n. 82/2005 (Digital Administration Code) and the d.p.r. of 28 December 2000 n. 445.

HEREBY ASK

The release of n. _____ copy(ies) of GMP certificate(s) relative to the manufacturing site.

¹or € 16.00 to be paid on the AIFA bank account

²Improper entry be deleted; in case of delegate a statutory declaration in accordance with artt. 38-47 of d.p.r. n. 445/2000 to be attached

Attachments to the present document:

- payment receipt ³;
- payment receipt of the revenue stamps due for the request of the certificate and for the certificate (see instruction of payment).

- digital copy of mod. F23 and related payment receipt⁴

- scanned self-certification with revenue stamps⁵

- Only for the foreign companies that do not have a local representative or an accredited attorney at AIFA: **payment receipt of the bank transfer** (see instruction of payment)⁶

In accordance to article 38, comma 3, of d.p.r 28.12.2000, n. 445, this communication must be sent together with a photocopy of proper identification to the PEC address: protocol@pec.aifa.gov.it.

Place and date _____

In witness
(signature and stamp)

³ The amount due is established by the Decree dated December 6, 2016 (G.U. n. 25 of January 31, 2017). The payment has to be done in accordance with table published on the AIFA's institutional website, Italian section: Servizi Amministrativi/Versamento Tariffe e Diritti Annuali/Elenco Tariffe (Codice Tariffa E.5.1)

⁴ In case of request of more copies of a document, it is possible to pay the revenue stamps with a single mod. F23, calculating that the amount corresponding to the revenue stamps for the single document must be multiplied for the number of copies requested. The total amount should be reported in the section 13 "importo".

⁵ The Legal Representative/delegate shall purchase the revenue stamps, attach them on the self-certification (see template provided) reporting the serial numbers of the revenue stamps, cancel them by affixing, part on the brand and part on the sheet, the subscription or the date, or a stamp, then scan the self-certification (in pdf or jpeg, png format).

⁶ Only for the foreign companies that do not have a local representative or an accredited attorney at AIFA, the payment of the amount corresponding to the revenue stamps may be made by bank transfer to the following:

IBAN IT07Y0100003245348008120501

See instruction of payment.

Instruction of payment

Fee to be paid by bank transfer to the following bank accounts:

1) Bank account addressed to: Ministero della Salute
Amount: € 85,89 for each copy of the GMP certificate
IBAN: IT 39A0760114500001004782767
Bank name: Poste Italiane Spa
SWIFT CODE: BPPIITRRXXX

2) Bank account addressed to: AIFA
Amount: € 26,47 for each copy of the GMP certificate
IBAN: IT49E0503403200000000010448
Bank Name : Banco BPM S.p.a.
SWIFT CODE: BAPPIT21060 or BAPPIT22

1 Revenue stamp (€ 16,00) for the request + 1 revenue stamp (€ 16,00) every 4 pages of each copy of GMP certificate to be paid

Only for the foreign companies that do not have a local representative or an accredited attorney at AIFA, it will accept, on an extraordinary basis, stamp duty payments made via bank transfer to the following

IBAN: IT07Y0100003245348008120501.

If necessary, the following details can be added:

BIC code: BITAITRRENT (which identifies the Bank of Italy);

Beneficiary: "Bilancio dello Stato" [State Budget].

In order to reconcile the transaction and connect the transfer to the application or to the document for which the stamp duty is due, in the payment description, the GMP Certificate number should be indicated, in addition to the tax code (or, if the tax code is not available, the name) of the person responsible for paying the stamp duty. Please make sure that all information provided is complete and accurate.

The company will have to provide evidence of the payment by sending the corresponding receipt; in order for AIFA to check to that the bank transfer has been correctly executed.