

Specific request form for inspection of starting materials for pharmaceutical use

Information concerning an establishment carrying out any of the activities mentioned in article L.5138-4 of the Public Health Code, and requesting an inspection by ANSM in order to check the compliance to the good practices mentioned in article L.5138-3 of the Public Health Code (www.legifrance.gouv.fr). This form, duly filled in, must be returned in paper format and sent at the address indicated above.

Article D.5321-7 of the French Public Health Code, Decree n°2012-1016 of September 3rd, 2012 – Art. 1 (for information purpose only) :

[...] 2. Pursuant to Point 2 of Section I:

"For the performance of an inspection expressly requested by an establishment carrying out the activities mentioned in Article L.5138-4 in order to verify observance of the best practices mentioned on Article L.5138-3, and to issue, as appropriate, the certificate confirming such observance, the amount of the fee is comprised of a fixed portion of 1,000 euros and a variable portion calculated based on each day of inspection started at the site and limited to 9,000 euros, according to the following scale:

"- If the establishment inspected is located in a country that is a member of the European Community or in a country that is a party to the European Economic Area Treaty: €300 per day;

"- If the establishment inspected is located in any other country: €3,000 per day. [...]"

Name of the establishment to be inspected	
Complete address of establishment to be inspected (including the country)	
SIRET (French establishment only)	
Name of the contact in the establishment to be inspected Function Telephone Fax E-mail address	
Name of the starting materials for pharmaceutical use concerned by the request accompanied by the registration numbers concerned if necessary (CEP, DMF, MA)	
Date wished for inspection	
Name and Signature of the entitled person (Stamp of the establishment) [Place], [Date]	