LIST OF DOCUMENTS FOR REGISTRATION OF THE ACTIVE PHARMACEUTICAL INGREDIENT IN RUSSIAN FEDERATION (2012)

	Administrative documents
1.	**Power of Attorney** *(legalized copy by Russian Embassy or apostilled) (draft is provided upon a request)*
2.	**Original payment order of state tax for registration of API**
3.	**INN, trade name of API**
4.	**Certificate of Analysis of active substance(s) issued by API manufacturer** (*for 3 recent batches valid at least 6 months*) (*copy with signature and stamp of the finished product manufacturer's authorized person*)
5.	**Certificate of suitability issued by EDQM for API** (*in case of presence*) (*copy with signature and stamp of the finished product manufacturer's authorized person*)
6.	**Copies of Registration Certificates (Marketing Authorizations) in case if the product is registered in other countries** (*in case of presence*)
	General info
7.	**Nomenclature (IUPAC name), structure, description, general physicochemical properties of API**
	Data about manufacturing of API
8.	**Confirmation of Juridical address of manufacturer and of Marketing Authorization Holder –Certificate of registration of the company** *(legalized copy by Russian Embassy or apostilled)*
9.	**GMP-certificate of API-manufacturer, in which must be mentioned the API name** *(legalized copy by Russian Embassy or apostilled)*
10.	**Manufacturing License (***(legalized copy by Russian Embassy or apostilled)*
11.	**Short scheme and detailed description of API manufacturing process with indication of stages, starting materials, substances**
12.	**Validation of manufacturing process**
	Data about quality control
13.	**Release and shelf-life Specification and analytical procedures of API**
14.	**Validation of analytical procedures**
15.	**Certificate of Analysis for reference standards** (*copy with signature and stamp of the finished product manufacturer's authorized person*)
16.	**Container closure system –** description (*including quantity of the product in primary and secondary packaging for Russian market*), packaging specification, certificates of analysis
17.	**Stability summary and conclusion, stability report for 3 batches**