REGAPHARM

LIST OF DOCUMENTS FOR GMP CERTIFICATION (MANUFACTURING SITE INSPECTION)

	Administrative documents	Type of document
1.	Power of Attorney (From MA holder to Regapharm)	*Apostilled*
2.	Power of Attorney (From FDF Producer to MA holder)	*Apostilled*
3.	If Producer is a contract manufacturer – Contract Manufacturing agreement	*Copy*
4.	If a Producer is part of Group of MA holder – official letter stating relations between them	*Apostilled*
5.	GMP-certificate of API-manufacturer *(apostilled) – in the document obligatory must be mentioned the following information: INN or chemical name of API, name and address of API manufacturer*	*Apostilled*
6.	Manufacturing License of the API product manufacturer	*Apostilled*
7.	Name and address (juridical and production site) of the finished product manufacturer on all stages: finished product, primary packaging, secondary packaging, batch release	Copy
8.	GMP-certificate (Good Manufacturing Practice) of the finished product manufacturer	*Apostilled*
9.	Manufacturing License of the finished product manufacturer	*Apostilled*
10.	Guarantee letter about confirmation of possibility of inspection of manufacturing place.	*Original or a copy with signature and stamp of the finished product manufacturer's authorized person*
11.	SITE MASTER FILE (for FDF production site)	Copy