REGAPHARM

LIST OF DOCUMENTS FOR REGISTRATION OF THE FINISHED PHARMACEUTICAL PRODUCT (DRUG)

	Administrative documents	Type of document
1.	**Power of Attorney**	***Apostilled***
2.	Patent for registered brand name *(in case of existence)*	Copy
3.	Summary of Product Characteristics (SPC) or instruction for administration for specialists	Copy
4.	Certificate of Pharmaceutical Product	***Apostilled***
5.	SOP of Pharmacovigilance (issued by holder/manufacturer)	Copy
6.	Copies of Registration Certificates (Marketing Authorizations) from other countries in case if the product is registered in other countries (*in case of existence*)	Copy
7.	**PSUR (periodic safety updated record)**	Copy
8.	Colored mock-ups of primary and secondary packaging (with pantone codes)	Part from CTD dossier
	Data about API (active pharmaceutical ingredient) used for manufacturing of the finished pharmaceutical product	
9.	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***
10.	Certificate of analysis of API issued by API manufacturer (*for recent 3 batches valid at least 6 months*). *Original or a copy with signature and stamp of the finished product manufacturer's authorized person*	*Original or a copy.*
11.	Certificate of analysis of API issued by manufacturer of finished product (*for the same batches as CoAs provided in point 9*). *Original or a copy with signature and stamp of the finished product manufacturer's authorized person*	*Original or a copy.*
12.	Certificate of suitability for API issued by EDQM (*in case of existence*)	Copy
13.	Nomenclature (INN or chemical IUPAC name), classification, structural formula, molecular formula, molecular weight, general physicochemical and microbiological properties of API, impurities of API and their description	Copy
14.	Specification and analytical methods for quality control of API *(+ Monograph from EP, USP, BP*)	Copy
15.	Data about validation of analytical procedures of API: short summary (it is not required in case API has monograph in EP, USP, BP or Russian Ph.)	Copy
16.	Stability data for API for 3 batches: justification of the shelf-life, storage conditions, type of stability study *(could be provided as a table, report or short review)*	Copy
17.	API manufacturing process scheme: should be provided as a flow chart with reflection of consequence of all manufacturing stages (and steps) and their obligatory enumeration. On the scheme must be shown: raw material used, intermediate products and product yield.	Copy

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18.	Description of API manufacturing process + process validation: is described consecutively by stages (and steps) in accordance to the scheme provided in p.16. Also intermediate control should be provided.	Copy
19.	Material balance: - batch size (including product yield); - quantity of starting material used for manufacturing of one API batch and/or all chemical reactions (main and auxiliary) on every stage with molecular weight of substances; - explanation of the principal of API batch number generation.	Copy
20.	**Certificate of analysis of reference standards used for quality control of API**	**Copy**
21.	**Certificate of analysis of all packaging materials of API**	**Copy**
22.	**Pharmaceutical development: formulation development; manufacturing process development, justification of pharmaceutical compatibility, microbiological characteristics.**	**Copy**
23.	**Samples of API for expertise**	
	Data about manufacturing of finished pharmaceutical product	
24.	Name and address (juridical and production site) of the finished product manufacturer on all stages: finished product, primary packaging, secondary packaging, batch release	Copy
25.	GMP-certificate (Good Manufacturing Practice) of the finished product manufacturer	***Apostilled***
26.	Manufacturing License of the finished product manufacturer	***Apostilled***
27.	Finished product manufacturing process scheme: should be provided as a flow chart with reflection of consequence of all manufacturing stages (and steps) and their obligatory enumeration. Intermediate control on every stage should be shown.	Copy
28.	Description of finished product manufacturing process with intermediate control: is described consecutively by stages (and steps) in accordance to the scheme provided in p.22.	Copy
29.	Material balance: - quantity of active and auxiliary substances used for manufacturing of one batch of the finished product; - one batch size expressed in quantity of finished product packs received; - explanation of the principal of the finished product batch number generation.	Copy
30.	Finished product manufacturing process validation	Copy
31.	Pharmaceutical development: formulation development; manufacturing process development, justification of pharmaceutical compatibility of components, microbiological characteristics.	Copy
32.	**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***	***Apostilled***

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	Data about quality control of finished pharmaceutical product	
33.	Full composition of finished product per one dosage unit	Copy
34.	Release and shelf-life specification and analytical procedures for quality control of finished pharmaceutical product	Copy
35.	Validation of analytical procedures with information about number of batches (quantity of samples) used for validation	Copy
36.	Certificate of analysis for 3 batches of the finished product (*for recent batches valid at least 6 months*). *Original or a copy with signature and stamp of the finished product manufacturer's authorized person*	*Original or a copy.*
37.	Certificate of analysis of excipients (*for recent batch valid at least 6 months*). *Original or a copy with signature and stamp of the finished product manufacturer's authorized person*	*Original or a copy.*
38.	Certificate of analysis of reference standards used for quality control of the finished product. *Original or a copy with signature and stamp of the finished product manufacturer's authorized person*	*Original or a copy.*
39.	Characterization of impurities of finished pharmaceutical product	Copy
40.	Description of container closure system (primary and secondary packaging)	Copy
41.	Justification of container closure system choosing	Copy
42.	Certificate of analysis of primary and secondary packaging. *Lay-out or schematic drawing of the package could be provided in case on necessity*.	Copy
43.	Stability data tables for 3 batches under normal (and/or accelerated) conditions for the whole shelf-life, performed on all quality tests included in the specification for finished product + stability summary with conclusion about received stability data for all types of primary packaging	Copy
44.	Information about storage conditions and shelf-life of the finished product	Copy
45.	Samples of finished product for expertise	
	Data about NON-clinical pharmacological and toxicological studies of finished pharmaceutical product	

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46.	**Report about results of the own preclinical study which contains description, results and statistical analysis of the results** (*copy with signature and stamp of the authorized person*): - Non-clinical Pharmacology – major pharmacodynamics studies; - Non-clinical Pharmacokinetics – major pharmacokinetics studies; absorption; distribution; metabolism; excretion; drug interaction; - Non-clinical Toxicology – single-dose toxicity (acute), repeat-dose toxicity (subchronic and chronic), genotoxicity, carcinogenicity, reproductive and developmental toxicity, local tolerance, other studies; - General conclusions of the study; - Literature references.	
47.	**Literature overview of preclinical data:** - Non-clinical Pharmacology – results of studies which confirm the pharmacological activity of pharmaceutical product; - Non-clinical Pharmacokinetics – absorption; distribution; metabolism; excretion; pharmacokinetic Drug Interaction; - Non-clinical Toxicology – single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity, reproductive and developmental toxicity, local tolerance, other studies.	
	Data about CLINICAL studies of finished pharmaceutical product	
48.	**Own clinical trial reports** (*copy with signature and stamp of the authorized person*) (*in case of existence*): a) Reports of international multicenter clinical trials a part of which were conducted in Russian Federation (*in case of presence*) b) Pharmacology – major pharmacodynamics studies c) Pharmacokinetics – major pharmacokinetics studies; absorption; distribution; metabolism; excretion; drug interaction; d) Efficacy and safety studies e) Post-registration studies *(in case of presence)*	
49.	**Literature clinical efficacy and safety overview**	

Major part of these documents are fully represented in dossier of CTD format of a product.