List of Quality Documents to be Reviewed During Inspection

№	Requested document
	Pharmaceutical quality system documentation
1	Copy of manufacturing site license
2	Copy of site GMP certificate (issued by local Authority)
3	CA/PA for observations from the previous inspection
4	Description of the product XXX production flow – name, address and manufacturing stages for each involved site. Information about quality agreements between involved sites and agreements status.
5	Analysis of Pharmaceutical quality system functionality by management for effectiveness evaluation (last report) – Quality Management Review report
6	Annual Product Review Product XXX for 2019 and procedure for quality review creation (sections: review of finish drug product quality, review of complaints, review of deviations, review of changes). Procedure for APR creation.
7	Procedure for product release. List of persons who performs product release.
8	Procedure for change control management and list of major changes for the Product XXX for 2019/2020
9	Procedure for deviation management and list of deviations for the Product XXX for 2019/2020
10	Self-inspection procedure. List of persons who perform self-inspection. Information about self-inspections for the production facility (rooms) used in Product XXX manufacturing process with status of self-inspections (dates, conclusions, responsible auditors)
11	Procedure for complaints management. List of complaints for 2019/2020 for Product XXX (if applicable)
12	Procedure for recalls management. List of recalls for 2019/2020 for Product XXX for (if applicable)
13	List of approved suppliers of materials for Product XXX
14	Job description for key personnel: Head of manufacturing, Head of Quality Control
15	Detailed layout of XXX manufacturing facility with indication of rooms grades, personnel & material flows, equipment location, indication of manufacturing line used for manufacturing of Product XXX
16	Detailed layout of QC laboratories used for Product XXX testing
17	Detailed diagrams of HVAC system for facility where Product XXX is produced
18	Detailed layout of warehouses involved in Product XXX manufacturing
19	Procedure for handling of intermediate and finished products on warehouse (receiving, storage)
20	Copy of Master Batch Record for Product XXX packaging (batch number is up to manufacturing site'sdecision)
21	In-process controls of Product XXX manufacturing process (procedure that defines performing of In-process controls)
22	Storage conditions for Product XXX (procedure that defines storage conditions)
23	List of planned validation and qualification activities for 2020 (related to equipment and production rooms used for Product XXX manufacturing
24	Report and protocol of qualification of production rooms used for Product XXX manufacturing
25	Report and protocol of manufacturing line qualification used for Product XXX manufacturing
26	Specification for FDP Product XXX manufacturing
27	Specification for LDP (before packaging) Product XXX manufacturing
28	Stability study report for Product XXX including data along all product shelf life. Procedure for products stability study.
29	Plan for Product XXX stability study
30	Analytical methods validation (or methods transfer report) for Product XXX *(methods will be selected after specification receiving)*
31	Procedure for OOS management. List of OOS for 2019/2020 for Product XXX