Annex 12
to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-registration) and for Expert Evaluation of Materials about Introduction of Changes to Registration Materials during Validity Period of Registration Certificate
(item 4 of section IV)

THE LIST
of documents required for conducting expert evaluation of registration materials for state registration of API

1. Administrative data.
2. Table of contents.
3. Registration form.
4. Document confirming that the manufacturer has a right for API large-scale manufacturing according to the requirements of country where the manufacturing site is placed.
5. The quality certificate for one batch of API.
6. General information.
6.1. Nomenclature.
6.2 Structure.
6.3 General properties.
7. Manufacture:
7.1. Manufacturer(s).
7.2. Manufacturing process flow diagram and its brief description.
7.3. Impurities: process- and product-related.
8. Control.
8.1. Specification.
8.2. Analytical procedures and their validation
9. Stability data.
10. Packaging.
11. Labelling.
The labelling shall contain information established by the API manufacturer within the data management system at the manufacturing site according to GMP for starting and intermediate products. This labelling shall be given in appropriate section of methods of quality control (MQC).

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Note. If API, which is submitted for registration, has a Master File, the materials related only to Open Part shall be submitted for expert evaluation.

{Annex 12 in wording of MoH Ukraine Order №460 as of 23.07.2015}