IAAP
International Association of
Anthroposophic Pharmacists

Criteria for the adoption of new manufacturing methods and substances in the APC

1. Manufacturing methods

1. The method must be in use for the production of a pharmaceutical product used within anthroposophic medicine.
2. A published reference for the use in anthroposophic medicine must exist (and sent with the application for adoption).
3. The applicant must describe the method to such a detail, that a skilled pharmacist with the necessary equipment is able to produce a pharmaceutical product with reproducible quality. In other words: the quality of the description should equal other pharmacopoeias like the Ph. Eur., the HAB or the Ph. Helv.
4. The structure and wording of the manufacturing method must comply with the structure and wording of the existing manufacturing methods of the APC, which in turn uses the Ph. Eur. as a standard.

2. Substances (monographs)

1. The substance must be in use for the production of pharmaceutical products used within anthroposophic medicine.
2. A published reference for the use in anthroposophic medicine must exist (and sent with the application for adoption).
3. The monograph must contain a heading “Preparations” naming manufacturing methods to be used (e.g. according to Ph. Eur. monograph 2371 method 3.1.1) or with references to individual monographs.
   The use of the production method should be justified with an anthroposophical rationale.
4. The manufacturer must have an in-house monograph with analytical criteria (quality standards) for the release of the substance (for substances with toxic relevant compounds including an assay).
5. Analytical methods should be tested also by other manufacturers, if applicable (validation in cross check, “Ringversuche”), or by external laboratories.

For the adoption of a substance in an appendix, only the numbers 1-4 are applicable.

Decision of the APC Committee 2022-Jan-31