- Analysis for lack of contamination by pesticides, heavy metals, and synthetic drug adulterants.
- The breakdown or dissolution of the analyzed components in physiological solutions.
- List of inert substances (excipients) added to the product.
- Storage conditions and stability over the length of the trial.

10.2.8 Information on the Plant Product Proposed for Phase III Studies

10.2.8.1 Plant Substance

- Botanical description
- Statement that the plant is cultivated according to Good Agricultural Practices or harvested according to Good Wildcrafting Practices
- Extraction procedure
- Quantity and identity of active ingredient(s) and of sizeable chemical constituent
- Statement that extraction and analytic procedures are performed under Good Manufacturing Practices (GMPs) (e.g., that the manufacturing processes and their controls provide the appropriate levels of assurance for the important quality characteristics of the product)

10.2.8.2 Plant Product

- Manufacturing methods
- Analysis of commonly accepted or supposed active ingredient(s) via chemical or biological parameters
- Analysis of a sizeable chemical constituent (analytical marker compound)
- Analysis via chemical fingerprint (analytical markers)
- Analysis for the lack of contamination by pesticides, heavy metals, and synthetic drug adulterants
- The breakdown or dissolution of the analyzed components in physiological solutions
- In-process controls for manufacturing process
- List of inert substances (excipients) added to the product
- Description of the reference batch
- Storage conditions and stability over the length of the trial
- Environmental impact statement
- Statement that the plant product is manufactured and analyzed according to GMP (e.g., that the manufacturing processes and their controls provide appropriate levels of assurance for the important quality characteristics of the product)