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DIETARY SUPPLEMENT INGREDIENT (BOTANICAL ORIGIN)
MAIN GMP followed by Indena

1. Quality Unit

To prevent adulteration and misbranding, including ensuring that dietary ingredients meet specification for identity, purity, quality, strength and safety.
We agree with the requirements listed into the paragraph 111.37 of the new draft guidance for dietary ingredient/dietary supplements.

2. Botanical starting materials

Botanical controls should be performed on the starting plant material to assure identification and adequate purity of the botanical material.
Quantitative testings are used if necessary to guarantee final content of the labeled constituents.
Analytical fingerprints should be included into the identification testings to assure genuinity of the final extract.
Qualification of the suppliers of the botanical starting material should be performed by Quality Unit to include information about eventual treatment with pesticides as well as drying and storage conditions of the biomass.

3. Manufacturing

Manufacturing of the dietary ingredients is performed following Master Batch Record preparation and Approval by Production and Quality Unit.
The Master Batch record includes all the critical in process controls and manufacturing parameters with the related limits.
Specification and Quality Control methods for the intermediate products are also defined.
Any deviation should be documented and explained. Any critical deviation should be investigated.
Changes to manufacturing process and testings should be approved by the Quality Unit.

4. Controls of the dietary ingredient

Qualified analytical methods for the release of the final dietary ingredients should be developed in order to assure the requested content of the labeled constituents.
If official methods (i.e. AOAC methods) are not used they should be validated.
Reference standards to be used for the assays should be fully qualified.
The testings should include control for contaminants i.e. pesticides, heavy metals, aflatoxins (if there are reasons for concern) and microbial controls.
Out of specification (OOS) results should be investigated to avoid OOS batches to be released following a simple re-testing.
Eventual re-working and/or re-processing should be authorized by Quality Unit.

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5. Cleaning

Cleaning methods should be in place to assure adequate cleaning of the main manufacturing equipment to include associated pumps and piping. Visual inspection should be adequate as a cleaning control for equipment dedicated to dietary ingredients. When the same equipments are used for pharmaceutical active ingredients, validated analytical methods for the assay of the pre-determined residuals limits should be in place to assure adequate cleaning of the pieces of equipment. In addition cleaning validations should be performed to assure dietary ingredients to be free from active contaminants.
The cleaning status of the main pieces of equipment should be indicated.

6. Re-testing period

Re-resting date/period should be attributed to the dietary ingredient based on the stability data performed on stability samples stored in containers that simulate the market containers.

7. Qualification of suppliers of Dietary ingredients

Suppliers of dietary ingredients should be qualified by the manufacturers of the Dietary Supplements.