

## **Regulatory Insights**

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Agency

**CFDA** 

**Manufacture Techniques of Recorded** 

**Health Food (Trail)** 

保健食品备案产品主要生产工艺(试行)

This regulation applies to health food (dietary supplement) which is manufactured to supply vitamins, minerals and other nutrition to human bodies.

- 1. Tablets: smashing, sieving, mixing, granulation, drying, tableting, coating, packaging, etc.
- 2. Capsule: smashing, sieving, mixing, granulation, drying, capsuling, packaging, etc.
- 3. Softgel: drying, mixing, homogeneity, filtration, pelleting, packaging, etc.
- 4. Oral Liquid: mixing, dissolution, confecting, canning, packaging, etc. (sterilization method and technical indexes shall be recorded, such as sterilization by moist heat, hot-pressing sterilization, flowing steam sterilization, etc.).
- 5. Particles: smashing, sieving, mixing, granulation, drying, packaging, etc.
- 6. Any ingredients, after premixing, embedding and microencapsulation, shall be labeled as premixing (\*\*, \*\*, \*\*) embedding (\*\*, \*\*, \*\*) and microencapsulation (\*\*, \*\*, \*\*), \*\* should be the ingredients name before pretreatments.

## **Original Chinese Document listed Below**

## 保健食品备案产品主要生产工艺(试行)

该备案产品主要生产工艺适用于补充维生素、矿物质等营养物质的保健食品(营养素补充剂)。

- 一、片剂:粉碎、过筛、混合、制粒、干燥、压片、包衣、 包装等。
- 二、硬胶囊: 粉碎、过筛、混合、制粒、干燥、装囊、包装等。
  - 三、软胶囊: 干燥、混合、均质、过滤、压丸、包装等。
- 四、口服液:混合、溶解、配制、过滤、灌装、包装等(涉及灭菌的,应填报具体灭菌方法及工艺参数,如湿热灭菌、热压灭菌、流通蒸汽灭菌等)。

五、颗粒:粉碎、过筛、混合、制粒、干燥、包装等。

六、经预混、包埋、微囊化等前处理的原料,应以预混(\*\*、\*\*、\*\*)、包埋(\*\*、\*\*、\*\*)、微囊化(\*\*、\*\*、\*\*)等形式,标注经预混、包埋、微囊化等前处理的原料名称