Regulatory Insights

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保健食品备案产品剂型及技术要求
（2021 年版）
Dosage Forms and Technical Requirements of Health Food Recording Products
(2021 version)

The dosage forms and main production processes of each dosage form (or food forms) are as follows:

1. Tablets: crushing, sieving, mixing, granulating, drying, tableting, coating, packaging, etc.
2. Hard capsules: crushing, sieving, mixing, granulating, drying, encapsulating, packaging, etc.
3. Soft capsules: drying, mixing, homogenizing, filtering, pelletizing, packaging, etc.
4. Oral solution: mixing, dissolving, preparing, filtering, filling, packaging, etc. (If sterilization is involved, the specific sterilization method and process parameters should be filled in, such as moist heat sterilization, autoclaving, circulating steam sterilization, etc.) .
5. Granules: crushing, sieving, mixing, granulating, drying, packaging, etc.
6. Jelly candy: sol, sugar, boiling, blending, filtering, aeration, forming, drying, sand mixing, coating, polishing, coating, packaging, etc.
7, powder: crushing, sieving, mixing, packaging, packaging, etc.
8. The pre-processed raw materials that have been pre-mixed, embedded, and microencapsulated, should be marked as pre-mixed(**、**、**)、embedded(**、**、**)、microencapsulated(**、**、**).

The dosage forms and technical requirements of each dosage form are as follows:

(1) The above dosage forms (or food forms) and main production processes can be selected for the recording of vitamin and mineral supplementing products.
(2) Tablets, capsules, softgel , oral solutions, and granules are the dosage forms included in the current "Chinese Pharmacopoeia". The index setting in the technical requirements should refer to the current "Chinese Pharmacopoeia" and "National Food Safety Standard Health Food" (GB16740).
(3) The gummy and powder included in the recording system this time belong to the form of food, and their technical indicators do not have corresponding national standards. For details of the technical requirements for gummy and powder for health food, please refer to the appendixes.
(4) The dosage forms and technical requirements of the five newly added health food raw materials such as Coenzyme Q10 should meet the relevant requirements of the "Technical Requirements of the Five Health Food Raw Materials for Health Food Recording".

(5) According to the successive release of the health food raw material list, the dosage forms (or food forms) should be subject to the dosage forms (or food forms) specified in the "Health Food Raw Materials List" and its supporting documents.

Technical requirements for health food recording dosage form – Gummy

1. Overview of gummy candy

Gelatin candy is made of sugar or syrup or sweetener, edible gum (or starch) as the main raw materials, and is made into elastic and chewy candy through related processes.

2. Related content of the gummy candy product introduction book

The following content only stipulates the relevant requirements that need to be met for the shape of the gummy candy, but does not involve other regulations that the raw materials need to meet when the product is made.

The relevant content requirements in the product introduction book are as follows:

[Suitable crowd] People over 4 years old
[Unsuitable crowd] People under 3 years old
[Consumption amount and consumption method] The maximum daily consumption is 20g; the consumption method is "should chew thoroughly before taking."
[Specifications] Each capsule does not exceed 6g
[Shelf Life] Not more than 24 months
[Precautions] Do not swallow. People who consume this product should have the ability to chew solid food. At the same time, it is recommended to add a reminder that “should be chewed and eaten under the supervision of adults for those under 13 years of age”.

3. The index setting of the technical requirements of gummy candy products

The following content only stipulates the relevant requirements that need to be met for the shape of the gummy candy, but does not involve other regulations that the raw materials need to meet when the product is made.

The relevant content requirements of product technical requirements are as follows:

【Sensory requirements】

Item	Specification
Color	Filling in requirements: conform to the appearance characteristics of the corresponding product, and have the color and luster that the variety should have.
Taste and Odor	Taste and smell Filling requirements: have the smell and taste that the product should have, no unpleasant smell, no peculiar smell
Status	The block shape is relatively complete, the size is basically the same, there is no obvious deformation, no adhesion. In addition, the following requirements should be met for different glue types: Vegetable gum type: slightly elastic and chewy. Animal glue type: elastic and chewy, no wrinkle skin. Starch type: Tough taste, slightly chewy, no starch binding phenomenon, using starch as raw material, there may be a small

	amount of uniform cooked starch on the surface, with elasticity and toughness. Mixed rubber type: elastic and chewy. Sandwich type: elastic and chewy; closed sandwich type without leakage of filling Coating, coating polishing type: the coating is relatively complete. Other types: in line with the expected state of the variety.

【Physical and Chemical Index】

Item	Specification
Pb, mg/Kg	≤0.5
As, mg/Kg	≤0.5
Hg, mg/Kg	≤0.3
Loss on drying, g/100g	Vegetable glue type: ≤18.0 Animal glue type: ≤20.0 Starch type: ≤18.0 Mixed type: ≤35.0 Sandwich type, coating and coating polishing type: meet the requirements of the main candy Other glue types: ≤20.0
Reducing sugar (calculated as glucose), g/100g	≥10.0 Sandwich type, coating and coating polishing type: meet the requirements of the main candy. Sugar-free gummy does not have this indicator.
Monosaccharides and disaccharides, g/100g	≤0.5, only sugar-free gelatinous candies set this index

【Microbiological indicators】

Item	Specification	Testing Method
Total number of colonies, CFU/g	≤30000	GB 4789.2
Coliform flora, MPN/g	≤0.92	GB 4789.3MPN counting method
Mold and yeast, CFU/g	≤50	GB 4789.15
Staphylococcus aureus	≤0/25g	GB 4789.10
Salmonella	≤0/25g	GB 4789.4

【Net content and allowable negative deviation index】

Net content and allowable negative deviation indicators should meet the requirements of JJF 1070

4. Product name

Brand name + common name + gummy candy

5. Application Scope

Products that use vitamins and minerals included in the health food raw materials list as raw materials can be used in the form of gummy. Whether other raw materials listed in the health food raw material list are allowed to use, will be determined according to the regulations when the raw material supporting documents are released.

Technical requirements for health food recording dosage form – Powder

1. Overview of powder

Powder is a dry powder finished product made by pulverizing and uniformly mixing raw materials and auxiliary materials.

2. Related contents of the powder product introduction book

The following content only stipulates the relevant requirements that need to be met for the form of powdered foods, but does not involve other requirements that need to be met when the raw materials are made into products.

The relevant content requirements in the product introduction book are as follows:
[Suitable crowd] The dosage form should be suitable for all crowd
[Unsuitable crowd] There is no specific unsuitable crowd for this dosage form
[Dosage and method of consumption] The maximum daily consumption is 20g; package increase indicates that "powder is generally dissolved or dispersed in water or other liquids, or it can be taken directly with water". For the "direct oral" eating method, the unsuitable crowd should include "people under 6 years old".
[Specifications] For large-dose packaging, the volume per package is limited to no more than 500g (in principle, no more than 1 month's dosage). Large-dose packaging should be accompanied by dividing utensils.
[Shelf Life] Not more than 24 months

3. Technical requirements for powder products

The following content only stipulates the relevant requirements that need to be met for the form of powdered foods, but does not involve other requirements that need to be met when the raw materials are made into products.
The relevant content requirements of product technical requirements are as follows:

【Sensory requirements】

Item	Specification
Color	Filling in requirements: conform to the appearance characteristics of the corresponding product, and have the color and luster that the variety should have.
Taste and Odor	Taste and smell Filling requirements: have the smell and taste that the product should have, no unpleasant smell, no peculiar smell
Status	Should be dry, loose, evenly mixed, consistent in color

【Physical and Chemical Index】

Item	Specification
Particle size	Comply with any of the coarsest powder, coarse powder, medium powder and fine powder in the Chinese Pharmacopoeia
Pb, mg/Kg	≤2.0

	Infant solid health food≤0.3
As, mg/Kg	≤1.0 Infant solid health food ≤0.3
Hg, mg/Kg	≤0.3 Infant solid health food ≤0.02
Moisture,%	≤9.0
As,%	Required

【Microbiological indicators】

Item	Specification	Testing Method
Total number of colonies, CFU/g	≤30000	GB 4789.2
Coliform flora, MPN/g	≤0.92	GB 4789.3MPN counting method
Mold and yeast, CFU/g	≤50	GB 4789.15
Staphylococcus aureus	≤0/25g	GB 4789.10
Salmonella	≤0/25g	GB 4789.4

【Net content and allowable negative deviation index】
Net content and allowable negative deviation indicators should comply with JJF 1070 regulations

4.product name
Brand name + common name + powder (if the raw material name contains "powder", it will not be added again)

Original Chinese Document listed Below

保健食品备案产品剂型及技术要求
（2021年版）

一、保健食品备案产品剂型（或食品形态）及主要生产工艺如下：

（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：混合、均质、过滤、压丸、干燥、包装等。

（四）口服溶液：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）颗粒剂：粉碎、过筛、混合、制粒、干燥、包装等。

（六）凝胶糖果：溶胶、化糖、熬煮、混合、调配、过滤、充气、成型、干燥、拌砂、包衣、抛光、涂挂、包装等。

（七）粉剂：粉碎、过筛、混合、分装、包装等。

经预混、包埋、微囊化等前处理的原料，应以预混（**、**、**）、包埋（**、**、**）、微囊化（**、**、**）等形式在生产工艺中标注经预混、包埋、微囊化等前处理的原料名称。

二、保健食品备案产品剂型及技术要求如下：

（一）补充维生素矿物质产品在备案时可以选用以上剂型（或食品形态）及主要生产工艺。

（二）片剂、硬胶囊、软胶囊、口服溶液、颗粒剂为现行《中国药典》中收

载的剂型，技术要求中指标设定参考现行《中国药典》和《食品安全国家标准保健食品》（GB16740）。

（三）此次纳入备案的凝胶糖果和粉剂属于食品形态，其技术指标无相应的国家标准，凝胶糖果技术要求和粉剂的保健食品技术要求详见附件。

（四）辅酶 Q_{10} 等五种保健食品原料备案产品剂型及技术要求需符合《辅酶 Q_{10} 等五种保健食品原料备案产品剂型及技术要求》相关要求。

（五）根据保健食品原料目录的陆续发布情况，不同原料可以制备的剂型（或食品形态）以《保健食品原料目录》及其配套文件发布时规定的剂型（或食品形态）为准。

附件：1.保健食品备案剂型凝胶糖果的技术要求（2021 年版）

2.保健食品备案剂型粉剂的技术要求（2021 年版）

附件 2-1

保健食品备案剂型凝胶糖果的技术要求（2021 年版）

1.凝胶糖果概述

用于保健食品备案的凝胶糖果是以纳入保健食品原料目录的原料，与食糖或

糖浆或甜味剂、食用胶（或淀粉）等辅料，经相关工艺制成具有弹性和咀嚼性的糖果。

2.凝胶糖果产品说明书有关内容

以下内容仅针对凝胶糖果食品形态规定了需要满足的有关要求，不涉及使用的原料辅料在制成产品时还需要符合的其他规定。

产品说明书中有关内容要求如下：

【适宜人群】4 岁以上人群

【不适宜人群】3 岁以下人群

【食用量及食用方法】每日最大食用量为 20g；食用方法为“应充分咀嚼后服用”。

【规格】每粒不超过 6g

【保质期】不超过 24 个月

【注意事项】请勿吞服。食用本产品的人群应当具备有咀嚼固体食物的能力。同时对于适宜人群含有“13 岁以下”的，建议增加“应在成人监督下充分咀嚼食用”的提示。

3.凝胶糖果产品技术要求的指标设定

以下内容仅针对凝胶糖果食品形态规定了需要满足的有关要求，不涉及使用的原料辅料在制成产品时还需要符合的其他规定。

产品技术要求有关内容要求如下：

【感官要求】

项目	指标

色 泽	填写要求：符合相应产品的外观特性,具有品种应有的色泽。
滋味、气味	填写要求：具有产品应有的气味和滋味,无异臭,无异味
状 态	块形较完整，大小基本一致，无明显变形，无黏结。 此外，对于不同胶型应符合以下要求： 植物胶型：略有弹性，有咀嚼性。 动物胶型：有弹性和咀嚼性，无皱皮。 淀粉型：口感韧性，略有咀嚼性，无淀粉裹筋现象，以淀粉为原料的，表面可有少量均匀熟淀粉，具有弹性和韧性。 混合胶型：有弹性和咀嚼性。 夹心型：有弹性和咀嚼性；密闭的夹心型无馅心外漏 包衣、包衣抛光型：包衣较完整。 其他型：符合品种应有的状态。

【理化指标】

项 目	指 标
铅（以 Pb 计），mg/kg	≤0.5
总砷（以 As 计），mg/kg	≤0.5
总汞（以 Hg 计），mg/kg	≤0.3
干燥失重，g/100g	植物胶型：≤18.0

	动物胶型：≤20.0 淀粉型：≤18.0 混合型：≤35.0 夹心型、包衣和包衣抛光型：符合主体糖果的要求 其他胶型：≤20.0
还原糖（以葡萄糖计），g/100g	≥10.0 夹心型、包衣和包衣抛光型：符合主体糖果的要求。 无糖胶型凝胶糖果不设该指标。
单糖和双糖,g/100g	≤0.5，仅无糖胶型凝胶糖果设定该指标

【微生物指标】

项 目	指标	检测方法
菌落总数，CFU/g	≤30000	GB 4789.2
大肠菌群，MPN/g	≤0.92	GB 4789.3MPN 计数法
霉菌和酵母，CFU/g	≤50	GB 4789.15
金黄色葡萄球菌	≤0/25g	GB 4789.10
沙门氏菌	≤0/25g	GB 4789.4

【净含量及允许负偏差指标】

净含量及允许负偏差指标应符合 JJF 1070 规定

4.产品名称

商标名+通用名+凝胶糖果

5.使用范围

以纳入保健食品原料目录中的维生素矿物质为原料的产品可以使用凝胶糖果食品形态。其他列入保健食品原料目录的原料能否允许使用该食品形态，将根据原料配套文件发布时的规定进行确定。

附件 2-2

保健食品备案剂型粉剂的技术要求
（2021 年版）

1.粉剂概述

用于保健食品备案的粉剂是以纳入保健食品原料目录的原料与辅料经粉碎、

均匀混合制成的干燥粉末状成品。

2.粉剂产品说明书有关内容

以下内容仅针对粉剂食品形态规定了需要满足的有关要求，不涉及使用的原料辅料在制成产品时另需要符合的其他规定。

产品说明书中有关内容要求如下：

【适宜人群】该剂型应该适宜于所有人群

【不适宜人群】该剂型暂无特定的不适宜人群

【食用量及食用方法】每日最大食用量为 20g；增加提示“粉剂服用时一般溶于或分散于水或者其他液体中服用，也可直接用水送服”。对于食用方法为“直接口服”的，不适宜人群应包括“6 岁以下人群”。

【规格】对于大剂量包装的，限定每个包装的装量不超过 500g（原则上不超过 1 个月的服用量）。大剂量包装应附分剂量的用具。

【保质期】不超过 24 个月

3.粉剂产品技术要求有关内容

以下内容仅针对粉剂食品形态规定了需要满足的有关要求，不涉及使用的原料在制成产品时另需要符合的其他规定。

产品技术要求有关内容要求如下：

【感官要求】

项 目	指 标
色泽	填写要求：符合相应产品的外观特性,具有品种应有的色泽。

滋味、气味	填写要求：具有产品应有的气味和滋味,无异臭,无异味
状态	应干燥、疏松、混合均匀、色泽一致

【理化指标】

项 目	指 标
粒度	符合《中国药典》中粗粉、中粉、细粉、最细粉中任意一种
铅（以 Pb 计），mg/kg	≤2.0 婴幼儿固态保健食品的铅≤0.3
总砷（以 As 计），mg/kg	≤1.0 婴幼儿保健食品的总砷≤0.3
总汞（以 Hg 计），mg/kg	≤0.3 婴幼儿保健食品的总汞≤0.02
水分，%	≤9.0
灰分，%	必填项

【微生物指标】

项 目	指 标	检测方法
菌落总数，CFU/g	≤30000	GB 4789.2
大肠菌群，MPN/g	≤0.92	GB 4789.3MPN 计数法
霉菌和酵母，CFU/g	≤50	GB 4789.15
金黄色葡萄球菌	≤0/25g	GB 4789.10
沙门氏菌	≤0/25g	GB 4789.4

【净含量及允许负偏差指标】

净含量及允许负偏差指标应符合 JJF 1070 规定

4.产品名称

商标名+通用名+粉（原料名称已带“粉”的不再重复添加）