

Factor #5: Make sure your product's inactive ingredients are safe and suitable.

You should also make sure your inactive ingredients are safe and suitable for your product. Inactive ingredients are described as pharmaceutical necessities and excipients that are used to manufacture drug products. An inactive ingredient is any component of a drug product other than the active ingredient.

Examples are: fillers, tablet lubricants and binders, disintegrating agents, colorants, flavoring agents, preservatives, suspending agents, and sweeteners. Current regulations (21 CFR § 330.1(e)) require that OTC drugs marketed under the OTC monograph system contain only suitable inactive ingredients that are safe in the amounts administered, and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets the claimed standards of identity, strength, quality, and purity.

Manufacturers of OTC drug products must ensure that these provisions are met. Thus, inactive ingredients that have no prior history of safety and suitability in a product such as yours may require pre-market approval by FDA through the NDA provisions before the product may be legally marketed.

[Review this link](#) in order to determine whether an inactive ingredient has been used in an approved drug product. This may be helpful in evaluating whether the inactive ingredient is safe and suitable for your product.

Reference

- 21 CFR § 330.1(e) - The Manufacturer's Burden