Lonza
Specialty Ingredients

Lonza Hand Hygiene
Frequently Asked Questions

Lonza, LLC produces cGMP compliant Active Pharmaceutical Ingredients:

- Lonzagard® BKC cGMP (Benzalkonium Chloride)
- Lonzagard® Benzethonium Chloride USP (BZC)

Lonzagard® BKC & BZC* actives can be used in the formulation of antibacterial soaps, hand washes**, body washes**, gels*, scrubs and rubs* Lonza, LLC also produces Lonzagard® NAHS 10X containing Lonzagard® BKC cGMP, which can be used to make either foaming hand sanitizer liquid or sanitizing wipes.

*BZC active cannot be used to make liquid leave-on products.

**Frame formulations for rinse-off products are available upon request.

Frequently Asked Questions

Is a new drug application required?

- A hand sanitizer product is considered an OTC (Over the Counter) Drug Product. There is no New Drug Application required at FDA as long as you follow the OTC monograph. Following the monograph is the fastest way to market.

Topical Antimicrobial Drug Products for Over-the-Counter Human Use (Consumer Antiseptic **Rubs**): Final Monograph dated 4/12/2019.
Topical Antimicrobial Drug Products for Over-the-Counter Human Use (Consumer Antiseptic **Washes**); Final Monograph 9/6/2016
Healthcare Antiseptic Products Monograph, Publication of Final Monograph 20 December 2017 (82 FR 60474)

Can we produce hand hygiene products in our factory?

The production site needs to be a Registered Drug Establishment Site.
Requirements for FDA Application and production:

- Company info (DUNS# - must match what is in the D&B Website – this is part of FDA's Validation)
- Plant information (address, contact person with email and phone number)
- **The production plant must be a cGMP compliant facility.**

Our factory is now registered with the FDA. Can we now make FDA drug products?

- Once your factory is registered, the individual products (all sizes) will have to be assigned a National Drug Product Code before shipping. This is the customer's responsibility.

Requirements:

- Company code assigned via FDA
- Formulation
- Dosage
- Production location
- Annual FDA renewals for each registered product
- Specific sizes of products to be sold (each size is assigned a different NDC)
- Changes to product label at any time require submission to the FDA for approval.

What is the timing for these processes?

- The Regulatory document process is rather quick. Once the file is submitted electronically to the FDA, passing FDA validation can take 1-3 days. The FDA does not approve or disapprove the application.
- However, timing to set up a plant under cGMP may be quite extensive. Once the plant is registered with the FDA, they are open to FDA inspection. The FDA does inspect plants regularly, including foreign sites.

What is the upper limit of the active ingredient that the end use product can use?

FDA suggested use rates:

- Lonzagard® BKC cGMP (Benzalkonium Chloride) = 0.1% to 0.13%
- Lonzagard® Benzethonium Chloride USP (BZC) = 0.1% to 0.2%

What is the difference between Lonzagard® BKC and Lonzagard® NAHS 10X?

- Lonzagard® NAHS 10X is a 10X concentrate containing BKC as the active ingredient, along with added inert ingredients. Once the Lonzagard® NAHS 10X concentrate is diluted in a cGMP compliant facility, using the Lonza provided manufacturing instructions, this finished formulation is the only liquid needed to produce foaming hand sanitizer or antibacterial wipes.

Lonzagard® NAHS 10X – Do I just dilute the concentrate and I'm done?

- Yes, but keep in mind that Lonzagard® NAHS 10X can only be used to create foaming hand sanitizer or antibacterial wipes.
- **You must manufacture the finished product in a cGMP compliant facility, and you must have an FDA establishment number and National Drug Code (NDC).**

Is this EPA registered as well, or only FDA registered?

– Hand sanitizing products in the US are FDA regulated products. Products applied to the body are FDA regulated. Surface antibacterial products are EPA registered and regulated.

Can these offerings be used in Canada? Mexico?

– In Canada, BKC and BZC are approved medicinal ingredients for use in hand sanitizers under the Antiseptic Skin Cleanser Monograph. The End Use Products must be manufactured under cGMP. The Importer is required to hold a Drug Establishment License in Canada.
– Lonza recommends the customer work with an FDA consultant if looking to sell Lonzagard® hand hygiene offerings into Canada or Mexico to assure compliance to applicable laws in those regions.

Does Lonza have the supporting data for these products, or does the customer need to generate the data required by the FDA?

– There is no data that needs to be submitted to the FDA as these products fall under the FDA Monograph. Production plant requirements may require customer internal data.

Can I add any fragrance or dye to the Lonzagard® NAHS 10X formulation?

– The fragrance and/or dye only needs to have an INCI name, other than that there are no restrictions per the FDA. However, it is the customer's responsibility to ensure that the formulation is suitable for its needs.

What changes can I make to the Lonzagard® NAHS 10X formulation and still cite your data?

– No data needs to be cited per the FDA. The only changes that are allowed to be made to the Lonzagard® NAHS 10X formulation are dye and fragrance.

What kind of apparatus do I need to make it foaming, or does it foam itself when I dilute it?

– A foaming pump dispenser is required for foaming capabilities.

Do I have to make the Lonzagard® NAHS 10X formulation foaming?

– The Lonzagard® NAHS 10X is to be used to make leave-on foaming hand sanitizer or wipes only.

Keeping Our World Healthy®

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