

Lonzagard® Actives and Formulations

cGMP Compliant Hand-Hygiene Offerings



« The World Health Organization has confirmed hand hygiene compliance is critical to preventing the spread of disease¹ »

As The Food & Drug Administration (FDA) finalizes the hand hygiene monographs, scrutiny of antimicrobial rinse-off and leave-on hand-care products has increased. In this dynamic and evolving regulatory landscape, formulators must take steps to ensure they comply with strict requirements for cGMP produced active and end formula manufacturing. These requirements are outlined in the Food, Drug and Cosmetic Act (FD&C) regulation for Over-The-Counter (OTC) drugs.

- Antimicrobial hand-care products are regulated as OTC drugs under FD&C §201(g)
- Compendial grade, Active Pharmaceutical Ingredient (API) specifications must conform with United States Pharmacopeia- National Formulary (USP-NF) monograph
- APIs and finished products must be manufactured in compliance with quality manufacturing standards, called current Good Manufacturing Processes (cGMP)^{1,2,3}
- Non-conformance with requirements is subject to enforcement actions outlined in 21 CFR 210.1
- Since the process to finalize the hand-care drug monographs began in 2014, FDA has actively enforced requirements for OTC drugs:
 - 17 warning letters have been issued, including violations for non-conformance to cGMP
 - 308 Product Recalls
 - Fines and penalties have been issued ranging from \$500,000 to \$20 million.
- The FDA has shown increased scrutiny of antimicrobial rinse-off and leave-on hand care products in all areas as a whole, extending beyond CGMP related issues. In June 2018, the FDA issued a permanent injunction against a California company and its chief executive officer for misbranding its hand sanitizer product. The complaint was filed by the US Justice Department on behalf of the FDA.
- In April 2018 FDA issued a warning letter to a Florida company manufacturing topical skincare products, citing “significant violations of current good manufacturing practice (cGMP) regulations for finished pharmaceuticals.” Company has since filed chapter 11 citing recall costs for OTC drug products.

« Compliance is also critical for a healthy hand-hygiene business: High product Stewardship standards can help protect your business and company's reputation »

Technical and regulatory personnel at manufacturers and marketers can help protect their companies' brands and reputation by ensuring they understand the regulation, formulating with compliant ingredients and producing in compliant facilities.

- Ensure formulations meet latest FDA monograph requirements for the relevant product category⁴
- Use Active Ingredients (API) conforming to USP-NF drug monograph and manufactured under cGMP quality manufacturing standards
- Obtain and follow the latest guidance for good manufacturing practice of topical antimicrobials³
- NF/USP grade actives produced under cGMP conditions
- cGMP compliant Non-Alcohol Hand Sanitizer (NAHS) Concentrate
- Rinse-off frame formulations to help speed product development
- Regulatory expertise and support

¹ The Evidence For Clean Hands” and “Testing the WHO Guidelines on hand hygiene in health care in eight pilot sites worldwide” – World Health Organization Website.

Lonza can help with a line-up of cGMP compliant hand hygiene offerings as well as expert technical and regulatory guidance

Compliant Active Ingredients

Product	Chemistry	Applications
Lonzagard cGMP BKC	Benzalkonium Chloride (50%)	Consumer Antiseptic Washes: Antibacterial Soaps, Hand Washes, & Body Washes Healthcare Antiseptics: Healthcare Personnel Hand Washes & Rubs Surgical Hand Rubs & Scrubs Patient Pre-operative Skin Preparations Consumer Antiseptic Rubs: Antibacterial Hand Sanitizers and Hand Sanitizing Wipes
Lonzagard Benzethonium Chloride	Benzethonium Chloride 50%	Consumer Antiseptic Washes: Antibacterial Soaps, Hand Washes, & Body Washes Healthcare Antiseptics: Healthcare Personnel Hand Washes & Rubs Surgical Hand Rubs & Scrubs Patient Pre-operative Skin

Compliant Non-Alcohol Hand Sanitizer 10X Concentrate

- Lonzagard® NAHS 10X Concentrate
 - formulated with Lonzagard BKC cGMP active ingredient
 - Bacterial efficacy at 30 seconds in both Liquid and Wipe Formats
 - Moisturizers added for skin comfort and protection
 - NSF Category E2



Hand Sanitizer Formulations

Ingredient Trade or Chemical Name	%	Moisturizing Hand Sanitizer Foam	Moisturizing Hand Sanitizer Wipes
	% or Load Ratio		
Lonzagard® NAHS 10X Concentrate	10.0		10.0
Water	90.0		90.0
Non-Woven Substrate	–		Diluted Hand Sanitizer liquid to non-woven substrate: 4:1
% Reduction S. aureus 30 Seconds	≥ 99.999 (time kill)		≥ 99.999 (time kill)
% Reduction E. coli 30 Seconds	≥ 99.999 (time kill)		≥ 99.999 (time kill)
% Reduction P. aeruginosa 30 Seconds	≥ 99.999 (time kill)		≥ 99.999 (time kill)
% Reduction S. marcescens 30 Seconds	≥ 99.999 (time kill)		≥ 99.999 (time kill)
% Reduction S. enterica 30 Seconds	≥ 99.999 (time kill)		≥ 99.999 (time kill)

Use Areas

- Healthcare
- Institutional & Industrial (I&I)
- Janitorial
- Food processing / service / retail
- Consumer

Rinse-Off Frame Formulations

Formulation	5981-45A	5981-45B	5981-45C	5981-46
Performance				
Foaming	Fast breaking foam	High foaming	High foaming	High foaming
Rinseability/skin conditioning	Rinse easily	Skin Conditioning	Highly Skin Conditioning	Skin Conditioning
% reduction Staph aureus				
15 seconds	>99.999	>99.999	>99.999	>99.999
30 seconds	>99.999	>99.999	>99.999	>99.999
% reduction Staph aureus				
15 seconds	>99.999	>99.999	>99.999	>99.999
30 seconds	>99.999	>99.999	>99.999	>99.999



Keeping Our World Healthy®

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1 Section 501(a)(2)(B) of the FD&C Act requires all drugs (including APIs) be produced in compliance with cGMP.

2 FDA recommends following the guidelines of international cGMP convention ICH Q7, Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (or acceptable alternate cGMP quality system)

3 FDA provided guidelines for producing finished drug product under cGMP in 21 CFR §210-211

4 Consumer Rinse-off monograph finalized Sept. 2016, Healthcare [rinse-off and leave-on] Finalized Dec. 2017, Consumer leave-on schedule to be finalized Jan. 2019.

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