

Quick NOTES

Guidance Document: Disinfectant Drugs

OCTOBER 2007
Disinfectant Drugs



WHAT'S NEW:

- Guidance Document – Disinfectant Drugs (effective Oct 29, 2007)

Guidance Document, "Disinfectant Drugs":
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/disinf_desinf_e.html#top

WHO DOES THIS APPLY TO:

- Fabricators, packagers, labelers, importers, testers, wholesalers, and distributors are required to meet the following divisions of the *Food and Drug Regulations*. Certain types of products are exempt from Division 1A and 2 and may follow Guide-0049 in lieu of Good Manufacturing Practices (GMPs).

Policies & Standards – Standard for the Fabrication, Control and Distribution of Antimicrobial Agents for Use on Environmental Services and Certain Medical Devices Version 2 (GUIDE-0049) (June 2006):
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/gui_49_tc-tm_e.html

	Division 1	Division 1A	Division 2	Guide 0049
	DIN Application	Drug Establishment Licensing	Good Manufacturing Practices	Standard
Environmental Surfaces	Y	N	N	Y
Invasive Devices	Y	Y	Y	N
Non-invasive Devices	Y	N	N	Y
Devices for Circulation or Reintroduction of Body Fluids	Y	Y	Y	N
Intact Skin Contact	Y	N	N	Y
Contact Lens Solutions	Y	Y	Y	N

*Standard for the Fabrication, Control and Distribution of Antimicrobial Agents for Use on Environmental Surfaces and Certain Medical Devices

**Products which have been chosen to be governed by Guide-0049 are not permitted Certificates of Pharmaceutical Product or fall under the Mutual Recognition Agreement (MRA).

9-6975 Meadowvale Town
Centre Circle, Suite 410,
Mississauga, Ontario,
L5N 2V7, Canada
TOLL FREE: 1-877-877-5152
PHONE: 905-363-1182
FAX: 905-542-7981
info@qualityandcompliance.com
www.qualityandcompliance.com
www.validapharm.com
www.nhpcpliance.com





Quick NOTES

OCTOBER 2007
Disinfectant Drugs



VALIDAPHARM™



OVERVIEW:

- Disinfectants are antimicrobial agents capable of destroying pathogenic and potentially pathogenic micro-organisms on environmental surfaces and inanimate objects. They are intended to be used for the prevention of infectious disease transmission to human beings and animals from hard non-porous surfaces, regardless of use sites, places or facilities or inanimate objects. These products are regulated by the *Food and Drugs Act and Regulations*.
- Disinfectants include: bactericides, fungicides, virucides, mycobactericides, tuberculocides, sporocides, sterilants, or combinations of these.
- The criticality of medical devices related to risk of contamination is divided into critical, semi-critical, and non-critical. The disinfectant classes respectively are critical sporicides, high-level disinfectants, and intermediate or low-level disinfectants.
- The evaluation criteria for various disinfectants are spelled out in the guidance document. Criteria are mainly based on the Canadian General Standards Board (CGSB) guideline CAN/CGSB-2.161-97, entitled "Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices."

KEY POINTS:

Guidance Document, "Disinfectant Drugs":

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/disinf_desinf_e.html#top

- Separate safety and efficacy testing guidelines for hard surface disinfectants, disinfectant-sanitizers and food contact sanitizers.
- Warning and first aid information.
- Shift based on current science, with the particular focus on additional labeling requirements, from HIV-1 to bloodborne pathogens including HIV-1 and hepatitis B and C viruses.
- Inclusion of category IV monographs in the guidance document.

9-6975 Meadowvale Town
Centre Circle, Suite 410,
Mississauga, Ontario,
L5N 2V7, Canada

TOLL FREE: 1-877-877-5152

PHONE: 905-363-1182

FAX: 905-542-7981

info@qualityandcompliance.com

www.qualityandcompliance.com

www.validapharm.com

www.nhpcompliance.com





Quick NOTES

OCTOBER 2007
Disinfectant Drugs



FAQ:

1. Am I required to follow Guide-0049?

- No, you may follow Division 2 GMPs. Guide-0049 outlines the minimum requirements in order to meet Division 2 GMPs.

Contact us with any questions regarding GMPs.

Call toll-free: 1-877-877-5152 ext.210

Email: gmills@qualityandcompliance.com

9-6975 Meadowvale Town
Centre Circle, Suite 410,
Mississauga, Ontario,
L5N 2V7, Canada
TOLL FREE: 1-877-877-5152
PHONE: 905-363-1182

FAX: 905-542-7981
info@qualityandcompliance.com
www.qualityandcompliance.com
www.validapharm.com
www.nhpcompliance.com

Guidance Document: Disinfectant Drugs
Author: Richard Parcels

Date of last revision: 16 December 2009
<http://www.qualityandcompliance.com>

