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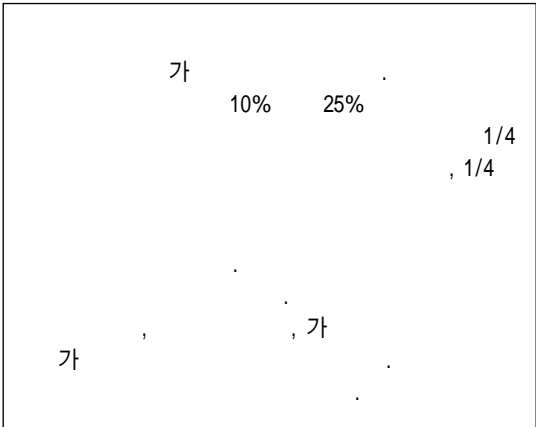


Biological challenge Bio-burden

가 (validation) 가

GMP SOP

[ 1] cGMP



(Standard Operating Procedure)

. ([ 1] )

BCR(Biological Clean Room)

( )

HSE(Healthy Survey for England)

, 1987 EPA

가 1995

WHO IARC( )

. IARC

(Nasal sinus cancer) (Naso-pharyngeal cancer)

( , )

가

BCR

. ([ 2] )

(Chlorine dioxide gas, ClO<sub>2</sub> gas) , Dryfog spray , (Hydrogen peroxide vapour, HPV)

가 BCR

[ 2] BCR

			Dryfog spray	
		(ClO <sub>2</sub> )		
	가	가		
	OEL	0.75ppm	0.1ppm	1ppm
	IDLH	30ppm	10ppm	N/A
	가	가	가	가
(Validation)	가	가		가
				( )

\* OEL(Occupational exposure limit) :

\*\* IDLH(Immediate Danger to Life and Health) :

가

Dryfog spray ( 10% ( ), (가

BCR , 가 bio-burden . ([ 3]

(30% w/w) ) (disinfection) (sanitization)

가 (validation)

[ 3]

Bio-Decontamination process			
(Penetrative sterilization) 6 log ( )	6 log	(6 log reduction), Biological challenge (validation) 가 , (Overkill) ( : (Autoclave))	
(Surface decontamination) 6 log ( )	6 log	(6 log reduction), Biological challenge (validation) 가 , (Overkill) 가 ( : , 가 )	
(Disinfection) 4~6 log ( )	4~6 log	(3~6 log reduction), Biological challenge (validation) 가 ( : (Dryfog system))	
(Sanitization) 4 log ( )		log reduction , ( : )	

(Qualification)

bio-burden

가

가

0 CFU

(Colony Forming Unit)

bio-burden

가

BCR

가

가

가

(de-

contamination assurance level)

bio-burden

log reduction

(decontamination

(

assurance level)

) 6 log reduction,

log

4 log reduction

가

Log re-

BCR

duction

, log

가

reduction

가

가

log reduction

가

bio-

BCR

Biological Indicator

BI

burden

Geobacillus stearother-

mophilus

(spore)

BI (validation)

Geobacillus stearothermophilus  
가

(HPV)

가  
가 (HPV)  
Dryfog system  
가

(2-6 $\mu$ m) BCR

( )

(6 log reduction)

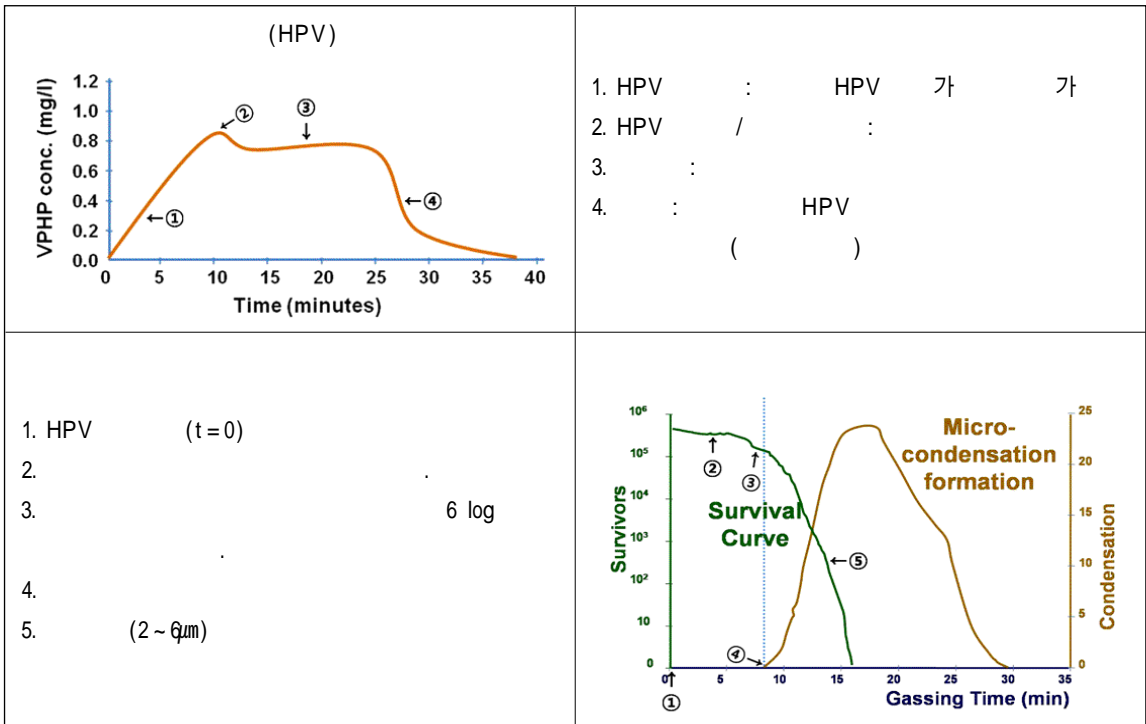
가 가 ([ 4 ] )

(HPV)

가

[ 4 ]

(HPV)



OSHA(Occupational Safety and Health Administration) OEL (Occupational exposure limit)

Isolator barrier (HPV)

Restricted Access Barrier System (RABS) BCR

BCR

가

(HPV)

SIP(Steam-In-Place)

CIP(Clean-In-Place) 가 BCR ( ) GIP(Gas-In-Place)

(Autoclaving) 가 가

(HPV)

BCR

가

bio-logical challenge 가

(microbiological control)

BCR 가

가

가

가

BCR HVAC (Heating, Ventilating, and Air Conditioning)

가 , HPV BCR

- BCR

BCR 가

SOP pass box pass room HPV SOP

가

(CIQ) 가 , Dry fogging system

(HPV) 가

, HPV

(validation) 가 1990


BCR GMP

HPV BCR

(

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가

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