## ISPE.

## Pharmaceutical Steam Sampling

**Overview of ISPE Good Practice Guide** 

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Compendial Requi	rements
U.S. Pharmacopeial	European Pharmacopoeia *
THE JAPANESE PHARMACOPOEIA	
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## USP Mongraph

"Pure Steam is water that has been heated above 100°C and vaporized in a manner that prevents source water entrainment. It is prepared from water complying with the EPA National Primary Drinking Water Regulations, or with drinking water regulations of the European Union or of Japan, or with WHO drinking water guidelines. It contains no added substance. The level of steam saturation or dryness and the amount of noncondensable gases are to be determined by the Pure Steam application."

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WHY?				
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EUROPEAN STANDARD       EN 285         NORME EUROPÉENNE       December 2015         EUROPÄISCHE NORM       December 2015         ICS 11.080.10       Supersedes EN 285:2006+A2         English Version       Sterilization - Steam sterilizers - Large sterilizers         Stérilisation - Stérilisateurs à la vapeur d'eau - Grands       Sterilisation - Dampf-Sterilisatoren - Großsterilisatoren	Special Requirements			
EUROPÄISCHE NORM       December 2015         ICS 11.080.10       Supersedes EN 285:2006+A2         English Version         Sterilization - Steam sterilizers - Large sterilizers         Stérilisateurs à la vapeur d'eau - Grands         Sterilisateurs à la vapeur d'eau - Grands         Sterilisateurs à la vapeur d'eau - Grands         Sterilisatoren - Groß-Sterilisatoren	EUROPEAN STANDARD NORME EUROPÉENNE	EN 285		
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	This European Standard was approved by CEN on 15 Noven	iber 2015.		
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EN 285 Dryness Equation 5 The calculation of the dryness concentration is then made using the following equation: $D = \frac{(T_2 - T_1)(C_{pw}(m_x - m_e) + A)}{L(m_r - m_z)} - \frac{(T_3 - T_2)C_{pw}}{L}$	
where:	
$L$ = latent heat of dry saturated steam at temperature $T_3$ in kilojoules per kilogram	
$m_{\rm e}$ = mass of the Dewar flask and stopper, pipes and tube, in kilograms	
$m_{\rm s}$ = mass of the Dewar flask, water charge stopper, pipes and tube, in kilograms	
$m_{\rm f}$ = mass of the flask, water charge, condensate, stopper, pipes and tube in kilograms	
$T_1$ = initial temperature of the water in the Dewar flask, in degrees Celsius	
T <sub>2</sub> = final temperature of the water and condensate in the Dewar flask, in degrees Celsius	
T <sub>3</sub> = temperature of dry saturated steam delivered to the sterilizer, in degrees Celsius	
C <sub>pw</sub> = specific heat capacity of water (4.18 kJ/kg*K)	
D = dryness value of the steam	
A = effective heat capacity of the apparatus (0.24 kJ/K)	
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Sampling Plans (cont'd) Sampling Plan Example			
	Frequency	Test	Location
	Weekly	Endotoxin, Nitrates, TOC, Conductivity	Generator
Pure Steam	Monthly	Endotoxin, Nitrates, TOC, Conductivity	One-Way Distribution most distant points
Ture steam	Biannually	Endotoxin, Nitrates, TOC, Conductivity	All Use Points
	Annually	Steam Quality (non- condensable gas, superheat, dryness)	Autoclave Use Points
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Dianhragm	iempe Liquid media		dia	Sterilisation <sup>1</sup>	Cada	
Diaphragm	materiar Design	size	Min.	Max.		Code
EPDM	Ethylene-propylene-diene rubber	8 - 100	-10	100	max. 150 °C <sup>2</sup> max. 60 min. per cycle	13/3A
EPDM	Ethylene-propylene-diene rubber	8 - 100	-10	100	max. 150 °C <sup>2</sup> max. 180 min. per cycle	17
PTFE/EPDM	Fully laminated PTFE diaphragm with EPDM back	8, 10, 100	-10	100	max. 150 °C <sup>2</sup> , no time limit per cycle	52/5A
PTFE/EPDM	Corwex two-piece PTFE diaphragm with loose EPDM back	25, 40, 50, 80	-10	100	max. 150 °C ², no time limit per cycle	5E
The sterilisation to If the sterilisation life of the diaphray This also applies PTFE diaphragme cycles must be ac GEMÜ 555 and 5 following valve an under for exterilion	Imperature is valid for steam (saturated steam) or superh temperatures listed above are applied to the EPDM diaph gms will be reduced. In these cases, maintenance cycles to DTFE diaphragms exposed to high temperature fluctuue s can also be used as moisture barriers; however, this will fapted accordingly. OS globe valves are particularly suitable for use in the are rangement for interfaces between steam pipes and proce of laterom pines and a disobversu have are bitterface to	neated water. hragms for longer p must be adapted a ations. I reduce their servi va of steam general ss pipes has prove the process pipes	eriods of tim accordingly. ce life. The m tion and dist m itself over	ne, the servic naintenance ribution. The time: A globe	e Steam input	Process pipe ile process

















