

Attachment 2
(Attachment to Meeting Summary 020603)

As a result of the open discussion 6 different flowcharts, modeled after the moist heat CPMP chart, were developed on the topic of processing choices for Sterile Products. Each (or all) of them could serve as the starting point for future meaningful discussions on the subject.

Processing Choices for Sterile Products

Can the product be sterilized achieving a minimum PNSU of 10^{-6} ?

No

Can the product be sterilized achieving a PNSU in the range of 10^{-3} - 10^{-6} ?

No

Use aseptic processing with all of the necessary controls.

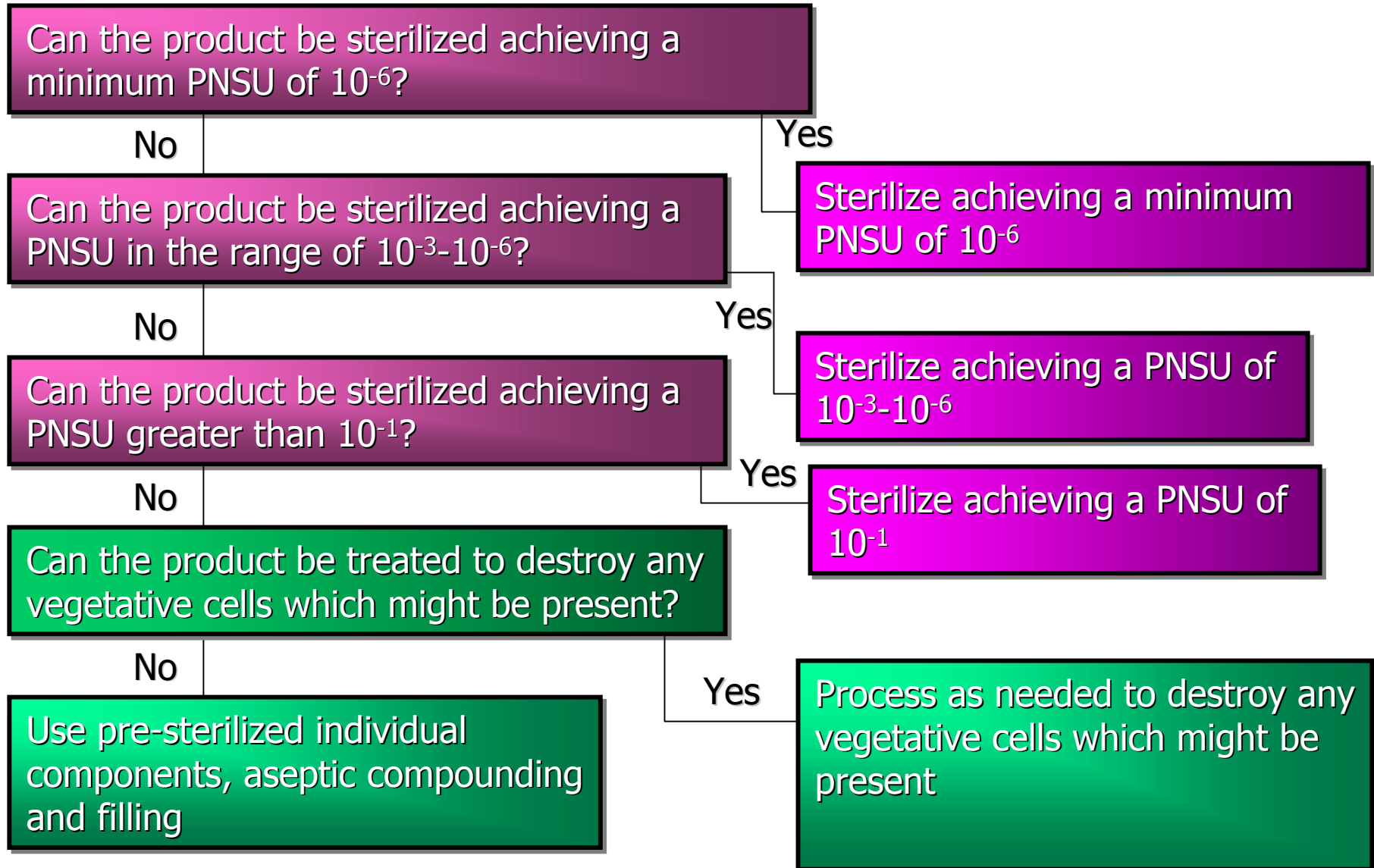
Yes

Sterilize achieving a minimum PNSU of 10^{-6}

Yes

Sterilize achieving a PNSU of 10^{-3} - 10^{-6}

Processing Choices for Sterile Products



Processing Choices for Sterile Products

Can the product be sterilized achieving a minimum PNSU of 10^{-6} ?

No

Use aseptic processing with all of the necessary controls.

Yes

Sterilize achieving a minimum PNSU of 10^{-6}

No

Can the product be sterilized achieving a PNSU greater than 10^{-1} assuming a D-value of 1 minute at 80°C ?

Yes

Sterilize achieving a PNSU of 10^{-1}

No

Use pre-sterilized individual components, aseptic compounding and filling with no post-fill treatment

Processing Choices for Sterile Products

Can the product be sterilized achieving a minimum PNSU of 10^{-6} ?

No

Use aseptic processing with all of the necessary controls.

Yes

Sterilize achieving a minimum PNSU of 10^{-6}

No

Can the product be sterilized achieving a PNSU greater than 10^{-1} assuming a D-value of 1 minute at 80°C ?

Yes

Sterilize achieving a PNSU of 10^{-1}

No

Can the product be treated to destroy any vegetative cells which might be present?

Yes

Process as needed to destroy any vegetative cells which might be present

No

Use pre-sterilized individual components, aseptic compounding and filling with no post-fill treatment

Processing Choices for Sterile Products

Can the product be sterilized achieving a minimum PNSU of 10^{-6} ?

No

Use aseptic processing with all of the necessary controls.

Yes

Sterilize achieving a minimum PNSU of 10^{-6}

No

Can the product be treated to destroy any vegetative cells which might be present?

Yes

Process as needed to destroy any vegetative cells which might be present

No

Use pre-sterilized individual components, aseptic compounding and filling with no post-fill treatment