# 1.1 Purpose:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

⚫ This SOP outlines the procedures for identifying, investigating, and addressing out -

of-stock (OOS) situations to ensure timely response, minimize customer impact, and

comply with USFDA regulations.

## Document 8

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

⚫ This SOP outlines the procedures for identifying, investigating, and addressing out -

of-stock (OOS) situations to ensure timely response, minimize customer impact, and

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## Document 9

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

⚫ This SOP outlines the procedures for identifying, investigating, and addressing out -

of-stock (OOS) situations to ensure timely response, minimize customer impact, and

comply with USFDA regulations.

# 1.2 Scope:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

⚫ This SOP applies to all departments involved in product manufacturing, distribution,

and customer service.

## Document 8

Similarity Score: 88%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: and customer verification

⚫ This SOP applies to all departments involved in product manufacturing, distribution,

and customer service and customer verification .

## Document 9

Similarity Score: 88%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: and customer verification

⚫ This SOP applies to all departments involved in product manufacturing, distribution,

and customer service and customer verification .

# 1.3 Definitions:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Out-of-Stock (OOS): A situation where a product is unavailable to meet customer

demand.

• Backorder: A customer order that cannot be fulfilled immediately due to insufficient

inventory.

• Stockout: A complete depletion of product inventory.

## Document 8

Similarity Score: 96%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: I have changed.

• Out-of-Stock (OOS): A situation where a product is unavailable to meet customer

demand.

• Backorder: A customer order that cannot be fulfilled immediately due to insufficient

inventory.

• Stockout: A complete depletion of product inventory. I have changed.

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Tag: A

Summary: Different

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Added Text: I have changed.

• Out-of-Stock (OOS): A situation where a product is unavailable to meet customer

demand.

• Backorder: A customer order that cannot be fulfilled immediately due to insufficient

inventory.

• Stockout: A complete depletion of product inventory. I have changed.

# 1.4 References:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• 21 CFR Part 110: Current Good Manufacturing Practice (CGMP) for Drugs .

• 21 CFR Part 211: Current Good Manufacturing Practice for Finished

Pharmaceuticals .

• [Relevant FDA guidance documents] .

2. Responsibilities

• Production: Responsible for monitoring inventory levels, initiating OOS

investigations, and implementing corrective actions.

• Quality Control: Responsible for investigating OOS root causes and approving

corrective actions.

• Supply Chain: Responsible for managing backorders, expediting orders, and

preventing future OOS.

• Customer Service: Responsible for communicating OOS to customers, managing

customer inquiries, and processing backorders.

3. OOS Identification and Notification

## Document 8

Similarity Score: 93%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: • Good Manufacturing Practice for Finished Pharmaceuticals .  
• [Relevant FDA guidance documents] .  
 data

• 21 CFR Part 110: Current Good Manufacturing Practice (CGMP) for Drugs .

• 21 CFR Part 211: Current Good Manufacturing Practice for Finished

Pharmaceuticals .

• [Relevant FDA guidance documents] .

• Good Manufacturing Practice for Finished Pharmaceuticals .

• [Relevant FDA guidance documents] .

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Summary: Different

Comparison Status: Compared

Added Text: • Good Manufacturing Practice for Finished Pharmaceuticals .  
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• 21 CFR Part 110: Current Good Manufacturing Practice (CGMP) for Drugs .

• 21 CFR Part 211: Current Good Manufacturing Practice for Finished

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preventing future OOS data.

• Customer Service: Responsible for communicating OOS to customers, managing

customer inquiries, and processing backorders.

3. OOS Identification and Notification

# 3.1 OOS Identification:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Inventory management systems will generate alerts for low stock levels or stockouts.

• Production planning will identify potential OOS based on production schedules and

demand forecasts.

• Customer service will report OOS based on customer inquiries.

## Document 8

Similarity Score: 28%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: Th ext has odified you c ch Exam e, unava ability estimated liv y date b n ifi f  
product u availability and e i ated deliv

Removed Text: Inv n ory ag ment systems will generate alerts for low sto levels or stockouts Production anning will identify potential OOS based on on schedu es   
 mand forecasts.  
• Custom ervice r p r OOS bas cu o inquiries

Modified Text: • The text has modified you can check.  
• Example, product unavailability and estimated delivery dates will be notified of  
product unavailability and estimated deliver .

• The text has modified you can check.

• Example, product unavailability and estimated delivery dates will be notified of

product unavailability and estimated deliver .

## Document 9

Similarity Score: 28%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: Th ext has odified you c ch Exam e, unava ability estimated liv y date b n ifi f  
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Removed Text: Inv n ory ag ment systems will generate alerts for low sto levels or stockouts Production anning will identify potential OOS based on on schedu es   
 mand forecasts.  
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Modified Text: • The text has modified you can check.  
• Example, product unavailability and estimated delivery dates will be notified of  
product unavailability and estimated deliver .

• The text has modified you can check.

• Example, product unavailability and estimated delivery dates will be notified of

product unavailability and estimated deliver .

# 3.2 Internal Notification:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• The responsible department will immediately notify their supervisor and relevant

departments of an OOS situation.

## Document 8

Similarity Score: 7%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: is is modified text will be notified of roduct unavailability and estimated delivery  
dates will be notified of roduct unavailability and estimated delivery dates be  
notified of roduct unavailability and estimated delivery dates

Removed Text: e res onsible de artment immediately notify their su ervisor and relevant  
departments of an OOS situation

Modified Text: • This is modified text will be notified of product unavailability and estimated delivery  
dates will be notified of product unavailability and estimated delivery dates will be  
notified of product unavailability and estimated delivery dates.

• This is modified text will be notified of product unavailability and estimated delivery

dates will be notified of product unavailability and estimated delivery dates will be

notified of product unavailability and estimated delivery dates.

## Document 9

Similarity Score: 7%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: is is modified text will be notified of roduct unavailability and estimated delivery  
dates will be notified of roduct unavailability and estimated delivery dates be  
notified of roduct unavailability and estimated delivery dates

Removed Text: e res onsible de artment immediately notify their su ervisor and relevant  
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Modified Text: • This is modified text will be notified of product unavailability and estimated delivery  
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notified of product unavailability and estimated delivery dates.

• This is modified text will be notified of product unavailability and estimated delivery

dates will be notified of product unavailability and estimated delivery dates will be

notified of product unavailability and estimated delivery dates.

# 3.3 External Notification:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Customers will be notified of product unavailability and estimated delivery dates.

• Regulatory authorities will be notified in accordance with applicable regulations.

4. OOS Investigation

## Document 8

Similarity Score: 75%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: Add d pd ed text t d y th mpa s

Removed Text: R g l ry author ti s will be o i d in ac dance w th applicable regulati s

• Customers will be notified of product unavailability and estimated delivery dates.

• Added updated text to identify the comparison.

4. OOS Investigation

## Document 9

Similarity Score: 75%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: Add d pd ed text t d y th mpa s

Removed Text: R g l ry author ti s will be o i d in ac dance w th applicable regulati s

• Customers will be notified of product unavailability and estimated delivery dates.

• Added updated text to identify the comparison.

4. OOS Investigation

# 4.1 Investigation Initiation:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• A designated team will initiate an OOS investigation within [timeframe] of

identification.

• The investigation will determine the root cause of the OOS, including factors such as

production delays, supply chain disruptions, or increased demand.

## Document 8

Similarity Score: 98%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: chain

• A designated team will initiate an OOS investigation within [timeframe] of

identification.

• The investigation will determine the root cause of the OOS, including factors such as

production delays, supply chain disruptions, or increased demand chain .

## Document 9

Similarity Score: 98%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: chain

• A designated team will initiate an OOS investigation within [timeframe] of

identification.

• The investigation will determine the root cause of the OOS, including factors such as

production delays, supply chain disruptions, or increased demand chain .

# 4.2 Data Collection:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Relevant data will be collected, including production records, inventory levels,

customer orders, and quality control records.

## Document 8

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Relevant data will be collected, including production records, inventory levels,

customer orders, and quality control records.

## Document 9

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Relevant data will be collected, including production records, inventory levels,

customer orders, and quality control records.

# 4.3 Root Cause Analysis:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• A thorough analysis will be conducted to identify the underlying causes of the OOS.

• Potential corrective actions will be developed.

5. OOS Communication

## Document 8

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• A thorough analysis will be conducted to identify the underlying causes of the OOS.

• Potential corrective actions will be developed.

5. OOS Communication

## Document 9

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• A thorough analysis will be conducted to identify the underlying causes of the OOS.

• Potential corrective actions will be developed.

5. OOS Communication

# 5.1 Internal Communication:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Information regarding the OOS and investigation findings will be shared with relevant

departments.

• Communication plans will be developed to address internal concerns and coordinate

response efforts.

## Document 8

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Information regarding the OOS and investigation findings will be shared with relevant

departments.

• Communication plans will be developed to address internal concerns and coordinate

response efforts.

## Document 9

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Information regarding the OOS and investigation findings will be shared with relevant

departments.

• Communication plans will be developed to address internal concerns and coordinate

response efforts.

# 5.2 External Communication:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Standard templates will be used for customer notifications, including information

about the OOS, estimated delivery dates, and alternative products (if available).

• Customer inquiries will be managed professionally and promptly.

• Media inquiries (if applicable) will be handled according to the company's media

relations policy.

6. Corrective and Preventive Actions (CAPA)

## Document 8

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Standard templates will be used for customer notifications, including information

about the OOS, estimated delivery dates, and alternative products (if available).

• Customer inquiries will be managed professionally and promptly.

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6. Corrective and Preventive Actions (CAPA)

## Document 9

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Standard templates will be used for customer notifications, including information

about the OOS, estimated delivery dates, and alternative products (if available).

• Customer inquiries will be managed professionally and promptly.

• Media inquiries (if applicable) will be handled according to the company's media

relations policy.

6. Corrective and Preventive Actions (CAPA)

# 6.1 CAPA Implementation:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Corrective actions to address the immediate OOS situation will be implemented

promptly.

• Preventive actions to prevent recurrence of the OOS will be developed and

implemented.

## Document 8

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Corrective actions to address the immediate OOS situation will be implemented

promptly.

• Preventive actions to prevent recurrence of the OOS will be developed and

implemented.

## Document 9

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Corrective actions to address the immediate OOS situation will be implemented

promptly.

• Preventive actions to prevent recurrence of the OOS will be developed and

implemented.

# 6.2 CAPA Effectiveness:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• The effectiveness of corrective and preventive actions will be monitored and

evaluated.

7. Backorder Management

## Document 8

Similarity Score: 92%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: • Some other text.

• The effectiveness of corrective and preventive actions will be monitored and

evaluated.

• Some other text.

7. Backorder Management

## Document 9

Similarity Score: 92%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: • Some other text.

• The effectiveness of corrective and preventive actions will be monitored and

evaluated.

• Some other text.

7. Backorder Management

# 7.1 Backorder Process:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Customer orders for OOS products will be placed on backorder.

• Backorders will be prioritized based on order date, customer importance, and product

availability.

• Customers will be regularly updated on the status of their backorders.

8. Product Recall (if applicable)

## Document 8

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Customer orders for OOS products will be placed on backorder.

• Backorders will be prioritized based on order date, customer importance, and product

availability.

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8. Product Recall (if applicable)

## Document 9

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• Customer orders for OOS products will be placed on backorder.

• Backorders will be prioritized based on order date, customer importance, and product

availability.

• Customers will be regularly updated on the status of their backorders.

8. Product Recall (if applicable)

# 8.1 Recall Initiation:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• If a product recall is necessary due to safety concerns, the recall process will be

initiated in accordance with company and regulatory requirements.

9. Recordkeeping

## Document 8

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• If a product recall is necessary due to safety concerns, the recall process will be

initiated in accordance with company and regulatory requirements.

9. Recordkeeping

## Document 9

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• If a product recall is necessary due to safety concerns, the recall process will be

initiated in accordance with company and regulatory requirements.

9. Recordkeeping

# 9.1 Documentation:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• All OOS investigations, corrective actions, and customer communications will be

documented.

• Records will be retained in accordance with company and regulatory requirements.

10. Training

## Document 8

Similarity Score: 96%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: requirements

• All OOS investigations, corrective actions, and customer communications will be

documented.

• Records will be retained in accordance with company and regulatory.

10. Training

## Document 9

Similarity Score: 96%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: requirements

• All OOS investigations, corrective actions, and customer communications will be

documented.

• Records will be retained in accordance with company and regulatory.

10. Training

# 10.1 Training Requirements:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• All personnel involved in OOS handling will receive training on this SOP.

• Training will be conducted upon hire and annually thereafter.

11. Review and Update

## Document 8

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• All personnel involved in OOS handling will receive training on this SOP.

• Training will be conducted upon hire and annually thereafter.

11. Review and Update

## Document 9

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• All personnel involved in OOS handling will receive training on this SOP.

• Training will be conducted upon hire and annually thereafter.

11. Review and Update

# 11.1 SOP Review:

## Document 7

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

• This SOP will be reviewed annually or as needed to ensure its effectiveness and

compliance with regulations.

## Document 8

Similarity Score: 95%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: policies

• This SOP will be reviewed annually or as needed to ensure its effectiveness and

compliance with regulations policies .

## Document 9

Similarity Score: 95%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: policies

• This SOP will be reviewed annually or as needed to ensure its effectiveness and

compliance with regulations policies .