



Pharmaceutical Labeling Compliance Checklist

Label Content Accuracy

Verifies all text and data on the label are correct and match approved documentation.

Product Name

Dosage Strength

Quantity per Package

Route of Administration

- ☐ Oral
- ☐ Intravenous
- ☐ Topical
- ☐ Other

Directions for Use

Write something...

Storage Conditions

- ☐ Room Temperature
- ☐ Refrigerated
- ☐ Controlled Room Temperature

Regulatory Compliance

Ensures the label meets all applicable regulatory requirements (e.g., FDA, EMA).

Applicable Regulations

- ☐ FDA 21 CFR Part 211
- ☐ EU GMP Guidelines
- ☐ Other (Specify in Long Text)

Specify Other Regulations (if applicable)

Write something...

Date of Last Regulatory Update Review

Enter date...

Compliance Status

- ☐ Compliant
- ☐ Non-Compliant
- ☐ Requires Further Assessment

Summary of Regulatory Findings (if applicable)

Write something...

Supporting Regulatory Documentation

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Mandatory Statements

Confirms the inclusion of all legally required statements and warnings.

Product Name Inclusion

- ☐ Included Correctly
- ☐ Missing
- ☐ Incorrect

Dosage Strength Confirmation

- ☐ Correct Dosage Strength
- ☐ Incorrect Dosage Strength
- ☐ Missing

Lot Number Inclusion

- ☐ Included Correctly
- ☐ Missing
- ☐ Incorrect

Expiration Date Inclusion

- ☐ Included Correctly
- ☐ Missing
- ☐ Incorrect

Storage Conditions Displayed

- ☐ Displayed Correctly
- ☐ Missing
- ☐ Incorrect

Reviewer Signature

Units of Measure

Checks for correct units and abbreviations used on the label.

Primary Unit of Measure

- ☐ mg
- ☐ g
- ☐ mL
- ☐ L
- ☐ IU
- ☐ Count

Secondary Unit of Measure (if applicable)

- ☐ µg
- ☐ ng
- ☐ kg
- ☐ kL
- ☐ None

Conversion Factor (if applicable)

Enter a number...

Abbreviation Used

Write something...

Is the unit presented as a decimal?

- ☐ Yes
- ☐ No

Barcodes & Serialisation

Validates barcode accuracy, serialisation data, and associated systems integration.

Barcode Sequence Number

Enter a number...

Barcode Symbology (e.g., Code 128, DataMatrix)

Write something...

Serialisation Data Format

Write something...

Serialisation Check Digit


Enter a number...

Barcode Verification Result (Pass/Fail)

☐ Pass

☐ Fail

Barcode Image Verification (Optional)

 Upload File

Layout & Font

Confirms the visual layout, font sizes, and overall design adhere to specifications and readability standards.

Font Size (Points)

Enter a number...

Font Type

☐ Arial

☐ Times New Roman

☐ Helvetica

☐ Calibri

Font Weight

- ☐ Normal
- ☐ Bold
- ☐ Italic

Alignment

- ☐ Left
- ☐ Center
- ☐ Right

Line Spacing (Points)

Enter a number...

Text Rotation

- ☐ None
- ☐ 90 Degrees
- ☐ 180 Degrees
- ☐ 270 Degrees

Color & Graphics

Ensures colors and graphics are accurate, reproducible, and meet regulatory guidelines.

Color Accuracy - Visual Comparison

- ☐ Matches Standard
- ☐ Slight Variation
- ☐ Significant Variation

Color Measurement - L*a*b* Value (L)

Enter a number...

Color Measurement - L*a*b* Value (a)

Enter a number...

Color Measurement - L*a*b* Value (b)

Enter a number...

Image of Graphic - Front Label

 Upload File

Image of Graphic - Back Label

 Upload File

Graphic Reproduction Consistency

- ☐ Consistent
- ☐ Minor Variations
- ☐ Significant Variations

Language Requirements

Verifies correct language translations and localisations where applicable.

Target Market Language(s)

- ☐ English
- ☐ French
- ☐ Spanish
- ☐ German
- ☐ Chinese
- ☐ Japanese
- ☐ Other (Specify in LONG_TEXT)

Other Language(s) Specification (if applicable)

Write something...

Translated Label Artwork

 Upload File

Translation Vendor Verification Status

- ☐ Verified
- ☐ Pending Verification
- ☐ Not Applicable

Translation Completion Date

Enter date...

Translator Signature

Review and Approval

Confirms proper review, approval and version control of label artwork.

Artwork Creation Date

Artwork Creator

- ☐ Graphic Designer A
- ☐ Graphic Designer B
- ☐ Graphic Designer C

Artwork Revision Notes

Reviewer 1 (Quality)

- ☐ Reviewer A
- ☐ Reviewer B
- ☐ Reviewer C

Review Date (Quality)

Signature (Quality Reviewer)

Approval Status

- ☐ Approved
- ☐ Rejected
- ☐ Pending Revision

Approval Comments (if rejected/pending)

Write something...

Material & Adhesion

Checks the label material is appropriate and provides adequate adhesion to the product container.

Label Material Type

- ☐ Paper
- ☐ Polypropylene
- ☐ Polyethylene
- ☐ Vinyl
- ☐ Other

Label Thickness (microns)

Enter a number...

Adhesive Type

- ☐ Water-based
- ☐ Hot Melt
- ☐ Pressure Sensitive
- ☐ Other

Adhesive Coverage (%)

Enter a number...

Adhesion Test Results (e.g., Peel Adhesion, Shear Strength)

Write something...

Supporting Documentation (e.g., Material Certificates, Test Reports)

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