

ACRO LABELS, INC.
STANDARD PHARMACEUTICAL CONTROL PROCEDURES

I. OBJECTIVE: The objective of this document is to detail the present methods used by Acro Labels Inc. in manufacturing pressure sensitive labels for the pharmaceutical industry.

II. PURPOSE: This writing is provided as the basis of a continued program by the pharmaceutical industry in an attempt to produce the highest quality products for the general public.

III. SCOPE: This procedure contains the controls exercised by Acro Labels, Inc.

IV. PHYSICAL FACILITY:

- A. Preproduction contained in separate room from pressroom.
- B. Inspection room separated from pressroom.
- C. Packaging room separated from pressroom.
- D. Printing plates, artwork, engravings, etc. stored out of pressroom.

V. PERSONNEL TRAINING: Personnel employed in the pharmaceutical area have been thoroughly trained in this procedure.

VI. ORDER ENTRY:

A. All written pharmaceutical orders are to be approved by the Office Manager and are required to contain the following information prior to processing.

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| . Customer name | . Face material |
| . Customer part no. | . Label Size |
| . Entry date | . Adhesive |
| . Required ship date | . Colors - PMS or match color chips, where available |
| . Customer purchase order number | . Classification of adhesive |
| . Description of label use, requirements and conditions | . Copy position (layout specifications) |
| . Application environment | . Die status (new/repeat) |
| . Treatment after application (storage/environment) | . Plate status (new/repeat) |
| . Service life | . Coatings (varnish type/purpose) |
| . Means of application (manual/machine applied) | . Packaging specifications (core size, shrink wrap, chip board, box weight, number of labels per roll and wind direction.) |
| . Means of imprinting | . Description of label copy, |
| . Quantity | . Label sample where available. |

In addition, the following is to be obtained where possible from the customer:

- . Sample of item to be labeled.
- . Complete customer packaging specifications.
- . Original artwork or customer approved artwork.

B. Artwork: Quality artwork practices contain the following.

- . Twice up art where possible.
- . One art board per copy.
- . Color separation on tissue overlay.
- . Photostat of original art.
- . Specifications secured to artboard.
- . Approval by one or more people.

C. Repeat Orders: Repeat orders may contain a sample pulled from the previous run, but sample must be marked "VOID" and must be adhered to the order, not contained loosely in the job jacket. Printing plates may be reused on repeat orders, only if the order is an exact repeat.

VII. ORDER PROCESSING: All of the above information and samples are to be placed in one job envelope (one envelope per customer code). Only one customer code job is to be at press side at one time.

VIII. PREPRODUCTION:

- A. Label Stock Inventory - Only label stock less than one year old may be used.
- B. Label Stock Material - No face stock, adhesive or backing substitutes may be made without customer approval.
- C. Dies - No substitution of size, layout or radius is to be made without customer approval.

IX. PRESSROOM:

- A. The press is cleared of any debris from previous runs. The press is purged of any label stock, inks, dies or printing plates from previous runs. Foreman to note approval of purged press area on production routing.
- B. The order jacket is received at press (only one lot - code number - jacket at one time)
- C. All materials for the job are brought to press.
- D. The shift supervisor approves the job so noting the approval on the production routing.
- E. All production waste to be deposited in appropriate container. Disposal shall be on a daily basis at minimum
- F. No samples removed from a press run (roll to sheet or roll to roll) will be retained by pressman at press station.
- G. No same size labels from different productions or same size products with different potencies or for different controls will be printed on the same sheet as a combination.
- H. When printing is completed each label order to be stored at separate location in inspection department.

X. INSPECTION:

A. Cut Labels

1. Before allowing the commencing inspection work in the area, the Lead Inspector will inspect it to insure its being free of all materials from previous runs, and given written approval, so noting on the production routing.
2. Only one customer lot number is to be inspected at one time.

3. Cut labels are to be subjected to the following inspection procedure, using the accepted "fanning" technique:
 - For control number - Front two fannings
 - For control number - Back two fannings
 - Product Name - Front two fannings
 - Product Name - Back two fannings,
 - General Quality - One fanning, front and back
 - Expiration Date - One fanning
 - Copy Number - One fanning
 - Potency - One fanning
4. Label inspection stations, floors, drawers, counter tops will be kept free of any loose or waste labels at all times, such materials to be disposed in proper containers.
5. Approved labels are to be boxed or shrink wrapped in packages as per customer specifications.
6. Labels are to be packaged before proceeding to next lot number, customer code.

B. Roll Labels

1. Foreman will inspect the work area prior to start-up to insure its being clear of all materials from previous runs and give written approval for start of production, so noting on the production routing.
2. Operator will have one order jacket only at his work station at any given time; as each order is completed its jacket, samples and finished labels will be physically removed before another jacket, printed labels, etc. are introduced into the area. At no time will roll fed cut labels be inspected at the same time when two or more are "similar", the term "similar" meaning of same size, same product with different dosage, potency or control number.
3. Label inspection stations, floors, drawers, counter tops will be kept free of any loose or waste labels at all times, such materials to be disposed of in proper containers.
4. Strobe inspection is to be carried out at rewind in the inspection area.
5. Defects are to be flagged on press and removed at inspection.
6. Splices are to be made between labels with a single strip of tape so as not to impede automatic dispensings or as per customer specifications.
7. Roll diameter 13" unless otherwise specified.

XI. PACKAGING:

A. Cut labels

1. Approved labels are to be boxed or shrink wrapped in packages as per customer specifications.
2. Chipboard, cut to the same size of the labels, placed on top and bottom of bundle for rigidity.
3. No combinations of labels are to be packed into chipboard boxes or shrink wrapped into bundles. Shrink wrap each stack & box appropriately. No combinations of customer code/ items to be packed together.

B. Roll labels

1. Each roll will have a core sticker marker with quantity per roll, label code number and date of manufacturer. Quantity on roll to be uniform and affixed to outside of roll as per customer specifications.

2. Rolls to be shrink wrapped as per customer specifications. Rolls to be packed in cases, one item per case. Cases not to exceed 35 lbs. in weight. Each case to be marked prominently on end with the following information:

- Date
- Total quantity per case
- Number rolls, count per roll
- Purchase order number
- Customer I.D. number
- Sample of label on end, defaced

XII. GENERAL RULES

- A. No more than one code number or lot number at press side at one time.
- B. No gang plates.
- C. Labels retained from the production run are to be stamped "VOID" and stapled together. No more than 10 such samples may be retained.
- D. Printing plates and plating negatives are to be destroyed upon notification from the customer in regard to copy revisions.