

# Batch Master Record

CLEANOUT: ☐

**BATCH NUMBER:** WHG-CMC-624  
**FINISHED GOOD:** 3000-000000  
**AMOUNT TO PRODUCE:** A1 Antifreeze@  
**LOT NUMBER:** 5,050-0000 lb  
**CONTAINER MEASURE (WEIGHT):** TSD-LOT  
 100 LB

**EXP. DATE:** 2/14/2020  
**PRINT DATE:** 2/14/2020  
**WAREHOUSE:** 01-1A  
**HRIS DATES:** 01-15-2019 to 01-15-2020

Remarks: Print on Batch Ticket

## TOTAL RAW MATERIAL REQUIREMENTS:

PRODUCT CODE	PRODUCT NAME / PACKAGE DESCRIPTION	LOT NUMBER/LOC	TOTAL WEIGHT QUANTITY (LBS)	TOTAL VOL. QTY (GAL)	USED
3000-000000	Ethylene Glycol 1.00 lb BULK	TSD-LOT TSD-LOC	2,432.0000 lb	281.8004	
0030-25Koz	Green Dye 25.00 K Can	TSD-LOT TSD-LOC	2.000 0000 g	0.7738	
0010-000000	Ethyl Alcohol 1.00 lb BULK	TSD-LOT TSD-LOC	877.5000 lb	109.3804	
1010-Bulk	Methanol 1.00 K BULK	TSD-LOT TSD-LOC	117.0000 lb	30.9327	
000 -000000	Ice (A) 1.00 lb BULK	TSD-LOT TSD-LOC	2,340.0000 lb	280.8001	

## STEP BY STEP INSTRUCTIONS

**STEP:** 1.0000      **WORK CENTER:** 1-Blending

**EQUIPMENT:** 00-Blending

**MATERIALS:**

3000-000000      TOTAL QUANTITY      5,050.00 lb

Ethylene Glycol      2,432.00 g

0030-25Koz      2.000 0000 g

Green Dye      0.7738

0010-000000      877.50 lb

Ethyl Alcohol      109.3804

000 -000000      2,340.00 lb

Ice (A)      30.9327

1010-Bulk      280.8001

Methanol

**INSTRUCTIONS:** Unlimited Instructions - Heat, move for 2 hours, QC, Filter, Package

**START TIME:**      **STOP TIME:**      **INITIALS:**

# Master Batch Production Record Sample

**Sarfaraz K. Niazi**



## **Master Batch Production Record Sample:**

Good Manufacturing Practices for Pharmaceuticals Joseph D. Nally, 2016-04-19 With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace pharmaceutical manufacturers suppliers contractors and distributors are impacted by continual change Offering a wide assortment of policy and guidance document references and interpretations this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP regulation and pharmaceutical manufacturing and control practices worldwide An essential companion for every pharmaceutical professional this guide is updated and expanded by a team of industry experts each member with extensive experience in industry or academic settings      **Active Pharmaceutical Ingredients**

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Requirements Guidebook for Finished Pharmaceuticals José Rodríguez-Pérez, 2014-08-15 This guidance book is meant as a resource to manufacturers of pharmaceuticals providing up to date information concerning required and recommended quality system practices It should be used as a companion to the regulations standards themselves and texts on the specific processes and activities contained within the QMS This book includes chapters on US current Good Manufacturing Practice GMP international GMP global GMP guides and harmonization detailed analysis of the requirements and guidances missing subparts what inspectors are looking for and the price of noncompliance It also includes an appendix with two tabulated comparisons the first compares US European PIC S Canadian and WHO cGMPs while the second compares US cGMPs with effective quality system elements The companion CD contains cGMP regulations for sterile products produced by aseptic processing it also includes updated data of statistical enforcement by the FDA both domestically and abroad a detailed glossary and dozens of FDA guidance documents as well as international regulations EU and Canada and harmonization documents WHO PIC S and ICH A very comprehensive checklist for a cGMP audit that is based on risk management criteria is also included Finally a comprehensive GMP exam is also included *Handbook of Pharmaceutical Manufacturing Formulations* Sarfaraz K. Niazi, 2016-04-19 Providing methodologies that can serve as a reference point for new formulations the second volume covers uncompressed solids which include formulations of powders capsules powders ready for reconstitution and other similar products Highlights from Uncompressed Solid Products Volume Two include the fundamental issues of good manufacturing **Data Integrity and Compliance** José Rodríguez-Pérez, 2019-05-08 Data integrity is a global mandatory requirement for the regulated healthcare industry It is more than a mere expectation it s a basic element of good documentation practices one of the most fundamental pillars of a quality management system Robustness and accuracy of the data submitted by manufacturers to regulatory authorities when bringing a medical product to market are crucial The purpose of this book is to consolidate existing data integrity principles and expectations from several regulatory sources including the U S Food and Drug Administration World Health Organization and European Medicines Agency into a single and handy document that provides detailed illustrative implementation guidance It serves as a means of understanding regulatory agencies position on good data management and the minimum expectation for how medical product manufacturers can achieve compliance *Food Regulation* Neal D. Fortin, 2011-09-20 Food Regulation Law Science Policy and Practice provides an in depth discussion of the federal statutes regulations and regulatory agencies involved in food regulation After an introduction to U S food and drug regulation it covers current food regulations inspection and enforcement international law the Internet and ethics While it contains detailed discussions of policies and case studies the book is accessible to students and professionals This is an excellent text for courses in food science food law etc and a practical reference for food industry professionals consultants and others *The Code of Federal Regulations of the United States of America* ,1999 The Code of Federal Regulations is the codification of the general and permanent rules published in

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