

# Batch Master Record

 CLEANOUT: 

**BATCH NUMBER:** WHG-CMC-624  
**FINISHED GOOD:** 3000-000000  
 AL Address@  
**AMOUNT TO PRODUCE:** 5,750,000 lb  
**LOT NUMBER:** T8D-LOT  
**CONTAINER MEASURE (WEIGHT):** 100 LB

**EXP. DATE:** 3/16/2020      08/30/20  
**PRINT DATE:** 3/16/2020  
**WAREHOUSE:** 01-1A  
**RMIS BATTEN:** W-17-28 1 00-1

Remarks: Print on Batch Ticket

## TOTAL RAW MATERIAL REQUIREMENTS:

PRODUCT CODE	PRODUCT NAME / PACKAGE DESCRIPTION	LOT NUMBER/LOC	TOTAL WEIGHT QUANTITY	UNIT	TOTAL VOL. QTY (GAL)	USED
3000-000000	Bethylene Glycol	T8D-LOT	2,432,000	lb		281,804
	1.00 lb BULK	T8D-LOC				
0530-25Kcan	Green Dye	T8D-LOT	1,850,000	g		9,778
	25.00 lb Can	T8D-LOC				
1010-000000	Ethyl Alcohol	T8D-LOT	877,500	lb		105,864
	1.00 lb BULK	T8D-LOC				
1050-BulkA	Methanol	T8D-LOT	117,000	lb		35,937
	1.00 lb BULK	T8D-LOC				
090-000000	Ice (A)	T8D-LOT	2,340,000	lb		288,801
	1.00 lb BULK	T8D-LOC				

## STEP BY STEP INSTRUCTIONS

**STEP:** 1-0000      **WORK CENTER:** 1-Blending  
**EQUIPMENT:** 00-Blending

MATERIALS:	TOTAL QUANTITY
3000-000000	5,750,000 lb
Bethylene Glycol	
0530-25Kcan	1,850,000 g
Green Dye	
1010-000000	877,500 lb
Ethyl Alcohol	
090-000000	2,340,000 lb
Ice (A)	
1050-BulkA	117,000 lb
Methanol	

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

**START TIME:** \_\_\_\_\_      **STOP TIME:** \_\_\_\_\_      **INITIALS:** \_\_\_\_\_

# Master Batch Production Record Sample

**Ying-Ying Zheng**



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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

**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

Active Pharmaceutical Ingredients Stanley Nusim, 2016-04-19 To successfully bring an Active Pharmaceutical Ingredient API to market many steps must be followed to ensure compliance with governmental regulations This book is an unparalleled guide to the development manufacturing and regulation of the preparation and use of APIs globally This second edition brings readers up to date with the quality control regulations for APIs that have been added or amended since the first edition These updates help ensure that pharmaceutical professionals and drug manufacturers meet the established and required guidelines set forth by the US and international regulatory industries

**Handbook of Pharmaceutical Manufacturing Formulations, Third Edition** Sarfaraz K. Niazi, 2019-11-25 The Handbook of Pharmaceutical Manufacturing Formulations Third Edition Volume Two Uncompressed Solid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing With thoroughly revised and expanded content this second volume of a six volume set compiles data from FDA and EMA new drug applications patents and patent applications and other sources of generic and proprietary formulations including author's own experience to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting A must have collection for pharmaceutical manufacturers educational institutions and regulatory authorities this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent Features Largest source of authoritative and practical formulations cGMP compliance guidance and self audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing bioequivalence testing and full compliance with drug product safety elements Written by a well recognized authority on drug and dosage form development including biological drugs and alternative medicines *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

**Federal Register** ,1978-09 **Control Procedures in Drug Production** William Leonard Blockstein,1966 *United States of America V. Article of Drug Labeled "White Quadrisect"* ,1972 *The United States pharmacopeia* ,2012 *United States Pharmacopeia Dispensing Information* ,1998 *Pharmaceutical Dosage Forms, Parenteral Medications* Kenneth E. Avis,Leon Lachman,Herbert A. Lieberman,1984 *Production Part Approval Process (PPAP)* ,2000 *Food, Drug, Cosmetic Law Reporter* ,1963 **Grist from the Mill** ,1978 **McGraw-Hill Encyclopedia of Science & Technology** ,1987 **Vaccine Manual** Noel Mowat,Mark M. Rweyemamu,Food and Agriculture Organization of the United Nations,1997 This manual represents a response to a recommendation arising from an expert consultation on vaccine production and quality control held in 1991 It attempts to birng together information on the state of the art in veterinary vaccine development *Electrochemical and Metallurgical Industry* ,1960 **European Plastics News** ,1986

**McGraw-Hill Encyclopedia of Science & Technology** Sybil P. Parker,1992 For nearly four decades the McGraw Hill Encyclopedia of Science Technology has lead the world to the ever expanding frontiers of science Our seven previous editions are the most consulted most respected and best reviewed science and technical references in the English language And our new Eighth Edition will build on the strength of its predecessors and become the science and technology reference of choice for thousands of libraries around the world Contains 7 100 entries 1 600 new revised entries definition overview concise explanation etc **Hazards of Medication** Eric Wentworth Martin,1971

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