

Batch Master Record

CLEANOUT: ☐

BATCH NUMBER: WHG-CMC-624
FINISHED GOOD: 3000-000000
AMOUNT TO PRODUCE: 5,750.0000 lb
LOT NUMBER: T8D-LOC
CONTAINER MEASURE (WEIGHT): 100 LB

EXP. DATE: 2/14/2020
PRINT DATE: 2/14/2020
WAREHOUSE: 01-1A
RMIS BATTEN: W- 1 F-2 B- 1 H- 1

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	T8D-LOC T8D-LOC	2,432.0000 lb	281.8004	
0030-25Koz	Green Dye 25.00 K Can	T8D-LOC T8D-LOC	2.000.0000 g	0.7738	
1010-000000	Ethyl Alcohol 1.00 lb BULK	T8D-LOC T8D-LOC	877.5000 lb	109.8804	
1010-Bulk	Methanol 1.00 K BULK	T8D-LOC T8D-LOC	117.0000 lb	30.9327	
190-000000	Ice (A) 1.00 lb BULK	T8D-LOC T8D-LOC	2,340.0000 lb	280.8811	

STEP BY STEP INSTRUCTIONS

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

EQUIPMENT: 00-Blending

MATERIALS:

3000-000000 TOTAL QUANTITY 5,750.00 lb

Ethylene Glycol 2,432.00 g

0030-25Koz 2.000.00 g

Green Dye 0.7738 lb

1010-000000 877.50 lb

Ethyl Alcohol 2,340.00 lb

190-000000 117.00 lb

Ice (A) 30.9327

Methanol 280.8811

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

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

Master Batch Production Record Sample

**Noel Mowat, Mark M.
Rweyemamu, Food and Agriculture
Organization of the United Nations**

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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 **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 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 **Pharmaceutical**

Manufacturing Formulations Dr. Priyanka Gupta Manglik, 2024-08-15 This book provides detailed insight into the various aspects of pharmaceutical manufacturing covering formulations process design technology and regulatory requirements essential for professionals in the pharma industry

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 is 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

Control Procedures in Drug Production William Leonard Blockstein, 1966

United States of America V. Article of Drug Labeled "White Quadriseet", 1972 The United States Pharmacopeia, the National Formulary, 2008 The USP NF is a combination of two compendia the United States Pharmacopeia USP and the National Formulary NF It contains standards for medicines dosage forms drug substances excipients biologics compounded preparations medical devices dietary supplements and other therapeutics The current version of USP NF standards deemed official by USP are enforceable by the U S Food and Drug Administration for medicines manufactured and marketed in the United States *United States Pharmacopeia Dispensing Information*, 1998

Production Part Approval Process (PPAP), 2000

Pharmaceutical Dosage Forms, Parenteral Medications Kenneth E. Avis, Leon Lachman, Herbert A. Lieberman, 1984 Food, Drug, Cosmetic Law Reporter, 1963 **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 bring together information on the state of the art in veterinary vaccine development *Electrochemical and Metallurgical Industry*, 1960

Grist from the Mill, 1978

Good Manufacturing Practices for Pharmaceuticals Sidney H. Willig, James R. Stoker, 1997 Revised to ensure GMP compliance this text examines US laws affecting domestic and multinational pharmaceutical manufacturing It recommends practical ways to interpret and comply with FDA CGMP regulations while meeting the goals of a comprehensive controls system to preserve product integrity

Hazards of Medication Eric Wentworth Martin, 1971

Computer Operations Don B. Medley, Jerry L. Koory, 1988

Whispering the Techniques of Language: An Emotional Quest through **Master Batch Production Record Sample**

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<http://www.technicalcoatingsystems.ca/About/browse/Documents/Making%20Communicative%20Language%20Teaching%20Happen.pdf>

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