



# Batch Master Record

CLEANOUT:

**BATCH NUMBER:** 890-CM-624  
**FINISHED GOOD:** 3000-00000  
**AMOUNT TO PRODUCE:** 5,450,000 lb  
**LOT NUMBER:** T80-LOT  
**CONTAINER MEASURE (WEIGHT):** 100 LB

**DATE DATE:** 7/20/20  
**PRINT DATE:** 7/20/20  
**WAREHOUSE:** 00-1A  
**HRIS RATING:** A- 1 1-2 B 1 00-1

Remarks: Print on Batch Ticket

## TOTAL RAW MATERIAL REQUIREMENTS:

PRODUCT CODE	PRODUCT NAME / PACKAGE DESCRIPTION	LOT NUMBER/LOC	TOTAL WEIGHT QUANTITY (LBS)	TOTAL VOL. (GALS) USED
7000-00000	Whylene Glycol	T80-LOT	2,432,500 lb	35.0004
	1.00 lb BAG	T80-LOC		
3000-20000	Green Dye	T80-LOT	5,450,000 g	0.7700
	25.00 lb Can	T80-LOC		
2000-00000	Ethyl Alcohol	T80-LOT	877,500 lb	105.5004
	1.00 lb BAG	T80-LOC		
1000-00000	Methanol	T80-LOT	117,000 lb	38.4507
	1.00 lb BAG	T80-LOC		
000-00000	Ice (A)	T80-LOT	2,345,000 lb	208.0013
	1.00 lb BAG	T80-LOC		

## STEP BY STEP INSTRUCTIONS

STEP: 1-0000      WORK CENTER: 1-Blending

EQUIPMENT: 01-Blending

MATERIALS:	TOTAL QUANTITY
3000-00000	5,450,000 lb
Whylene Glycol	
3000-20000	5,450,000 g
Green Dye	
2000-00000	877,500 lb
Ethyl Alcohol	
000-00000	2,345,000 lb
Ice (A)	
1000-00000	117,000 lb
Methanol	

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

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

# Master Batch Production Record Sample

**SJ Ball**



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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 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** 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 **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 **Federal Register**, 1978-09 United States of America V. Article of Drug Labeled "White Quadrisect", 1972 *United States Pharmacopeia Dispensing Information*, 1998 Pharmaceutical Dosage Forms, Parenteral Medications Kenneth E. Avis, Leon Lachman, Herbert A. Lieberman, 1984 The United States pharmacopeia, 2012 **Production Part Approval Process (PPAP)**, 2000 **Grist from the Mill**, 1978 Food, Drug, Cosmetic Law Reporter, 1963 *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 **Drug, Device and Diagnostic Manufacturing** Carol DeSain, 1993 *European Plastics News*, 1986 **The Pharmaceutical Quality Control Handbook** Rhys Bryant, 1984 Hazards of Medication Eric Wentworth Martin, 1971

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