

 Government of India Pharmaceutical Company	BATCH MANUFACTURING INSTRUCTIONS AND RECORD	Page 1 of 10
Equipment / Production	Title Tablets 25 mg/100 Tablets 100 mg/100	Batch Record 000-001
Prepared by	Name Signature Date	Revision No. 2
Approved by	Production Manager	Effective Date 10/01/2020
	QA Manager	

1. Product Details	
Description	Tablets 25 mg/100 Tablets 100 mg/100 Appearance: Color, shape, weight, etc. for this individual record Storage time: 18 months
Batch Quantity	Batch size: 100 kg Approximate: 1000 / 1000000
Packaging	Aluminum foil with a white cap
Storage Conditions	Preserve in light resistant and rigid container under temperature 15-25°C (59-77°F) (20-25°C)

1. Production Batch Record Summary		
Based By: Issue for material for Batch Record is issued for the copy not completed, accurate copy of the Master Batch Record		
(Print) Issued By: Quality Assurance Signature Date		
Based By: Production for material for Batch Record is issued for the copy not completed and correct Production is completed for the Batch Record following process		
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1. Reference Documents	
SOP - 001, Low Temperature SOP - 002, Temperature and Humidity Monitoring SOP - 003, Training, Cleaning Procedures SOP - 004, Material Handling and Engineering	

Batch No. 11-000001	Manufacturing Date 15/01/20	Expiry Date 15/01/20
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	Pharmaceutical Guidelines Drugs India Batch Manufacturing Record	Page No. 1 of 10
Product	Intermediate Tablets 100 mg	S.M.S. No. 15/001/000
Batch Size	100,000 Tablets	S.M.S. Revision No./Date 00/00000000
Batch No.	10000/10	Int. M.P.S. No. 15/001/000
Batch No.	10000/10	M.P.S. Revision No. & Date 00/00000000

Batch Quantity	100 kg	Composition
Working Added (g/l)		Each film coated tablet contains: Intermediate Tablets 100 mg Equivalent to Intermediate: 100 mg Tablet Coating: 100 mg
Theoretical Yield		
Yield (%)		Yield (%)
Accepted Yield (%)		Accepted Yield (%)
Yield		Yield
The Recovery Signature	Name	
Reason for Change	Name	
My Master No.	1000/10/000	Material code No. 10000000
Batch Size	100 kg/100 kg or 100 kg/100 kg or 100 kg/100 kg	
Storage Conditions	Store in cool dry & dark place	
Marked by	100/1000000000000000	
Batch No.		
	Production	Composition
Date of completion		
Date of completion		
Date of completion		
Production Production		
Batch No.		
Marked by Production		
Date		
The batch has been not been completed according to the instructions given in M.P.S. No. 15/001/000. Signature about attached: 100		
Batch Size	100 kg	Date of Batch
Working Added (g/l)		Quantity
Theoretical Yield		
Yield (%)		Yield (%)
Accepted Yield (%)		Accepted Yield (%)
Yield		Yield

Prepared by	Marked by	Reviewed by	Approved by
Quality Assurance	Production	Production Dept	QA & QC Dept
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Master Batch Production Record Sample

Lauren Gardner

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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 Competitive problems in the drug industry United States. Congress. Senate. Select Committee on Small Business. Subcommittee on Monopoly,1975 Handbook of Downstream

Processing E. Goldberg,2012-12-06 The last two decades have seen a phenomenal growth of the field of genetic or biochemical engineering and have witnessed the development and ultimately marketing of a variety of products typically through the manipulation and growth of different types of microorganisms followed by the recovery and purification of the associated products The engineers and biotechnologists who are involved in the full scale process design of such facilities must be familiar with the variety of unit operations and equipment and the applicable regulatory requirements This book describes current commercial practice and will be useful to those engineers working in this field in the design construction and operation of pharmaceutical and biotechnology plants It will be of help to the chemical or pharmaceutical engineer who is developing a plant design and who faces issues such as Should the process be batch or continuous or a combination of batch and continuous How should the optimum process design be developed Should one employ a new revolutionary separation which could be potentially difficult to validate or use accepted technology which involves less risk Should the process be run with ingredients formulated from water for injection deionized water or even filtered tap water Should any of the separations be run in cold rooms or in glycol jacketed lines to minimize microbial growth where sterilization is not possible Should the process equipment and lines be designed to be sterilized in place cleaned in place or should every piece be broken down cleaned and autoclaved after every turn *Integrated Pharmaceutics* Antoine Al-Achi,Mali Ram

Gupta,William Craig Stagner,2022-09-07 This work is an examination of all aspects of the science in developing effective dosage form for drug delivery Pharmaceutics refers to the subfield of pharmaceutical sciences that develops drug delivery products or devices to optimize the drug s performance once administered This multidisciplinary field draws on physical chemistry organic chemistry and biophysics to generate and refine these crucial elements of medical care Moreover incorporating such disparate dimensions of drug product design as material properties and legal regulation bridges the gap between effective chemicals and viable medical treatments Integrated Pharmaceutics provides a comprehensive introduction

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