

 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. 1
Approved by	Production Manager	Effective Date 10/10/2020

1. Product Details	
Description	Aspirin 75 mg/100 Tablets 100 mg/100 Aspirin 75 mg tablets, round, white, for film-coated tablets (Change form: 10 mg)
Batch Quantity	Batch size: 100 kg Approx. No. Tablets: 1,000,000
Packaging	Aspirin 75 mg tablets, 100 mg
Storage Conditions	Store in a light-resistant, well-ventilated container (e.g., 100 mg/100 100 mg/100)

1. Production Batch Record Summary			
Issued 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	
Issued To: Production for material for Batch Record is issued for the copy not completed and correct Production is completed for the Batch Record, following process			
_____ (Print) Issued By: Quality Assurance	_____ Signature	_____ Date	

1. Reference Documents			
SOP - 001: Raw Material			
SOP - 002: Inspection and Quality Monitoring			
SOP - 003: Training, Cleaning, and Storage			
SOP - 004: Material Handling and Packaging			

Batch No. 11-000001	Manufacturing Date 15/10/20	Expiry Date 15/10/22
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	Pharmaceutical Guidelines Drugs India Batch Manufacturing Record	Page No. 1 of 10
Product	Aspirin 75 mg/100 kg	S.M.S. No. 11/100/100
Batch Size	1,00,000 Tablets	S.M.S. Revision No./Date 01/10/2020
Batch No.	110001/10	S.M.S. Revision No. & Date 01/10/2020

Batch Quantity	100 kg	Composition Each film-coated tablet contains: Aspirin 75 mg/100 Equivalent to Aspirin 75 mg/100 Tablet (Tablet Strength 75 mg)
Working Added (kg)		
Received Total		
Qty. Issued		Qty. Issued
Received Issued By		Received Issued By
Qty.		Qty.
The Receiver Signature		
Reason for Change		
Qty. Issued No.	110001/10	Material Code No. 110001/10
Batch Size	100 kg/100 kg or 100 kg/100 kg or 100 kg/100 kg	
Storage Conditions	Store in a cool, dry, dark place	
Marked by	100 kg/100 kg/100 kg	
Batch No.		

	Inspection	Composition	Testing
Lot of material used			
Lot of completion			
Batch Size			
Process Product Name			
Batch No.			
Marked by Material			
Qty.			

The batch has been not been completed according to the instructions given in M.P.S. No. 11/100/100.
 Reference should be made to M.P.S.

Batch Size: 100 kg Working Added: 100 kg Total Yield: 100 kg Total 100 kg/100 kg	Total of Working Quantity: Total Yield: 100 kg Total 100 kg/100 kg
Prepared by	Marked by
Quality Assurance	Production
_____ Name	_____ Name

Approved by	Marked by	Received by	Approved by
Quality Assurance	Production	Production Dept	QA & QC Dept
_____ Name	_____ Name	_____ Name	_____ Name

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Sarfaraz K. Niazi



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Pharmaceutical Dosage Forms Kenneth E. Avis, Herbert Lieberman, Leon Lachman, 2018-05-04 Completely updated and enlarged to three volumes originally published as two volumes the Second Edition of Pharmaceutical Dosage Forms Parenteral Medications examines every important aspect of sterile drug products This volume 3 offers comprehensive coverage of medical devices quality assurance and regulatory issues This in depth reference and text discusses regulatory requirements in record keeping based on the US Food and Drug Administration s FDA Current Good Manufacturing Practices places special emphasis on methods of detecting counting and sizing particles offers new perspectives on contemporary validation concepts and how they affect the validation process explains current FDA enforcement activities the voluntary compliance policy select court cases and how these relate to parenterals provides recent materials on the use of audits as a means of verifying the efficacy of manufacturing control systems highlights new US regulations for medical devices and examines quality assurance including new information on biological control tests for medical device materials With the contributions of leading experts volume 3 of Pharmaceutical Dosage Forms Parenteral Medications is intended as a day to day reference for pharmacists medical device manufacturers quality control and regulatory personnel chemists and drug patent and litigation attorneys as well as a text for upper level undergraduate graduate and continuing education students in the pharmaceutical sciences

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