

 Government of Karnataka Pharmaceutical Company	BATCH MANUFACTURING INSTRUCTIONS AND RECORD			Page 1 of 10
	Title Tablets 25 mg/500 Tablets/100,000			Batch Number 000-001
Prepared by	Name	Signature	Date	Version No. 1
Approved by	Production Manager			Effective Date 01/01/2010
	All Manager			

1. Product Details	
Description	Tablets 25 mg/500 Tablets/100,000 Appearance: Color, shape, weight, etc. for this batch/lot/serial Change form: If given
Batch Quantity	Batch size: 500 kg Approved lot size: 5000 kg
Packaging	Aluminium foil with tablet top
Storage Conditions	Store in light resistant and airtight container under temperature 15-25°C (59-77°F) (Q10)

2. Production Batch Record Issues	
Issue No.: Issue No. assigned to this Batch Record is issue no. for copy no. completed, accurate copy of the Batch Record.	
_____	_____
(Print Issue No. - Quality Assurance)	Date
Issue No.: Production lot assigned to this Batch Record is issue no. for copy no. completed and correct Production is complete for the Batch Record, starting process.	
_____	_____
(Print Issue No. - Quality Assurance)	Date

3. Reference Documents	
SOP - 001, Clean Room	
SOP - 002, Temperature and Humidity Monitoring	
SOP - 003, Training, Cleaning Procedures	
SOP - 004, Material Handling and Packaging	

Batch No. 11-00001	Manufacturing Date 11-0000	Expiry Date 11-0000
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	Pharmaceutical Company		Page No. 1 of 10
	Batch Manufacturing Record		
Product	Immediate Release Tablet 10 mg Batch Size : 1,00,000 Tablets Batch No. : 00001/10	Q.M.S. No. Q.M.S. Revision No./ Date Rev. Q.M.S. No. Q.M.S. Revision No. & Date	10,000/1000 00,000/000000 10,000/1000 00,000/000000
Batch Quantity	100 kg	Composition Each film coated tablet contains: Immediate Release IP Equivalent to Immediate Release IP Tablet Coating (Batch IP)	
Working Order (Lot)	_____	Lot No. Approved Working Order Date: _____	
Received Lot	_____	The Receiver Signature: _____ Date: _____	
Batch No.	_____	Approved by: _____ Date: _____	
Lot No.	_____	Approved by: _____ Date: _____	
Batch Size	1,000,00,000	Material Lot No.	0000000
Batch Lot	100 kg/100 kg or equal to water equivalent volume in a lot		
Storage Conditions	Store in cool, dry & dark place		
Worked by	100 Manufacturing lot		
Batch No.	_____		
Date of commencement	_____	Completion	_____
Date of completion	_____		
Batch Size	_____		
Production Product Name	_____		
Lot No.	_____		
Worked by Name	_____		
Date	_____		
The batch size has not been completed according to the composition given in Q.M.S. No. 10,000/1000.			
Reason: short material: 10%			
Batch Size	100 kg	Date of Working	_____
Working Order	_____	Quantity	_____
Lot No.	_____	Final Batch No. Final Batch No.	
Date	_____		
Prepared by	Worked by	Reviewed by	Approved by
Quality Assurance	Production	Production Dept	G.P.P. Dept
_____	_____	_____	_____
Date	Date	Date	Date

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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

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