For Batch : Coversyl 8 Mg Tablet - BMR Save

Bliss Infusions & Surgicals Pvt. Ltd.
19th Street, MIDC, Satpur, Nashik – 422 007

BATCH MANUFACTURING RECORD

PRODUCT : PARACETAMOL INJECTION	**DOC. NO. :**
MFR NO. : 14 (30 ml)	**VER. NO. :** 00 / 01/03/2004
BATCH NO.: **BATCH SIZE :**	**PAGE NO.:** 1 of 24

PARACETAMOL INJECTION VET.

SHELF LIFE : 24 Months or the expiry date of the active ingredient which ever is earlier.

BATCH NO. :	**BATCH SIZE :**
MFG. DATE :	**PACK SIZE :** 30 ml Amber Vials.
EXP. DATE :	LABEL CLAIM **:** Paracetamol IP ---------- 75 mg / ml Benzyl Alcohol IP ---------- 1.5 % v / v Water for Injection IP ---------- q. s.
DESCRIPTION OF THE PRODUCT : A clear colorless solution.	
DOCUMENT ISSUED BY : **DATE :**	**DOCUMENT RECEIVED BY :** **DATE :**

ACTIVITY	MANUFACTURING	WASHING & DRYING	FILLING & SEALING	VISUAL INSPECTION	PACKING
COMMENCED ON					
COMPLETED ON					

PERMISSIBLE YIELD : 90 to 96 %			ACTUAL YIELD		
	Minimum	**Maximum**		**In Nos.**	**In %**
30 ml	6,000	6,400	**30 ml**		

Batch manufacturing process is completed as per batch manufacturing record – **Yes / No**

Deviation sheet attached : **Yes / No**

FINAL DOC. CHECKED BY : **DATE :**	**FINAL DOC. FILLED BY :** **DATE :**

PREPARED BY	**CHECKED BY**	**AUTHORISED BY**

CHECK LIST OF BMR:

Sr. No.	CHECK LIST	CHECKED BY	
		PROD	QC
1.	Check List of BMR		
2.	Raw Material Requisition		
3.	Primary Packing Material Requisition		
4.	Machinaries And Equipments Cleaning Record		
5.	Manufacturing		
6.	Intimation for bulk analysis		
7.	Filtration		
8.	Washing Record		
9.	Washing of The Rubber Closure		
10.	Filling Record		
11.	Secondary Packing Material Requisition		
12.	Visual Inspection		
13.	Packing		
14.	Reconciliation of Packing Material		
15.	Reconciliation of the Batch		
16.	Rejection Destruction		
17.	Master Control Card		
18.	Quality Assurance: In Process Check Record		
19.	Intimation for Finished Product		

RAW MATERIAL REQUISITION

Dispensing Area Clearance**:** As per SOP No.

Mfg. Date**:**

Exp. Date**:**

PRODUCTION CHECKS: **CERTIFICATION**

1. Ensure that Line Clearance to be done as per SOP No. XII.1 _____
2. Ensure that dispensing both area is "CLEANED" and free from Previous product. _____
3. Ensure that weighing balance, scoop, containers are "CLEAN AND DRY" before weighing. _____
4. Ensure that "CLEAN" latex hand gloves are worn while handling raw materials. _____
5. Ensure that weighing balance checked for zero error before starting weighing.

Error observed _____

Zero adjusted by _____

Notes:

1. Transfer all raw material to mfg. Area through clean container having proper label and store in closed air tight container till taken for manufacturing.
2. Manufacturing should start within 24 hours after dispensing.
3.

Previous Product Dispensed	**Batch No.**	**Completed On**	**Cleaned By**	**Checked By**	
				Prod.	**QC**

Sr. No.	Ingredients	Unit	Item code	Labeled Qty.	Theoretical Qty.	A. R. No.	Actual added	Weighed by	Cked By
1.	Paracetamol IP	kg	R–73	75 mg / ml	15.00		15.000		
2.	Propylene Glycol IP	ltr	R–74	----------	100.0		100.0		
3.	Benzyl Alcohol IP	ltr	R–5	1.5 % v / v	3.000		3.000		
4.	Sodium Metabisulphite IP	Kg	R–77	----------	0.200		0.200		
5.	Water for Injection IP	ltr	R–81	q.s.	200		200		
6.	Benzyl Alcohol IP	ltr	R–5	----------	0.510		0.510		

Raw Material Requisition Raised on**:** _____ By**:** _____

Material Required on**:** _____ Material Issued By**:** _____On**:** _____

PRIMARY PACKING MATERIAL REQUISITION

Refer SOP. No.**:**

Mfg. Date**:**
Exp. Date**:**

Sr. No.	Packing Material	P.M. Code No.	Qty. Required	A. R. No.	Qty. Issued	Issued By	Received By
1.	30 ml Amber Vials	P – 16	6,670				
2.	Rubber Closure Latex 20mm	P – 28	6,670				
3.	Aluminium Seals 20mm T/O	P – 29	6,670				

Primary Packing Material requisition Raised on**:** _____ By**:** _____

Material Required on**:** _____ Material Issued By**:** _____ On**:** _____

MACHINARIES AND EQUIPMENTS CLEANING RECORD

Sr. No.	Machine	Cleaned By	Checked By
1.	Manufacturing tank		
2.	Filtrate Collection Tank		
3.	S. S. Pressure Vessel		
4.	S. S. Stirrer		
5.	293 mm / 142 mm membrane holder		
6.	Washing Table		
7.	Filling Table		
8.	Aluminium Seal Cap Sealing Machine		
9.	S. S. Trays		
10.	S. S. Stands		

CLEANING RECORD OF ACCESSORIES

Sr. No.	Item	Cleaned By	Checked By
1.	S. S. Spoon		
2.	S. S. Buckets		
3.	S. S. Container		
4.	Filtration & filling Pipes		
5.	Filling syringe with filling needle		

Bliss Infusions & Surgicals Pvt. Ltd. 19th Street, MIDC, Satpur, Nashik – 422 007	
BATCH MANUFACTURING RECORD	
PRODUCT : PARACETAMOL INJECTION **MFR NO. :** 14 (30 ml) **BATCH NO.:** **BATCH SIZE :**	**DOC. NO. :** **VER. NO. :** 00 / 01/03/2004 **PAGE NO.:** 6 of 24

MANUFACTURING

Previous Product Processed	Batch No.	Completed On	Cleaned By	Checked By	
				Prod.	QC

STG. NO.	PARTICULARS	OBSERVATION	DONE BY	CHECKED BY
A	**MANUFACTURING**	Date**:**		
1.	Take, a) Propylene Glycol IP ---------- 100.0 ltr b) Paracetamol IP ---------- 15.000 kg In manufacturing tank take Propylene Glycol IP & dissolve Paracetamol IP in it with constant stirring till we get clear solution.	Qty. _____ ltr Qty. _____ kg Time**:** From**:** To**:**		
2.	Take, a) Benzyl Alcohol IP ---------- 3.000 ltr Add & mix in STG No. (1) with constant stirring.	Qty. _____ ltr Time**:** From**:** To**:**		
3.	Take, a) Sodium Metabisulphite IP ---- 0.200 kg b) Water for Injection IP ---------- 5.0 ltr Dissolve (a) in (b) with stirring, then transfer this material in manufacturing tank of STG No. (2) with stirring.	Qty. _____ kg Qty. _____ ltr Time**:** From**:** To**:**		
4.	Make up the volume upto 200 ltr. With Water for Injection IP.	Vol. _____ ltr		
5.	Check pH of the solution. pH limit = 4.0 to 5.5	pH _____		
6.	Give the bulk sample to QC for bulk analysis.			
7.	On receipt of release report from QC, take the batch solution for filtration.			

Sign. of competent tech. Person.

INTIMATION FOR BULK ANALYSIS

Date of Intimation	Mfg. Date	Exp. Date	Sampling stage	Intimation given by Prod. Chemist	Sampled by QC chemist

TEST	RESULTS	LIMITS	INITIALS
Description			
pH of the solution		3.5 to 6.0	
Assay **:** Paracetamol IP		95 to 105 %	

Conclusion: The sample complies / does not comply with product specification No. 14

Date of issue of PASS / REJECTION slip.

QC Head.

1. **Description:** A clear, colourless oily solution.
Observation:

Complies/Does not comply.

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2. **Identification: a)** 1 mg of test sample in sufficient methanol to produce 100 ml. To 1ml of this solution add 0.5 ml of 0.1M Hydrochloric acid & dilute to 100 ml with methanol. Protect the resulting solution from bright light & immediately measure the absorbance at the maximum at about 249 nm.
Observation:

Spectrophotometer No.:
Limit: Absorbance about 0.44
Complies/Does not comply.

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b) Boil 2 ml of test sample in 1 ml of Hydrochloric acid for 3 minute, add 10 ml of water & cool, no precipitate. Add 0.5 ml of 0.0167 M Potassium dichromate to above solution. A violet colour develops which does not turn red.
Observation: A violet colour develops/ does not develop which turn/ does not turn red.

Complies/Does not comply.

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3. **pH :** pH meter No.:
_____ (Limit: 3.5 to 6.0)

Complies/Does not comply.

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4. **Assay:** Take 2 ml of injection, add 50 ml of 0.1N Sodium hydroxide & 100 ml of water. Shake for 15 minute, add sufficient water to produce 200-ml & mix. Take 10 ml of this solution in 100-ml volumetric flask & dilute upto mark with water. Take 10 ml of resulting solution in a 100-ml volumetric flask, add 10 ml of 0.1N Sodium Hydroxide & dilute upto mark with water. Measure the absorbance at **257-nm** taking 715 as the value of A (1%, 1 cm).

Observation: Spectrophotometer No.:

Balance No.

Paracetamol: Abs at 257 nm;

Test =

$$= \frac{\text{Test reading} \times 1000 \times 200 \times 100 \times 100}{715 \times 100 \times 2 \times 10 \times 10}$$

Limit: 95 to 105 %

Complies / Does not comply.

FILTRATION

STG. NO.	PARTICULARS	OBSERVATION		DONE BY	CHECKED BY
B	**FILTRATION**	Date**:**			
1.	Use 293 mm / 142 mm presterilised membrane holder containing prefilter of 1.2 µ followed by 0.2 µ membrane filter.				
2.	Check the integrity of the membrane filter before & after filtration as per SOP no. VIII.11.	Before filtration			
		After filtration			
3.	Prefilter the bulk through 1.2 µ prefilter followed by 0.2 µ membrane filter using Nitrogen pressure.				
4.	Filtration Started at ---------- Completed at ----------				
5.	Collect the filtrate in sterile glass Jar & start filling.				
6.	Solution loss during filtration & filling.	Qty.**:** _____			

Sign. of competent tech. person

WASHING RECORD

VIALS WASHING**:**

WASH THE VIALS IN WASHING SECTION AS BELOW**:**

1. Soak the vials in 1 % soap solution.
2. Brush each vial on brushing machine and pass over to jetting machine.
3. Vials are jet washed on two head rotary jetting machine by placing vials into vial cups in inverted manner one by one.
4. Adjust the needle position in such a manner that distilled water jet is in the center of the vial so that vial gets washed properly.

Inprocess Checks**:**

a) Jet position of needle.
b) Clarity of distilled water.
c) Clarity of washed vials.
d) Plate rotations.

Arrange the vials in a tray in inverted position and transfer for dry heat sterilization.

Washing Started at**:** on**:**

Date	Quantity Washed	Washing Rejection	Washing Done by	Checked by

Washing Completed at**:** on**:**

Sterilization of Vials in DHS:

Temperature **:** 180°C
Holding time **:** 2 hrs

Date	Nos. of vials loaded	DHS started at	Sterilization Time		Done by	Checked by
			From	To		

Sign of Competent Technical Person

WASHING OF THE RUBBER CLOSURE

A) Wash the rubber closer with 1 % soap solution. Then wash it with purified water till to free from soap.
Time**:** from**:** To**:**

B) Soak the rubber closure in solution of Benzyl Alcohol IP solution.

For 30 ml
Take 17 ltr. Water for Injection IP & dissolve 0.510 ltr Benzyl Alcohol IP stir to get clear solution. Add the rubber closure & dip well & allow for soaking. Soaking time – From **:** date **:** To **:** date **:**

C) Washing of the rubber closure **:**
Take soaked rubber closer & wash it with purified water thrice time in rubber closer washing machine, then wash it with distilled water twice.
Date**:**
Time**:** from**:** to**:**

D) Transfer the washed rubber closures in SS pot with lid & give for sterilization.

E) Autoclaving: at 121ºC / 15 psi for 15 min.

Date	**Particulars**	**Autoclave started at**	**Sterilization time**		**Temp.**	**Pressure**	**Done by**	**Cked by**
			From	**To**				
	Rubber Closures							
	Membrane Holder							
	Equipments **:** Machine parts, Silicone tubes, Filling tank.							
	Hand gloves							
	Garments							

WASHING OF ALUMINIUM SEALS

Take approximate 1200 Nos. of aluminium seals in a clean plastic crete & wash it with 70 % Isopropyl Alcohol & drain the IPA solution.

Washing done by**:**
Time**:**
From**:** To**:**

Sign. of competent tech. person.

FILLING RECORD

Take the product for filling only after receiving approval from QC. Fill the product in the vials, plug with 20-mm rubber closure & aluminum seal using filling & sealing machine.
Visually inspect randomly filled & sealed vials for proper sealing & absence of foreign matter at visual inspection table.

Previous Product Processed	**Batch No.**	**Completed On**	**Cleaned By**	**Checked By**	
				Prod.	**QC**

INPROCES CHECKS DURING FILLING

Sr. No.	**Parameter**	**Standards**	**Frequency**	**Checked by**
1.	Fill volume (on 3 vials)	For 30 ml **:** 30.0 to 31 ml	30 minutes	Prod. Chemist
2.	Aluminium cap sealing performance (on 25 vials)	Proper sealing.	30 minutes	Prod. Chemist
3.	Visual inspection (on 25 vials)	Absence of particulate matter.	30 minutes	Prod. Chemist
4.	Clarity	Clarity of solution.	30 minutes	Prod. Chemist

ENVIRONMENTAL CONTROL Check the parameters as per SOP No.

Date	**Control checks**	**Filling & sealing area**	**Checked by**
	Area cleanliness		
	Temperature	ºC	
Spraying of disinfectant			

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PRODUCT : PARACETAMOL INJECTION **MFR NO. :** 14 (30 ml) **BATCH NO.:** **BATCH SIZE :**	**DOC. NO. :** **VER. NO. :** 00 / 01/03/2004 **PAGE NO.:** 14 of 24

Filling started at**:** on**:**

Date	Time	Volume of the filled vials			Qlty. Of sealing	Operator		Checked by
		1	2	3		Filling	sealing	

Filling completed at**:** on**:**

Total nos. of vials filled **:**
Nos. of vials rejected **:**
Nos. of vials filled
(Good, qty. send for pacing) **:**

Productive hours**:**

Filling started at	Filling stopped at	Break down	M/C productive hours

Actual filling time**:**

Total good quantity transferred to quarantine**:**

Sign. of competent tech. person.

SECONDARY PACKING MATERIAL REQUISITION

Refer SOP. No.**:**

Mfg. Date**:**
Exp. Date**:**

Sr. No.	Packing Material	P.M. Code No.	Qty. Required	A. R. No.	Qty. Issued	Issued By	Received By
1.	Labels	PLB –	7,000				
2.	Punching Box	BL – 5	457				
3.	Shipper	BL – 6	31				
4.	BOPP Tape	BL –16	01				

Secondary Packing Material requisition Raised on**:** _____ By**:** _____

Material Required on**:** _____ Material Issued By**:** _____ On**:** _____

VISUAL INSPECTION

To check the visual inspection on visual inspection table as per SOP.

Quantity taken for visual inspection**:**
Visual Inspection done by**:**

Visual Inspection started at**:** on**:**

Date	Type of rejection							Prod. chemist
	Black particle	White particle	Fiber	Glass particle	Volume variation	Sealing defect	other	

Visual Inspection completed at**:** on**:**

Total rejection**:**
Quantity transferred for packing**:**

Sign of competent technical person

PACKING

Start the packing as per SOP.

Packing area line clearance**:** Date**:**

Previous Product Packed	**Batch No.**	**Completed On**	**Cleaned By**	**Checked By**	
				Prod.	**QC**

Final packing: Packing started at**:** on **:**

Sr. No.	**Operation**	**Date**	**Operator**	**Checked by**
1.	Gumming of the labels			
2.	Vials labeling			
3.	Punching box filling			
4.	Punching box labeling			
5.	Shipper filling, packing & labeling			

Packing completed at**:** on **:**

Rejection during packing**:**

Particular	**Quantity**
Filled vials	
Labels	
Punching box	
Shipper	

RECONCILIATION OF PACKING MATERIALS:

Sr. No.	Particulars	Quantity received	Quantity used	Quantity returned to stores	Quantity rejected
1.	30 ml Amber vials				
2.	20 mm rubber closures				
3.	20 mm aluminium seals				
4.	Labels				
5.	Punching box				
6.	Shipper				

RECONCILIATION OF BATCH:

Sr. No.	Particulars	Details	Sign.
1.	Quantity of units filled.		
2.	Quantity of units rejected & destroyed.		
3.	Quantity of units given for QC analysis.		
4.	Quantity of units transferred to BSR including control sample.		
5.	Yield = Actual units transferred to BSR X 100 / Theoretical units filled (Limit – 90 % to 96 %)		

REJECTION DESTRUCTION: destruction to be done as per SOP No.

Sr. No.	Particulars	Rejected quantity	Quantity destroyed	Destruction date	Checked by	
					Prod.	QC
1.	30 ml Amber vials					
2.	20 mm rubber closures					
3.	20 mm aluminium seals					
4.	Labels					
5.	punching box					
6.	Shipper					

MASTER CONTROL CARD

PACKING DETAILS			BSR TRANSFER DETAILS		
DATE	**UNITS PACKED**	**TOTAL**	**DATE**	**UNITS TRANSFERRED**	**TOTAL**
	TOTAL			TOTAL	

Sr. No.	PARTICULAR	QUANTITY
1.	Quantity transferred to BSR	
2.	Bulk sample	
3.	I. P. Q. C. samples	
4.	Finished samples	
5.	Control samples	
6.	Other samples	
	Grand total	

% Yield (in liters) = $\frac{\text{Grand total units X Pack size}}{1000}$

PACKING INCHARGE	**APPROVED CHEMIST**	**PRODUCTION MANAGER**	**Q.C. MANAGER**

QUALITY ASSURANCE: IN PROCESS CHECK RECORD

B.No.: Pack size :
Date**:** Checked by :

O B S E R V A T I O N S

a) Formula card No.**:** M.F.C. No. 14

Date	b) Steps being carried out	DEVIATION NOTICED **:**
		ACTION RECOMMENDED **:**
		ACTION TAKEN **:**

c) Description**:**

e) Fill volume in ml**:**
For 30 ml = NLT 30 ml.

Date	Time	1	2	3	Sealing Quality	Visual inspection

QUALITY ASSURANCE: IN PROCESS CHECK RECORD

Date e) **PACKING :-**

Batch Details : -

Batch No. : -

Mfg. Date : -

Exp. Date : -

M.R.P. Rs Inclusive of all Taxes

Mfg. Lic No. 809

Line Clearance : -

Line Identification: -

Observation on the Finished Packs:

Checked at Random packed vials and Shippers

No. of Vials / Shippers

Batch Details tallied on vials labels and shippers.

Clarity of overprinted batch details.

Sealing of vials.

CONCLUSION: The observations of many of the tests carried out are indicative of the fact that the various specifications laid down for this batch has been /not been followed.
Signature / Date. :

INTIMATION FOR FINISHED PRODUCT

Date of Intimation	Mfg. Date	Exp. Date	Filled quantity	Quantity Sampled	Intimation given by prod. Chemist	Sampled By QC chemist

TESTS	RESULTS	LIMITS	INITIALS
DESCRIPTION		-------	
IDENTIFICATION		-------	
pH of Solution		3.5 to 6.0	
Extractable Volume		For 30 ml: NLT 30 ml	
ASSAY : - Paracetamol IP		90 to 110 %	
Particulate Matter		----	
Sterility Test		----	

Conclusion: - The Sample complies / Does not Comply with Product Specification No. STP. 14.

Date of Issue of PASS / REJECTION slip.

Q.C. HEAD

3. **Description:** A clear, colourless oily solution.
Observation:

Complies/Does not comply.

---

4. **Identification: a)** 1 mg of test sample in sufficient methanol to produce 100 ml. To 1ml of this solution add 0.5 ml of 0.1M Hydrochloric acid & dilute to 100 ml with methanol. Protect the resulting solution from bright light & immediately measure the absorbance at the maximum at about 249 nm.
Observation:

Spectrophotometer No.:
Limit: Absorbance about 0.44
Complies/Does not comply.

---

b) Boil 2 ml of test sample in 1 ml of Hydrochloric acid for 3 minute, add 10 ml of water & cool, no precipitate. Add 0.5 ml of 0.0167 M Potassium dichromate to above solution. A violet colour develops which does not turn red.
Observation: A violet colour develops/ does not develop which turn/ does not turn red.

Complies/Does not comply.

---

3. **pH :** pH meter No.:
_____ (Limit: 3.5 to 6.0)

Complies/Does not comply.

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4. **Assay:** Take 2 ml of injection, add 50 ml of 0.1N Sodium hydroxide & 100 ml of water. Shake for 15 minute, add sufficient water to produce 200-ml & mix. Take 10 ml of this solution in 100-ml volumetric flask & dilute upto mark with water. Take 10 ml of resulting solution in a 100-ml volumetric flask, add 10 ml of 0.1N Sodium Hydroxide & dilute upto mark with water. Measure the absorbance at **257-nm** taking 715 as the value of A (1%, 1 cm).
Observation:

Spectrophotometer No.:
Balance No.

Paracetamol: Abs at 257 nm;
Test =

$$= \frac{\text{Test reading} \times 1000 \times 200 \times 100 \times 100}{715 \times 100 \times 2 \times 10 \times 10}$$

Limit: 90 to 110 %
Complies / Does not comply.

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5. **Sterility Test:**
Report No.: _____

Complies / Does not comply.

6. Extractable Volume:

1) 2) 3) 4) 5)

6) 7) 8) 9) 10)

Mean:
(Between 30 to 31 ml)
Complies / Does not comply.

Analyst: Checked by: