



PHARMADEVILS

QUALITY ASSURANCE

CLEANING VALIDATION PROTOCOL

Document Name: Cleaning Validation Protocol For Cefixime-100 DT Tablets

Document No.:

Rev No.: 00

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Annexure-8
Microbiological Results



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S.No.	Sampling Location	Batch Number of Previous Product			Acceptance limit Total aerobic bacterial count NMT 100 cfu/swab. Yeast, mould and pathogens shall be absent.*
1.	Vibro Sifter				
	Outlet of Feeder Hopper				
	Inner Surface of Sifter Bowl				
	Sifter Sieve surface				
	Gasket of Sifter Ring				
2.	Multimill				
	Inner surface				
	Discharge Valve				
3.	Roll Compactor				
	Hopper				
	Roll of Machine				
	Outlet				
4.	Octagonal Blender				
	Side Wall Corner				
	Discharge Port				



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S.No.	Sampling Location	Batch Number of Previous Product			Acceptance limit Total aerobic bacterial count NMT 100 cfu/swab. Yeast, mould and
	Gasket				
5.	Tray Dryer				
	Upper Tray				
	Middle Tray				
	Lower Tray				
6.	Compression Machine-16 Stations				
	Turret				
	Discharge Chute				
	Inner Surface of Hopper				
	Punch Tip				
7.	Compression Machine-27 Stations				
	Turret				
	Discharge Chute				
	Inner Surface of Hopper				
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S.No.	Sampling Location	Batch Number of Previous Product			Acceptance limit Total aerobic bacterial count NMT 100 cfu/swab. Yeast, mould and
	Punch Tip				
8.	Auto Coater				
	Inner surface of pan				
	Edges of pan				
9.	Strip Packing Machine				
	Hopper				
	Tablet Falling Chute				
	Bowl				
10.	Blister Packing Machine				
	Hopper				
	Tablet Falling Chute				
	Feeding Box				
11.	Alu-Alu Packing Machine				
	Hopper				



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S.No.	Sampling Location	Batch Number of Previous Product			Acceptance limit Total aerobic bacterial count NMT 100 cfu/swab. Yeast, mould and
	Tablet Falling Chute				
	Feeding Box				

***If present specify type of organisms.**

Conclusion: _____

Checked By:

Verified By:

Approved By:

(Signature/Date)(Signature/Date)(Signature/Date)