Annexure-3
Product Details

PHARMADEVILS

QUALITY ASSURANCE

CLEANING VALIDATION PROTOCOL

Document Nam: Cleaning Validation Protocol for Cefixime-100 DT Tablets

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Table I: Product details

Product Name	Active Ingredient	Solubility in water	Strength	Batch Size	Lowest Recommended Daily Dose (LRDD)	Maximum Recommended Daily Dose (MRDD)
Cefacel-100 DT	Cefixime	Insoluble	100 mg	50 Kg	100 mg	400 mg
Cefacel-200 DT	Cefixime	Insoluble	200 mg	82.5 Kg	100 mg	400 mg
Cephalkem-DT 125	Cephalexin	Slightly Soluble	125 mg	90 Kg	125 mg	250 mg
Cephalkem-DT 250	Cephalexin	Slightly Soluble	250 mg	168 Kg	125 mg	250 mg
Cefacel-O/Xspin-O/Cwiz-OX	Cefixime	Insoluble	200 mg	77.55 Kg	100 mg	400 mg
	Ofloxacin	Slightly Soluble	200 mg		200 mg	800 mg
C-fonir 200 DT	CefpodoximeProxetil	Slightly Soluble	200 mg	55.00 kg	100 mg	400 mg

CLEANING VALIDATION PROTOCOL

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Ref. No.	Item / Justification
Solubility of API in water	
1	Cefixime is practically insoluble in water. As soluble products are removed easily during cleaning by solubilizing the product, so it can be rinsed away. Insoluble materials, on the other hand, will resist going into solution and must be removed by a physical means or using other methods.
2	Cephalexin is slightly soluble in water, so it can be removed during cleaning.
Potency	
5	Lowest recommended daily dose (LRDD) of Cefixime is 100, so it is potent drug.
7	Lowest recommended daily dose (LRDD) of Cephalexin is 125 mg, so it is less potent drug in the group.

Conclusion:_____
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Checked By: Verified By: Approved By:

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