



Document Name: Annexure 4 (Equipment Grouping)

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Annexure-4 Equipment Grouping



Pharma Devils

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QUALITY ASSURANCE DEPARTMENT**Document Name:** Annexure 4 (Equipment Grouping)**Revision No.:** 00**Document Number:****Effective Date:**

Product Name		Levonorgestrel	Mifepristone	Norethindrone
Type of product		Coated tablet	Uncoated tablet	Uncoated tablet
Equipment Used in Process	Contact Surface Area (cm ²)	Group- A		
RM Sampling, Dispensing, Blending and Sieving Isolator (only vibro sifter)	500	X	Y	X
Vibro sifter	23175	Y	Y	Y
Rapid mixer granulator (RMG)	24058	Y	Y	Y
Fluid bed dryer (FBD)	43680	Y	Y	Y
Tipper	5760	Y	Y	Y
Cone mill	4345	Y	Y	Y
Blender bin (100 L)	89544	Y	Y	Y
Tablet Compression Machine	6306.29	Y	Y	Y
Be- coater	45632.3	Y	X	X
Blister machine	8503	Y	X	Y
Blister machine (Alu-Alu)	2931	X	Y	X



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Deduster	5713	Y	Y	Y
Metal Detector	1428	Y	Y	Y
Glove Box	3176	Y	Y	Y
Paste Kettle	2953	X	Y	X
Scoop	1356	Y	Y	Y
Sampling rod	472	Y	Y	Y
Spatula	63	Y	Y	Y
Spatula	462.5	X	X	X



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Product Name		Misoprostol
Type of product		Uncoated tablet
Equipment Used in Process	Contact Surface Area (cm ²)	Group B
RM Sampling, Dispensing, Blending and Sieving Isolator	500	Y
Vibro sifter	23175	Y
Rapid mixer granulator (RMG)	24058	X
Fluid bed dryer (FBD)	43680	X
Tipper	5760	X
Cone mill	4345	X
Blender bin (100 L)	89544	Y
Tablet Compression Machine	6306.29	Y
Be- coater	45632.3	X
Blister machine	8503	X
Blister machine (Alu-Alu)	2931	Y



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Deduster	5713	Y
Metal Detector	1428	Y
Glove Box	3176	Y
Paste Kettle	2953	X
Scoop	1356	Y
Sampling rod	472	Y
Spatula	63	Y
Spatula	462.5	X

Note: Y = Equipment used in process

X = Equipment not used in process

Conclusion: _____

Checked By:
(Signature/Date)

Verified By:
(Signature/Date)

Approved By:
(Signature/Date)