



Document Name: Annexure-9 (Microbiological Results)

Revision No: 00

Document Number:

Effective Date:

Annexure-9

Microbiological Results



Document Name: Annexure-9 (Microbiological Results)

Revision No: 00

Document Number:

Effective Date:

Sr. No.	Sampling Location	Batch Number of Previous Product						Acceptance limit
1.	Fluid Bed Dryer	TBC	TYMC	TBC	TYMC	TBC	TYMC	Total aerobic bacterial count NMT 100 cfu/swab. Yeast, mould and pathogens shall be absent.*
	FBD Bowl sieve							
	Internal surface of FBD bowl							
	Internal surface of chamber							
	View window							
	Lower plenum							
	Upper plenum							
	Plenum gaskets							
2.	Rapid Mixer Granulator							
	Impeller							
	Chopper							
	Discharge port							
	Lid gasket							
	Internal surface of bowl							
	Loading port							
	Internal surface of lid							
	Discharge port gasket							
	Bottom surface of bowl							
3.	Vibro Sifter							
	Lower hopper							
	Lid							
	Upper hopper							
	Discharge chute							
	Internal surface of lid							
	Sieve							



Document Name: Annexure-9 (Microbiological Results)

Revision No: 00

Document Number:

Effective Date:

Sr. No.	Sampling Location	Batch Number of Previous Product						Acceptance limit
		TBC	TYMC	TBC	TYMC	TBC	TYMC	
4.	Blender Bin							Total aerobic bacterial count NMT 100 cfu/swab. Yeast, mould and pathogens shall be absent.*
	Inner surface of bin							
	Discharge port							
	Inner surface of charging port							
5.	Compression Machine							
	Connector							
	Powder Hopper							
	Force Feeder							
	Tablet discharge chute							
	Turret							
	Rejection box							
6.	Deduster							
	Inlet chute							
	Outlet chute							
	Spiral disc							
7.	Metal detector							
	Feeding chute							
	Outlet chute							
	Rejection box							
8.	Glove Box							
	Deflector plate							
	Spool piece							
	Inner surface							
	Gloves (internal surface)							



Document Name: Annexure-9 (Microbiological Results)

Revision No: 00

Document Number:

Effective Date:

		TBC	TYMC	TBC	TYMC	TBC	TYMC
9.	Paste Kettle						
	Inner surface						
	Stirrer						
10.	Blister Packing Machine						
	Hopper						
	Bowl disc						
	Feeding box & channel						
11.	Be- Coater						
	Inner surface of coating pan						
	Baffle						
	Discharge chute						
	Spray gun assembly						
	Internal surface of view window						
12.	Dispensing Isolator						
	Glove surface						
	Cage blender (inner surface)						
	Vibro sifter (inner surface)						
	Rapid transfer port						
	Isolator inner surface						
	Isolator front cover (inner surface)						
13.	Cone Mill						
	Charging port						
	Screen						
	Milling chamber						
	Blade assembly						
	Discharge port						

Total aerobic bacterial count
NMT 100 cfu/swab.
Yeast, mould and pathogens
shall be absent.*



Document Name: Annexure-9 (Microbiological Results)

Revision No: 00

Document Number:

Effective Date:

Sr. No.	Sampling Location	Batch Number of Previous Product						Acceptance limit
14.	Tipper	TBC	TYMC	TBC	TYMC	TBC	TYMC	Total aerobic bacterial count NMT 100 cfu/swab. Yeast, mould and pathogens shall be absent.*
	Inner surface							
	Discharge port							
	Gasket groove							
15.	Sampling and Cleaning Station							
	Bottom surface							
	Sampling station							
	Spray ball mounting plate							
	Gloves surface							
	Spray ball							
16.	Blister Machine (Alu-Alu)							
	Hopper							
	Bowl disc							
	Feeding box							
	Feeding channel							
17.	IPQC Isolator							
	Glove surface							
	Rapid transfer port							
	Isolator inner surface							
	Isolator front cover (inner surface)							
18.	Solution preparation vessel							
	Inner surface of lid							
	Stirrer							
	Inner surface of vessel							



Document Name: Annexure-9 (Microbiological Results)

Revision No: 00

Document Number:

Effective Date:

Sr.No.	Sampling Location	Batch Number of Previous Product						Acceptance limit
19.	Scoop	TBC	TYMC	TBC	TYMC	TBC	TYMC	Total aerobic bacterial count NMT 100 cfu/swab. Yeast, mould and pathogens shall be absent.*
	Scoop surface							
20.	Sampling rod							
	Inner surface of tube							
21.	Spatula							
	Spatula surface							

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

Conclusion: _____

Checked By:
(Signature/Date)

Verified By:
(Signature/Date)

Approved By:
(Signature/Date)