

Area Audited						Comments
Audit Date						
Week	Wk1	Wk2	Wk3	Wk4	Wk_	
GMP ITEMS	Comply ✓ Yes Or X No					
All baskets, containers, pallets and bulk raw material bins are clearly labelled.						
Area waste bins are not over flowing.						
Waste bins are used for appropriate materials only.						
Floors are free of tablets, waste, spills and excess materials.						
Personnel wearing uniform as stated in SOP MAN-005. Hair is covered, sleeves covering arm, no jewellery other than small sleepers.						
Equipment not in use is stored so it does not hinder access to the line.						
Documentation is located in one area. No stray documents are on the line.						
Entries into logbooks are complete and in permanent blue or black ink. (Register, Non-compliance, Start of-Day)						



Corrected entries in logbooks over the last week have a single line through the entry, initialled and dated.			
Computer monitors are clear of Post It Notes.			
Scales kept clear, items removed after being weighed.			
Calibration stickers on line equipment are current (Scales, Micrometers)			
IPA bottles labelled and within expiry			
All bottles containing thinners are labelled.			



ENVIRONMENT, HEALTH AND SAFETY ITEMS	Comply ✓ Yes Or X No					
Personnel wearing safety glasses and gloves when using IPA.						
Product and packing materials are stored within marked holding areas.						
Pallet lifting devices stored away from traffic areas.						
All fire/emergency exits and stairs are clear.						
Safety clothing/equipment worn and used correctly for the appropriate tasks, (aprons, gloves etc.).						
Fire extinguishers and hoses visible and accessible.						
All fire extinguishers in test (Tested 6 monthly).						
Safety signs are clearly visible.						



SOPs	Comply ✓ Yes Or X No	Comments				
SOP Files are accessible and filed alphanumerically.						
Superseded versions have been returned to Technical.						
BLUE DYE LEAK TEST AREA (2 audits/month required)	Comply ✓ Yes Or X No					
Blue Dye Leak Test area is clean, tidy and floor is free of spillage.						
IPA bottles labelled and within expiry.						
SOP is accessible and version current.						



PACKAGING AREAS	Comply ✓ Yes Or X No	Comments				
Only bulk tablets for the batch stored on line.						
Reclaimed tablets are covered. Area kept tidy with de-blistered waste disposed of.						
Tablet reclaim containers show no build up of residue.						
All tablets for reclaim are placed in labelled containers.						
Components stored neatly in Staging area.						
Gloves worn when handling product.						
Vacuum cleaner, hoses, electrical leads and compressed air stored in designated area.						



AREA(S) AUDITED				
Audit Date				
Week	Week 1	Week 2	Week 3	Week 4
Shift				
Auditor (Please Print Name)				
Auditor Signature				
Date				
Manager Signature				
Date				

COMPLETED FORMS ARE TO BE SENT TO TEAM QA AT THE END OF THE MONTH