1. Master Batch Record Approvals			
	Name	**Signature**	**Date**
Originator	**Ravikanth Kona**		
Production	**Ravikanth Kona**		
Quality Control	**Seon Hepburn**		
Quality Assurance	**Stephen Hoag**	Stephen W Hoag	

2. Product Details	
Description	Fexo A- Fexofenadine Hydrochloride 60 mg Tablets HPC: 5%; Inlet temp: 50 ^{0}C; Compression force: 5 kN
Part No.	F-7046
Batch Quantity	Batch size: 350 gm. Approx No. tablets: _____
Storage Conditions	Ambient - conditions, store in tight container protected from light and moisture

3. Production Batch Record Issuance

Issued By – Issuer has reviewed the Batch Record to ensure that the copy is a complete, accurate copy of the Master Batch Record.

Stephen W. Hoag		
(Print) Issued By – Quality Assurance	Signature	Date

Issued To – Production has reviewed the Batch Record to ensure that the copy is a complete and correct. Production is responsible for the Batch Record following issuance.

Ravikanth Kona		
(Print) Issued To - Production	Signature	Date

Lot Number:		

4. Signature and Training Log

All personnel making entries on this Batch Record must complete the Signature Log. Completion of the Signature Log indicates that each person has been thoroughly trained on this Batch Record and all documents listed in Section 5: Reference Documentation.

Note: The Signature Log completion does not supersede the requirements of *GMP Training Program* (SOP-006).

Name	Signature	Initials	Date
Ravikanth Kona			
Stephen W. Hoag			

5. Reference Documentation

SOP-003: Good Documentation Practices
SOP-006: GMP Training Program
SOP-005: Nonconformances
SOP-009: Material Storage and Inventory Procedure
SOP-011: Facility Cleaning Procedures
SOP-012: Temperature and Humidity Monitoring
SOP-015: Gowning Procedures
SOP-017: Retain Sample Program
SOP-019: Material weighing and Dispensing
SOP-020: Equipment Calibration
SOP-021: Batch Records
SOP-025: B2 Stokes tablet press
SOP-0 : V- blender
SOP-0 : Fluid bed

Lot Number:		

6. Bill Of Materials

Description	Part Number	Quantity Req'd	Lot No.	Qty Staged	Exp / Retest	Performed By / Date	QA Verified By / Date
Fexofenadine Hydrochloride	R-1057		CI0 6026				
Avicel PH 102 (Microcrystalline cellulose)	R-1002		P209820744				
Klucel EXF (Hydroxypropyl cellulose)	R-1019		25604				
Lactose monohydrate 110M	R-1012		10536575				
Mg Stearate - Kosher Passover (Covidien)	R-1017		K22610				
Kollidon K-30 (Polyvinyl pyrollydone)	R-1013		G10976PT0				
Ac-Di-Sol (Croscarmellose Na)	R-1016		P211822782				
Aerosil® 200 (Aerosilized silica)	R-1005		1011011900				
Sterile water	R-1038						

Lot Number:		

7. Processing Equipment					
Equipment Description	ID No.	Previous Cal.	Cal. Req'd	Performed By / Date	QA Verified By / Date
Fluid bed (Fluid Air® model # 0002)	UMB-				
B2-Stokes tablet press	UMB-0013	05/26/2010	Meets requirement	UMB internal calibration	
Balance – OHAUS CD 33	UMB-	02/23/2012	Meets requirement	Stanley (American Scale & Equipment co Inc)	
Check wt. wt. = _____ wt. = _____ wt. = _____	Mes. Wt. _____ _____ _____	Toler ±0.1% _____ _____ _____	Check at least 3 wts in the range to be measured	If tolerance outside 0.1% range call QA	
Balance – Mettler PC 440	UMB-	02/23/2012	Meets requirement	Stanley (American Scale & Equipment co Inc)	
Check wt. wt. = _____ wt. = _____ wt. = _____	Mes. Wt. _____ _____ _____	Toler ±0.1% _____ _____ _____	Check at least 3 wts in the range to be measured	If tolerance outside 0.1% range call QA	
V- blender (Kelly Patterson)	UMB-		Meets requirement	UMB internal calibration	
Timer – VWR Model# 62344-912	UMB-	2011-calibration expires 10/17/2013	Meets requirement	Control Company	

Lot Number:		

Sieve (Cole Palmer) sizes 18 and 30	NA	NA	NA	NA	
Masterflex® precision pump tubing (96410-14)	NA	NA	NA	NA	
Mettler Toledo LOD equipment	NA	NA	NA	NA	

8. Area Clearance		
Step	**Performed By / Date**	**QA Verified By / Date**
1. GMP Processing Area(s): Room: _____		
2. Review the GMP Processing Area Logbook(s) and ensure that the Logbook(s) is (are) complete, and up-to-date.		
3. Review all applicable GMP Processing Area Logbook(s) and verify that Cleaning and Sanitization has been performed according to *Facility Cleaning Procedures* (SOP-011), and that the Cleaning and Sanitizing occurred within the allowed time before a GMP operation. Date Cleaning Complete: _____ Date Sanitizing Complete: _____		
4. Verify that all work surfaces within the GMP Processing Area have been Sanitized (e.g., wiped with NLT 70% Isopropanol) on the day of production. Verify that this Sanitization has been recorded in the Logbook(s).		
5. Review Section 6: Bill of Materials, and ensure that it is complete, accurate, and that all necessary materials are present for the GMP operation. Ensure that all GMP Materials are Released, Approved and have sufficient time to the Use By Date.		

Lot Number:		

6. Review Section 7: Processing Equipment, and ensure that it is complete, accurate, and that all necessary equipment is present, cleaned and calibrated, as appropriate. Review the Logbook for each piece of GMP Equipment, and ensure that the Logbooks are correctly filled out. Fluid bed (UMB-00) - _____ Twin shell blender (UMB-00) –_____ B2-Stokes tablet press (UMB-0013) –_____		
7. Verify that the cGMP Processing Area does not contain any items from previous batches or cleaning activities and that no items unrelated to the current cGMP batch are present.		
8. Area Clearance Complete. QA shall Complete the Area Clearance Sign (SOP-021, Attachment 1) and affix it to the GMP Processing Area entrance.		

9. Production Procedure **Processing Step**	**Performed By / Date**	**Verified By / Date**

Lot Number:		

9. Production Procedure Processing Step	Performed By / Date	Verified By / Date
1. Weigh the API and excipients separately into a suitable container/plastic bags in Room 670. Check for lumps and screen the material if required using an 18 mesh screen. Fexofenadine Hydrochloride (R-1057) – 15% Required 52.5 gm; Weighed _____gm. Avicel PH 102 (Microcrystalline cellulose) (R-1002) - 38.63% Required 135.21 gm; Weighed _____gm. Lactose 110M (Lactose monohydrate) (R-1012) – 38.63% Required 135.21 gm; Weighed _____gm. Ac-Di-Sol (Croscarmellose Na) (R-1016) – 1.25% Required 4.38 gm; Weighed _____gm. Kollidon K-30 (Polyvinyl pyrollidone) (R-1013) – 6.5% **Note: 15% w/w solution in sterile water** Required 151.67 gm; Sprayed _____gm. Total weight of the blend (excluding the weight of the extragranular fraction) Label the container/bags - "Fexofenadine blend – Formulation A"		
2. Carefully transfer **ALL** the weighed materials into 8qt V-twin shell blender i.e blender **UMB-00** check the fill volume once **ALL** the materials are transferred to the twin shell blender container. Fill volume _____% (visual inspection). If the fill volume is 40 to 70% of the blender - proceed to blending step (Step 6)		
3. Blend for 5 min: Start Time: _____min; End Time: _____min		

9. Production Procedure Processing Step	Performed By / Date	Verified By / Date
4. With a clean sampling thief (Conbar - 5200) or spatula carefully collect 2 samples from each arm of the twin shell blender (approx 2 gm) into labeled scintillation vials (for Near infrared spectroscopy scans to test for blend uniformity). 5. Label the vial "Blend + lot number" 6. **Note:** Sample materials 3-5 cm from the surface of the powder bed with minimal disturbance to the powder bed.		
7. Carefully transfer the contents of the twin shell blender into a suitable plastic bag. **Note:** Minimize the height of pouring to reduce segregation. 8. Label the plastic bag "Fexo A blend + lot number"		
9. Double bag it and set it aside for Fluid bed granulation Weight of material being granulated _____ gms.		
10. Before granulation, follow area clearance steps 1-8.		
11. For Fluid bed equipment set-up and operation, follow SOP-0		
12. Program Pyrobuttons and NIR process analyzer (please refer equipment/software manual for detail procedures)		
13. Preheat Fluid bed to an air inlet temp of 50^0C, make sure this temperature is maintained for 5 min., then charge "Fexo A blend + Lot number" into fluid bed		

Lot Number:		

9. Production Procedure Processing Step	Performed By / Date	Verified By / Date
14. Before the granulation, record the following: • Relative Humidity: _____ (%) • Temperature:_____ (^{0}c) • LOD Initial blend:_____ (%) • Initial wt of binder sol:_____ gm • Atomization pressure:_____ psi • Binder sol flow rate:_____ gm/min • Granulation start time:_____ • Pyrobutton data collection start time:_____ • NIR data collection start time: _____		
15. During granulation increase the inlet air flow rate by 2 SCFM every 5 min. Record results in table below		
16. Stop spraying the binder solution when the desired amount is added Amount of binder sol sprayed: _____ ml 17. After binder solution spraying ends, lower the SCFM to 6 SCFM for the remaining of the time.		
18. Save the NIR moisture data every 20 min		

9. Production Procedure Processing Step	Performed By / Date	Verified By / Date

19. Record the following parameters every 5 min during granulation and drying.

Time (min)	Inlet air (SCFM)	Inlet temp (^{0}c)	Outlet temp (^{0}c)	Product temp (^{0}c)
0				
5				
10				
15				
20				
25				
30				
35				
40				
45				
50				
55				
60				
65				

20. Sample approximately 1 gm of material every 5 min through the sample port to determine the moisture levels and record the following parameters.

Time (min)	NIR Probe ID	LOD (%)
0		
5		
10		
15		
20		
25		
30		
35		
40		
45		
50		
55		
60		

9. Production Procedure Processing Step	Performed By / Date	Verified By / Date
21. Stop the drying process when desired granule moisture content is reached. Limit: NMT 1% of starting moisture Final Moisture: _____(%) 22. Sieve the granules using Mesh # 18 and transferee the material into appropriate bag and label: "Fexo A granules + lot number" 23. Record the following parameters at the end of drying: • **Granulation end time:** _____ • **Pyrobutton data collection end time:** _____ • **NIR data collection end time:** _____ • **Final weight of granules: _____ gm** 24. Calculate yield (%) = _____gm		
25. Read and save all the pyrobutton data		

9. Production Procedure Processing Step	Performed By / Date	Verified By / Date
26. Weigh the following extragranular portion: Granules (Fexo A granules + lot no) 85% Final granulation total blend 200 g; 85% granules Required ___170___ gm; Weighed _____gm. Avicel PH 102 (Microcrystalline cellulose) (R-1002) – 9% Required __18_gm; Weighed _____gm. Klucel EXF (Hydroxypropyl cellulose) (R-1019) – 5% Required __10____gm; Weighed _____gm. Magnesium Stearate - Kosher Passover (Covidien) (R-1017) – 0.5% Required ___1__gm; Weighed _____gm. Aerosil® 200 (Aerosilized silica) (R-1005) – 0.5% Required ___1__gm; Weighed _____gm. 27. Sieve the extragranular excipients using Mesh # 30 28. Carefully transfer **ALL** the weighed materials into 8qt V-twin shell blender i.e blender **UMB-00** . 29. Check the fill volume once **ALL** the materials are transferred to the twin shell blender container. Fill volume _____% (visual inspection).		
30. Blend for 2 min: Start Time: _____min; End Time: _____min		

9. Production Procedure Processing Step	Performed By / Date	Verified By / Date
31. Carefully transfer the contents of the twin shell blender into a suitable plastic bag. **Note:** Minimize the height of pouring to reduce segregation. 32. Label the plastic bag "Blend for tableting: "Fexo A + lot number"		
33. Set-up the tablet press with the hopper, feed frame and the force transducers (National instruments) attached to the computer system as described in the SOP-025. **Pay careful attention to the safety notes outlined in the Operating procedures of SOP-025.** 34. Ensure that the gap between the feed frame and the die table is paper thick (A regular A4 paper should be able to slide in and out between the die table and the feed frame)		
35. Carefully pour the material (**Blend for tableting: Fexo A + lot number**) into the feed frame of the tablet press. 36. Manually operate/rotate the tablet press to ensure that the feed frame is evenly filled with the granules and flow well onto the die table and die cavity.		
37. Continue the rotation to produce a couple of tablets - ensure that all the parts of the press are working (SOP-025). Target weight of the tablets is 470 mg, however a range 460 – 480mg [**Target weight = 470 mg**]. 38. Power on the computer and the National Instruments chassis attached to the force transducers on the tablet press. Start the national instruments software and begin monitoring the compression forces on the tablet press (as described in SOP-025).		

9. Production Procedure Processing Step	Performed By / Date	Verified By / Date
39. Turn on the tablet press, allow the machine to stabilize i.e. discard first 5 tablets and check the weight of the next 2 tablets. Adjust the height of the weight control cam to make 470±10 mg tablets. 40. Using the transducers and software (National instruments) adjust the compression force to _____mV.		
41. Throughout the collection time monitor and ensure that the compression force is within limits (Step 43). 42. Collect tablets until the end of production. Transfer these tablets into previously labeled containers "Fexo A-Fexofenadine Hydrochloride USP 60 mg" 43. At the end of the run perform cleaning according the SOP-027		
10. Post-Production Sampling, Material Transfer and Storage		

11. Yield Calculations

Granulation Yield

$$\text{Yield} = 100 \times \frac{\text{weight of granulation}}{\text{weight of powder (350 gm)}}$$

Yield = _____

Lot Number:		

12. Production Comment Log

Record any comments or observations from the production process. Initial and date each comment. Quality Assurance shall review, initial and date each comment or observation following production.

Comment / Observation	Step No	Performed By / Date	QA Verified By / Date
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

13. Exception Log

Record all Exceptions that occur during the production process. Quality Assurance shall review, classify, initial and date each entry following production, or as required. Planned Deviations and Nonconformances require a documented Nonconformance Report according to *Nonconformances* (SOP-005).

Exception	Documented By / Date	Class (E, PD, NC)	QA Verified By / Date
1.			
2. .			
3. .			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

E = Exception

PD = Planned Deviation

NC = Nonconformance

Lot Number:		

14. Post- Production Review			
The complete Post-Production Batch Record has been reviewed for completeness and accuracy. All pages are complete and all entries conform to Good Documentation Practices.			
	Name	**Signature**	**Date**
Production	Ravi Kona		
Quality Assurance	Stephen W. Hoag		

15. Quality Assurance Disposition			
The material produced through the execution of this Batch Record shall be Dispositioned by QA according to *Material Disposition and Status Labeling* (SOP-010). The Disposition shall be recorded below.			
☐	**RELEASED**	**Quantity (Units)**	
☐	**CONDITIONAL RELEASE**	**Quantity (Units)**	
☐	**RESEARCH USE ONLY**	**Quantity (Units)**	
☐	**REJECTED (Include Comments)**	**Quantity (Units)**	
UMB assigned Use-By Date (MM/DD/YY or MM/YY)		**Retest Expiration**	
Comments			
Stephen W. Hoag (Print) Performed By - Quality Assurance		Signature	Date

16. Version Summary
New

Lot Number:		