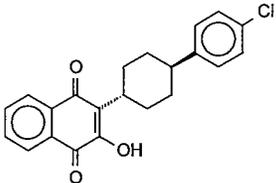
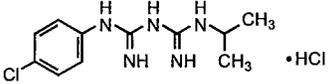


**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**21-078 / S-005**

**CHEMISTRY REVIEW(S)**

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION: HFD-590	2. NDA NUMBER: 21-078
3. NAME AND ADDRESS OF APPLICANT: (City and State) GlaxoSmithKline One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101		4. SUBMISSION TYPE: CBE 30	
		5. SUPPLEMENT(S):	
		NUMBER(S): SCS-005	DATE(S): 21-NOV-2002
6. NAME OF DRUG: MALARONE™ Tablets		7. NONPROPRIETARY NAME: Atovaquone/proguanil hydrochloride tablets	
8. SUPPLEMENT PROVIDES FOR: Scale-up in the manufacturing process and equipment for MALARONE™ (250 mg atovaquone/100 mg proguanil hydrochloride) Tablets.		9. AMENDMENTS/REPORTS:	
10. PHARMACOLOGICAL CATEGORY:  Antimalarial	11. HOW DISPENSED:  [X] Rx [ ] OTC	12. RELATED IND/NDA/DMF(S):	
13. DOSAGE FORM(S): Tablets		14. POTENCY(IES): 250 mg atovaquone/100 mg proguanil hydrochloride	
15. CHEMICAL NAME AND STRUCTURE:		16. MEMORANDA:	
<div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;">  <p>Atovaquone <i>trans</i>-2-[4-(4-Chlorophenyl)-cyclohexyl]- 3-hydroxy-1,4-naphthalenedione</p> </div> <div style="text-align: center;">  <p>Proguanil 1-(4-chlorophenyl)-5-isopropyl biguanide hydrochloride</p> </div> </div>		<div style="border: 1px solid black; height: 150px; width: 100%;"></div>	
18. CONCLUSIONS AND RECOMMENDATIONS: GlaxoSmithKline has submitted sufficient information to ensure the identity, quality, strength, purity and potency of Malarone Tablets prepared by the proposed manufacturing process. APPROVAL of this supplement is recommended.			
19. REVIEWER: Gene W. Holbert, Ph.D.	SIGNATURE: {See appended electronic signature page}	DATE COMPLETED: 05-MAY-2003	
20. CONCURRENCE: Norman R. Schmuff, Ph.D.	{See appended electronic signature page}		

WITHHOLD 8 PAGE(S)

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Chemistry Review

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Gene Holbert  
5/9/03 10:30:18 AM  
CHEMIST

Norman Schmuff  
5/9/03 01:34:56 PM  
CHEMIST