

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19002/S002

CHEMISTRY REVIEW(S)

SEP 4 1992

CHEMIST'S REVIEW		1. ORGANIZATION HFD - 110	2. NDA Number 19-002
3. Name and Address of Applicant (City & State) The R.W. Johnson Pharmaceutical Research Institute Welsh and McKean Roads Spring House, PA 19477-0776		4. Supplement(s) Number(s) Date(s) SCS -002 3/18/92	
5. Drug Name VASCOR	6. Nonproprietary Name Bepridil Hydrochloride		8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: Revised protocol for stability studies			
9. Pharmacological Category Anti-arrhythmic and Anti-hypertensive	10. How Dispensed <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC		11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Tablets	13. Potency(ies) 200, 300, and 400 mg/tablet		
14. Chemical Name and Structure 1. β -[(2-Methylpropoxy)methyl]-N-phenyl-N-(phenylmethyl)-1-pyrrolidine-ethylamine monohydrochloride monohydrate. 2. 1-[2-(N-Benzylanilino)-1-(isobutoxymethyl)ethyl]-pyrrolidine monohydrochloride monohydrate.		15. Records/Reports Current <input type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input type="checkbox"/> Yes <input type="checkbox"/> No	
16. Comments: Stability protocol is revised according to FDA's Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics - 1987. Note that the guidelines are still being revised to be in accord with EC and other areas of the world.			
17. Conclusions and Recommendations: Approve this supplemental application with the condition that the room temperature conditions be changed from ambient relative humidity to 25°C ± 2°C at a relative humidity to be stated (We are considering a value of NLT 60 % RH).			
18. REVIEWER			
Name Gerald L. Weiss	Signature <i>[Signature]</i>		Date Completed August 24, 1992
19. Distribution: <input checked="" type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

[Signature] 8/31/92

MAY 12 1994

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3. Name and Address of Applicant (City & State) -- The R.W. Johnson Pharmaceutical Research Institute Welsh and McKean Roads Spring House, PA 19477-0776		4. Supplement(s) Number(s) Date(s) SCS -002 3/18/92	
5. Drug Name VASCOR	6. Nonproprietary Name Bepridil Hydrochloride		8. Amendments & Other (reports, etc) - Dates SCS 002 4/14/94
7. Supplement Provides For: Revised protocol for stability studies			
9. Pharmacological Category Anti-arrhythmic and Anti-hypertensive	10. How Dispensed <input checked="" type="checkbox"/> / RX <input type="checkbox"/> / OTC		11. Related IND(s)/ NDA(s)/DMF(s)
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16. Comments: Stability protocol is revised according to FDA's Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics - 1987. Note that the guidelines are still being revised to be in accord with EC and other areas of the world. Room temperature conditions are changed from $\sqrt{\quad}$ ambient relative humidity to 25°C \pm 2°C at a relative humidity of 50% with the intention of increasing the RH to 60% \pm 5% by 1995.			
17. Conclusions and Recommendations: Approve this supplemental application with the conditions and commitments as stated. An approval letter is prepared.			
18. REVIEWER			
Name Gerald L. Weiss	Signature		Date Completed 5/9/94
19. Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

151
4/ 5-10-94