

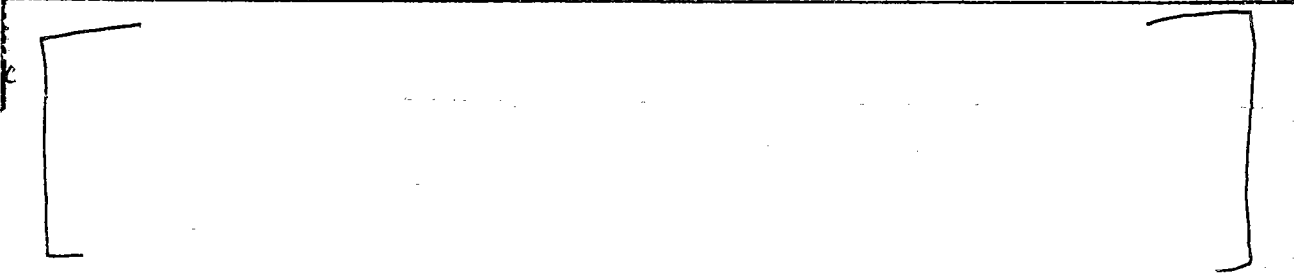
**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**17-558**

**CHEMISTRY REVIEW(S)**

CHEMIST'S REVIEW <i>(If necessary, continue any item on 8 1/2 x 11 inch paper. For continuation to item by number.)</i>		1. ORGANIZATION <b>OSE-DSDDP</b>	2. NDA NUMBER <b>17-558</b>
3. NAME AND ADDRESS OF APPLICANT (City and State) <b>A.H. Robins Co. Richmond, Va. 23220</b>		4. DATE NDA APPROVED! <b>approvable 9-27-74</b>	
5. IF PRIOR TO OCT 10, 1962, DATE APPROVED FOR EFFICACY		6. SUPPLEMENT NUMBER DATE	
6. NAME OF DRUG <b>Robinul Injectable</b>	7. NONPROPRIETARY NAME <b>glycopyrrolate</b>	9. PURPOSE OF SUPPLEMENT <b>FPL on original NDA includes: printed package insert printed 5ml. &amp; 20ml MDV immediate container &amp; carton labels 1ml ampul label copy &amp; 5 x 1ml ampul carton</b>	
10. AMENDMENT DATE(S)		11. OTHER DATE (Report, etc.) <b>NDA orig FPL 12/19/74 &amp; 1/10/75</b>	
12. PHARMACOLOGICAL CATEGORY <b>preoperative antimuscarinic</b>		13. AF NUMBER <b>16-375</b>	
14. DOSAGE FORM <b>sterile solution</b>		15. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	
17. POTENCY(ies) <b>0.2 mg/ml</b>		18. NAS/NRC <input type="checkbox"/> UNDER REVIEW <input type="checkbox"/> REVIEWED	
19. CHEMICAL NAME		20. RECORDS AND REPORTS CURRENT <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
21. CHEMICAL FORMULA  <b>the insert printed on one side only (GI indications to be printed on reverse side), agrees with 9-18-74 draft. the 20 ml. MDV labels agree to orig sub draft. the 1ml. ampul &amp; 5ml. MDV labels appear as submitted 3-29-74.</b>			



23. CONCLUSIONS <b>Recommend approval letter issue with qualifications as stated on attached draft.</b>		cc: <b>NDA 17-558 orig.</b>		R/D Init. by: <b>RAJeruss</b>	
		<b>HFD-102 (Dr. Kumkumian)</b>		<b>1/14/75</b>	
		<b>HFD-108</b>		<b>Final xerox pk</b>	
		<b>HFD-160</b>		<b>1/14/75</b>	
		<b>R/D SKoch: 1/14/75</b>			
24. NAME <b>S. KOCH</b>		SIGNATURE <b>Stanley Koch</b>		DATE COMPLETED <b>1-14-75</b>	
DISTRIBUTION		<input type="checkbox"/> ORIGINAL JACKET		<input type="checkbox"/> DUPLICATE JACKET	
				<input type="checkbox"/> REVIEWER	

NdA 17-558

Division of Surgical - Dental Drug Products

Chemist Review # 1

Date Completed: May 28, 1974

NDA 17-558

A. H. Robins Company  
1407 Cummings Drive  
Richmond, Virginia 23220

AF # 16-375

Product Name(s)

Proprietary: Robinul Injectable

Nonproprietary: glycopyrrolate Injectable

USAN : glycopyrrolate

Compendium: glycopyrrolate official in NF XIII

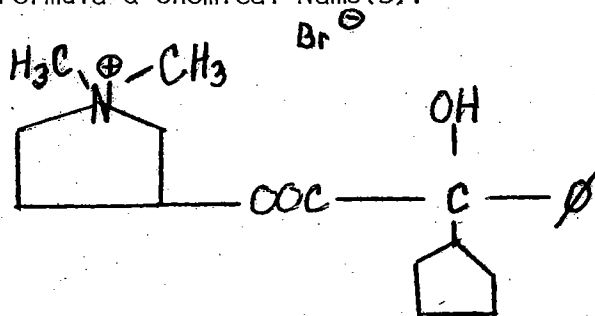
Code name a/o No.: AHR-504  
CAS-596-51-0

Dosage Form(s) & Route of Administration: Injection for IV, IM, SQ

Administration: RX

Pharmacological Category: anticholinergic for use in anesthesia; i.e., preoperative antimuscarinic.

Structural Formula & Chemical Name(s):



3-hydroxy-1, 1-dimethylpyrrolidinium Bromide • - Cyclopentyl mandelate  
1-methyl -3 - pyrrolidyl • - phenylcyclopentane glycolate methobromide

C<sub>19</sub>H<sub>28</sub>BrNO<sub>3</sub>

MW 398.34

M.P. 193.2 - 194.5°C

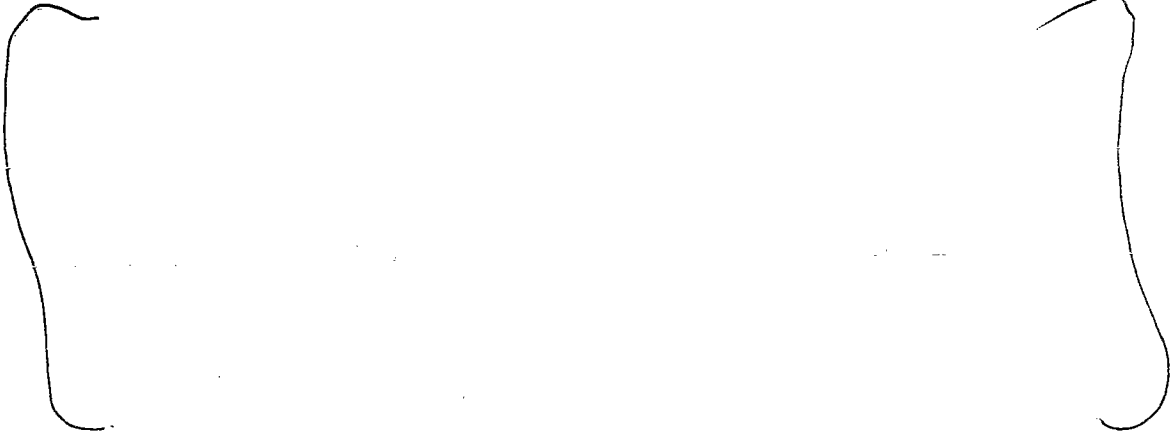
NDA 17-558

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Initial Submission: January 4, 1974, received BD same date

Amendments: March 29, 1974

Supporting documents: NDA 17-558-1511



Conclusion: This application is in "approval" form from the standpoint of manufacturing and controls.

Stanley Koch 6/10/74

cc:NYK-DO

HFD-100

HFD-160

R/D by Stanley Koch 6/10/74

R/D init. R.A. Jerussi 6/10/74

T/F: KD 6/19/74

*SKoch* 6/21/74