


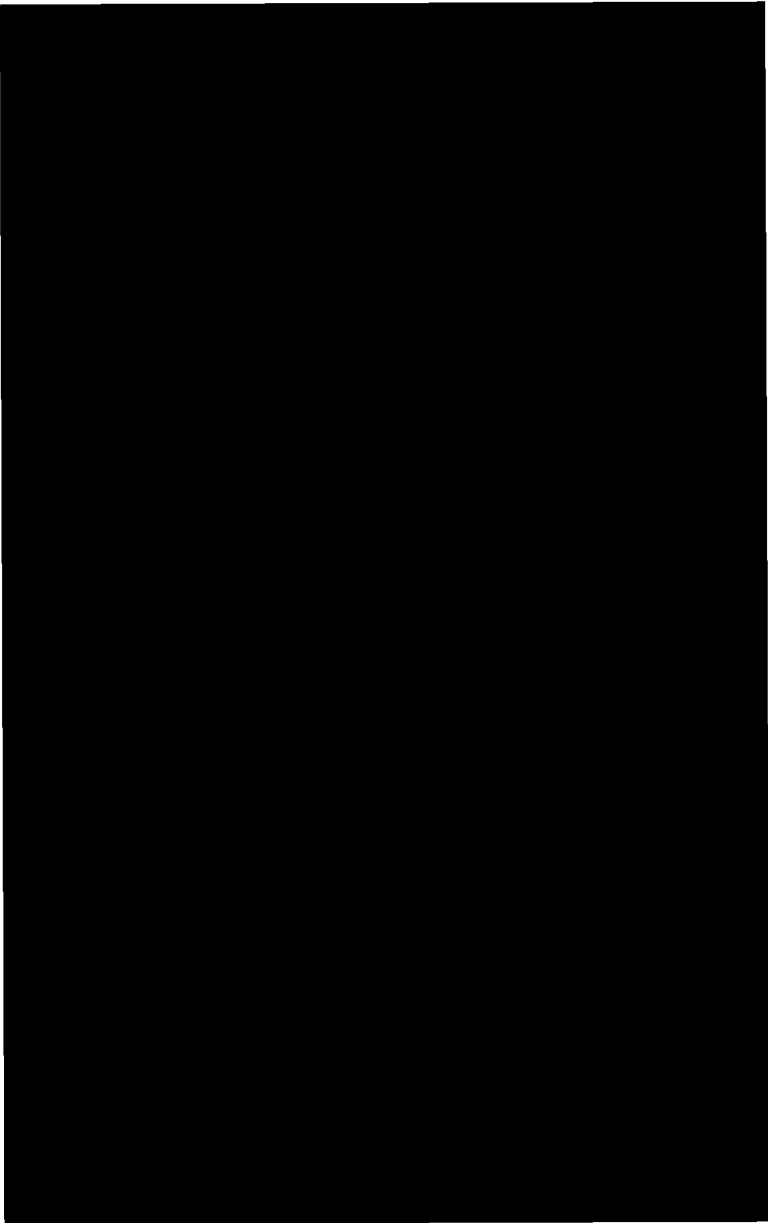

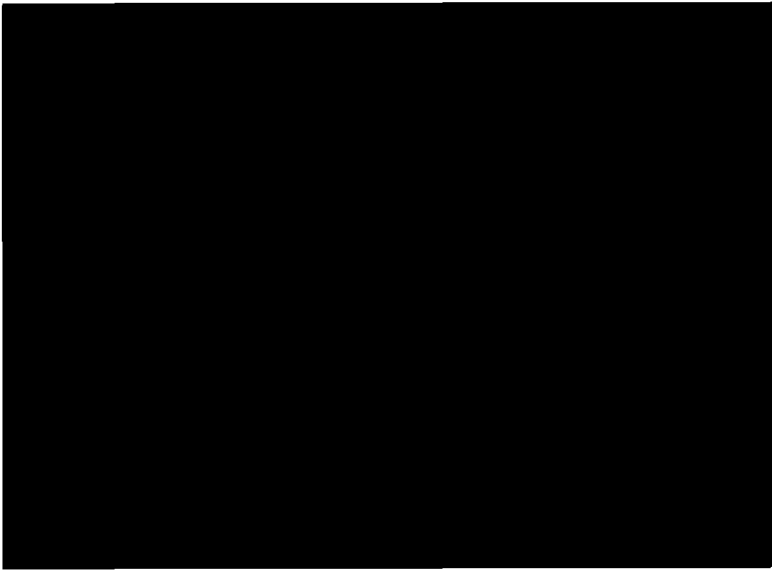


<u>Name of Company:</u> F.H. Faulding & Co. Limited (trading as David Bull Laboratories) <u>Name of Finished Product Medicine:</u> Acyclovir Injection <u>Name of Active Ingredient</u> Acyclovir B.P./U.S.P.	<u>Summary Table Referring to Part II of the Dossier</u>	<u>(For National Authority Use Only)</u>
PART IIB - METHOD OF PREPARATION		
Manufacturing Formula: (Cont.)	Pages: 40-41	(For National Authority Use Only) COMMENTS
		
Manufacturing Process:	Pages: 42-48	
All stages of manufacturing are carried out by: 		

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PART IIB - METHOD OF PREPARATION (Cont.)		
Method of Preparation of Dose Form: Pages: 42-48		(For National Authority Use Only) COMMENTS
		

<u>Name of Company:</u> F.H. Faulding & Co. Limited (trading as David Bull Laboratories) <u>Name of Finished Product Medicine:</u> Acyclovir Injection <u>Name of Active Ingredient</u> Acyclovir B.P./U.S.P.	<u>Summary Table Referring to Part II of the Dossier</u>	<u>(For National Authority Use Only)</u>
PART IIB - METHOD OF PREPARATION (Cont.)		
<u>Method of Preparation of Dose Form: (Cont.) Pages: 42-48</u>		<u>(For National Authority Use Only) COMMENTS</u>
		

<u>Name of Company:</u> F.H. Faulding & Co. Limited (trading as David Bull Laboratories) <u>Name of Finished Product Medicine:</u> Acyclovir Injection <u>Name of Active Ingredient</u> Acyclovir B.P./U.S.P.	<u>Summary Table Referring to Part II of the Dossier</u>	<u>(For National Authority Use Only)</u>
PART IIB - METHOD OF PREPARATION (Cont.)		
In-Process Controls: Page: 47		(For National Authority Use Only) COMMENTS
		
Assembling Process: Page: 48		
The vials are inspected for the absence of particulate matter prior to packing.		

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PART IIB - METHOD OF PREPARATION (Cont.)

Process Validation:	(For National Authority Use Only) COMMENTS
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