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

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

Name of Company:	Summary Table Referr	ina	(For National Authority
the state of the s	to Part II of the Dossier		Use Only)
F.H. Faulding & Co. Limited	<u> 1 6.1. 11 61 1110 2 0 0 0 1 0 1</u>	•	
(trading as David Bull Laboratories)			
(mading as David Dull Laboratories)			
Name of Finished Product Medicine:			
Acyclovir Injection			
Name of Active Insuralisat			
Name of Active Ingredient			
Acyclovir B.P./U.S.P.			
DART UR METUOR OF REELA	2471011 (0 1)		
PART IIB - METHOD OF PREPAR	RATION (Cont.)		
		(Fo	or National Authority Use Only)
Method of Preparation of Dose Form: (C	Cont.) Pages: 42-48		COMMENTS
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Name of Company:	Summary Table Referr		(For National Authority	
F.H. Faulding & Co. Limited (trading as David Bull Laboratories)	to Part II of the Dossier		Use Only)	
Name of Finished Product Medicine: Acyclovir Injection				
Name of Active Ingredient Acyclovir B.P./U.S.P.				
PART IIB - METHOD OF PREPARATION (Cont.)				
In-Process Controls:	age: 47	(Fo	or National Authority Use Only) COMMENTS	
Assembling Process:	Page: 48			
The vials are inspected for the absence prior to packing.	e of particulate matter			

dither,			
	Name of Company: F.H. Faulding & Co. Limited (trading as David Bull Laboratories) Name of Finished Product Medicine: Acyclovir Injection Name of Active Ingredient Acyclovir B.P./U.S.P.	Summary Table Referri to Part II of the Dossier	ing (For National Authority Use Only)
	PART IIB - METHOD OF PREPAI Process Validation:	RATION (Cont.) Page: 49	(For National Authority Use Only) COMMENTS
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