TLE <u>"</u>	avatan	BAC Free	, <i>V.</i> 004%			PRO	JECT	# <u>2</u>	257/9		
ont. from p	6 kg	<i>f</i>									
			#1000 #100 A 1000 1000 1000 1000 1000 10								
Pupo	e: To	Prepure Tra	volum BAC Fr Sterility vo	ee 0.004	Formu	lations	for	Stab.	lity		
	to-L	PET	Herilih un	1.1.1.	and me	that ist.	1.600		7		
	1. 0	7, 1 ² ,	- 31cr.11.4 Va	livation,	ury me	va valit	14/10/		***		
61	- faux	7.204									
	: 1				i			. :		1 :	
Exp	erimental:	1					•	·	مه چې د چوند پای		
	ъ.										
	Equipmen			. 37 . 54	5040 D						
	Mottler BC	203 DK Anar	ytical Balance, A	Asset No. 51.	5840, Rm. C	128 (referre	d to as B	alance 1)		
	Orion 520	A + nH Mater	Asset No. 1012 Asset No. A2220	05, KM, C12	8 (referred	to as Balance	e 2)				
elemen.	Corning H	ot Plate Stirrer	Rm C128	, KIII. C128							
			Jnit (1000 mL a	nd 150 mI)							
	Laminaire	Laminar Flow	Hood, Asset No.	13324-00 1	Rm B-132						
	Conner Ce	nter Clean Suit	e Rm. C143	, 00, 1							
!			· -								
:	Formulation	ns:									
	<u>FID</u>	Batch	Description	-						*************	
	107047	04-37157		AN BAC Fre							
	107337	04-37158	TRAVATA	AN BAC Fre	e, 0.004%-r	o Zinc Chlo	ride				
0.740	107339 107340	04-37159 04-37160				o Boric Aci					
	107340	04-37238	TDAVAT	AN DAC Fro	e, 0.004%-r	no Sorbitol o no Boric Acid	r Propyle	ne Glyc	Ol 		
	107515	0137230	HOLVALIA	IN DAC ITC	c, 0.004 / ₀ -1	io bone Aci	u - 10/2 Z	ine Cin	oride		
Con	nounding	Procedures: (s	see attached batc	h records wi	th adjunctiv	e data)					
<u> 231</u>		21000441051	occ unached but	ii iccords w	an adjunctiv	c data)					
A.	FID 10)7047 Bate	ch 04-37157 TI	RAVATAN	BAC Free, (0.004%					
A	57-2-04				,						THE PERSON NAMED IN
1			glass bottle with	a stir bar. (Balance 2)		ottle & t	57-204		ļ <u>i</u>	
		about 50 % o				<i>b</i> c	He 🥶 '				
1/	3. Weigh	ed and added th	e batch quantity	of the follo	wing excipion	ina io inc be	aro. UU	ric açıcı,			
W\			loride stock solu	tion. Stirred	the solution	to dissolve	these ing	redients.		l	
C. wit	(Balan I. Added		titus of AT 6001	0.20//250/ 1	100 40/27	70/ I D 1	C1 1	0. 1.0	•		
) N N	to the	Lottle	tity of AL-6221 ed to 95% of bat	0.2%/23% F ch weight w	ith purified:	% Propylen	e Glycol	Stock S	olution		
7.3			ition. Measured	he nH	iiii pui iiieu	water. (Dara	nce 2)				
-1		Initial pH = '	4.02	p							******
	. Adjust	ed pH if necess									į
			N HCL added =								
********		Amount of 1	N NaOH added=	16.4mL							~~- - <u>-</u> -
		1000/ 01			/ 04	~ ¬					
	. QSed t	o 100% of bate	h weight. (Balaı	ice 2) Fina	1 pH = 6.03	AS 7-6	2 - A U				
math of the beautiful to the same						173 1-0	2-0 1			and more recovery as	***************************************
		1		ļ			ļ	ļ			
			1001						i i		ŀ
		1070				***************************************	<u> </u>		**		· i
	AUJU	INCTIVE D	AIA	1			 				
P	AGE	1 Pases		<u> </u>			<u></u>				
P	EF LI	רב: צווווע									
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	<u> </u>	 		<u> </u>			<u> </u>	 	 		
		NIA AS T	7-2-04								į
1 1							(6	ont. on	page	7 <i>8</i>)
							ļ				
		namen management		1 1	1 1			- 1	1		
rified Ry	• A	Tedox	Daţe	l e	ntered By	· Odi		. :	<u> </u>	Date	

BOOK_	NO: 11118	PAGE <u>NO: 78</u>
TITLE _	Travaton BAC Free, 0.004%	PROJECT # _ 725 7/9
(cont. from	n page	
E	Batch 04-37158 TRAVATAN BAC	and the second of the second o
An	 Tare weighed a clean glass bottle with a stir bar. (Balar Added about 50 % of batch water. Weighed and added the batch quantity of the following sorbitol. Stirred the solution to dissolve these ingredient 	excipients to the beaker: boric acid and
Ward on	 4. Added the batch quantity of AL-6221 0.2%/25% HCO-4 to the beater, and QSed to 95% of batch weight with pu 5. Stirred to mix the solution. Measured the pH. Initial pH = 4.06 	40/37.5% Propylene Glycol Stock Solution urified water. (Balance 2)
	6. Adjusted pH if necessary. Amount of 1N HCL added = MA Amount of 1N NaOH added= 9.0 ml	
	7. QSed to 100% of batch weight. (Balance 2) Final pH =	AS 7-2-09
Charles of the control of the contro	1. Tare weighed a clean glass bottle with a stir bar. (Balance 2) 2. Added about 50 % of batch water. 3. Weighed and added the batch quantity of the following excitance of the patch quantity of AL-6221 0.2%/25% HCO-40/3 to the batch quantity of AL-6221 0.2%/25%	ipients to the beaker: sorbitol and solve these ingredients. (Balance 2) 87.5% Propylene Glycol Stock Solution ed water. (Balance 2)
13 7-		End of day sol but 7-2-04
Filter Filte	irs used: Liter Millipore Filter Unit Lot Han,	NO 3007 Expires Oct. 2005
	150 ml Millipure Filter Unit Lot H Filter 1000ml of Batch 043715 200 mc >6 I Liter Filter Unit Label as Lot o	04-37157-2 and print
a. F:	Lot Report. Cap Filter unit under the 150mL of Batch 04-37157 using a 15 as Lot 04-37157-3 and print Lot report. Cap	sond Millipore Filterunit. Label
	hood	(cont. on page <u>79</u>)
Verified	By: Date Entere	ed By:



BOOK NO: 11118			PAGE	NO: 79
TITLE Fravatur BAC Free, 0.004	%		PROJECT #	
(cont. from page. 78) 157-6-04		ADJUNCTIVE		
** > *** *** *** *** *** *** *** *** *** *	PAGI	=	4505	4
Filter (10 nt)!	REF	LNIII18:7	9	
3. Filter Balch 04.37158	using two	Liter Millipare	Filler Unils. (1000ml each unit).
Label 45 Lot 04-3715	8-1 and print	Lot report. Ca	p Filter unit.	
4. Filter Batch 04-3715	9 using two	1 Liter Milli	nove Filter Un	its. Cloude each uni
Label us 401 04-37159	-1 and print	ot report. U	ap Filter unit	\$
AS 7-6-04				78-78-88-78-78-78-78-78-78-78-78-78-78-7
PET submission of Lot 04-37	157-3:			
Submit Lot 04-37157	-3 for PET,	USP. Date	submitted 7-	6-04 by Adrian Source
LIMS Submission ID:	100076642			

H5 7-6-04				
Strility Validation:				
Deliver Lot 04-37157	7-2 to Kati	leer Alford	for sterility	Validation.
Delivered on 7-6-04	by Adrian Sau	ceda (1 Lite	r delivered)	77777 7777
AS >-6-04				
method Validation:				
Deliver Lot 04-37158-1	ard Lot 04-	37154-1 10	LOWANN Cruz	of Analytical
chemistry for Method Val				
by Adrian Sauced				
(**			
AS 7-6-04				
Lot Disposition Report:	***************************************			
Print Lot Disposition Report	to for Lots 04	37157-2,00	(-37157-3,	04-37158-1
and 04-37159-1. Place	with adjunc	tive data.	**************************************	
		End o	I day od far	ed 7-6-04
AS 7-7-04				10-00-01-00-01-01-01-01-01-01-01-01-01-0
ill: (In Conner Center Clean	Suite)			
Fill 4mL spp bottles wit	h 2.5 mL of	Batch 04-3	7157. Fill	800 bottles.
HOPE closures used. 1	abel Ziplock	buss as Los	104-37157	-1 to
store bottles. Bottles not				
used for stability testing				
			′ /	
*Note: Remainder of Batch o	14-37157 store	d in refriger	ator for Lake	· 45e.
NIA AC 2	1-7-04			A 2
			(cor	nt. on page <u>80</u>)
Arified By:	Insta	Entered By :	/ /	/ Date
/erified By :	Date	Entered by :	Al hand	Date 7 19-51.1

BOOKNO: 11118	PAGE NO: 80
TITLE Travation BAC Free, 0.004%	PROJECT #2257/9
(cont. from page. 79) A5 7-8-04	
(cont. nom page	
D. FID 107340 Batch 04-37160 TRAVATAN BAC F	ree, 0.004%-no Sorbitol or Propylene
16, 7-1°°	
Tare weighed a clean glass beaker with a stir bar. (Balance 2. Removed the stir bar. Weighed and added the batch quant (Balance 1)	ce 2)
(Datanee 1)	thy of ricO-40 directly in the beaker.
3. Added about 50 % of batch quantity of purified water.4. Stirred for at least 15 minutes until HCO-40 is dissolved.	MATHAL OF MATHAL
5. Weighed and added the batch quantity of the following ex	cipients to the beaker: boric acid and
6. Weighed the batch quantity of AL-06221 using a spatula.	(Ralance 1)
The spatula was placed in the bottle with the end containing 7. QSed to 95% of batch weight with purified water. (Balance)	OG AT 06221 :1: 4
o. Covered the opening with parafilm to minimize evaporation	on. Stirred overnight to dissolve the AL-
Stirring Start time and date: 4:15 pm 7-9-04 END of 6 45 7-9-04 Stirring Stop time and date: 8:30 nm 7-9-04 9. Measured the pH. Initial pH = 4.916	
10. Adjusted pH if necessary.	
Amount of 1N HCL added = w/A Amount of 1N NaOH added= 0.064	
,	
11. QSed to 100% of batch weight with purified water. (Balance	ce 2) AS 7-9-04
457-9-04	
Filher:	
Filke all 150ml of Batch 04-37160 using c	150ml Millipure Filter Unit
Filter all 150m L of Britch 04-37160 using c Label as Lot 04-37160-1 and print Lot repor	t. Cop Filkrunil under
Laminar flow hood.	
AS 2904	
PET Submission of Lot 04-3716-1:	
Submit Lot 04-37160-1 For PET, USP. F	
LIMS Submission 10: 100076746	ADJUNCTIVE DATA AS >-19 04
	GE 4 pages F 40 11118': 80
Lot Disposition Report: RE Print Lot Disposition Report for Lot 04-37160-	
Frint LOT VISPUSITION REPORT FOR LOT VI >7/60-	ENOFORY Edishuf 7-9-04
	- wordy in one
NIA a	
NIM AS 7904	
	(cont. on page
Voiting Dr. 1	d Pu
Verified By: Date Entere	d By: Date 7 (9.04)

воок	NO: 11	.118					PAGE		NO: 8	1	
TITLE Trave	tan BAC Fr	ze 0.0047	lu				PROJI	ECT#	22571	9	
(cont. from page	e 5/0)	AS 7-1284	/								
	Maria de deservador de la companya d	<u> </u>	., ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		***************************************		***************************************				+
E .	FID 107343	3 Batch	04-37328	TRAVAT Chloride	AN BAC	Free, 0.00)4%-no Bo	oric Acid	- 10X Zino		
<u> </u>	157-12-04		1 1		han (Dala	2)					
1. 2.	Removed th	ed a clean gla he stir bar. W	ass beaker eighed an	with a stir	bar. (Baia batch qua	ntity of H	CO-40 dir	ectly in th	ne beaker.		
	(Balance 2))								d m d d green	
3. 4.	Added abou	ut 50 % of l at least 15 mi	batch quar	itity of puri LHCO-40 i	fied water. s dissolved	1.					
5.	Weighed ar	nd added the	batch quai	ntity of the	following	excipients	to the bea	ker: sorb	oitol,	- >	***************************************
	propylene g	glycol, and zi ne batch quan	nc chlorid	e. Stirred th	ne solution	to dissolv	e these in	gredients.	(Balance	1)	
$\int_{\mathcal{L}_1} 6.$	The spatula	a was placed i	in the bott	le with the	end contain	ning AL-0	6221 imm	ersed in t	the solution	n.	
May 7.	OSed to 95	% of batch w	eight with	purified w	ater. (Bala	nce 2)					
13-04 8.	Covered the 06221.	e opening wit	th paratiin	i to minimi					oive me A		
1"	Stirring Sta	art time and d	ate: 200	om 7-12.0		d of day	7-12-04	′		10-14-14-16-1	
AS 7-13	3-4(Stirring Sto Measured t	op time and d	ate: 😗: 30	am 7-13-	<u>04</u>					and and are	
	0. Adjusted pl	H if necessar	у.								
	Aı	mount of 1N	HCL adde	d = 0.07g							
	Aı	mount of 1N	NaOH add	iea= M				.		Acres on	
. 1	1. QSed to 10	0% of batch	weight wi	th purified	water. (Ba	lance 2)	() # S	57-13-011 1. a		h-11-12 42 44	
raceria considera (garga)							EN of	**************************************	5 7-13-by	conten se	
AS 7-13-04		***************************************		var on one of the same of the	***************************************		er manage and producer second producers.				
Filter!										 , 	
Filter B	atch 04-3	7328 l	15ing	two !	Liter 1	nillipore	Filter U	'nits (1000 m L es	ach unil	9
Lahel	atch 04-3 as Lot c	14-37 <i>328</i>	'-1'.	ap Filt	er unit		V (2) 11 (V		DATA	HB 7-197	oy.
	**************************************							10	Nacar		
AS 7-13-04						PAG	- 1	LNIII	10:01		
Method Va	tidation:					REF		-70 /(1	/ 6 - 0 1		
7	Lot 04.	37328-1	to 4	nugan Cri	12 Of	analytica	1 chem	Street	for Met	hed	
	ion. Two							1			
, and a superior of the superi	V 1.09. V	merticol (Men)	od proces	1	The second secon					.,.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	:
15 7-13-04				:							
		//									
Lot 04-					<u>-</u>		, , ,	,, D= ,		297) 1	, }
Under La	minar Flou HDIE clogu	n hoou	Change	, the	Closure	es 0t	47 0	4-3/15	7-1 (8	00 box	ths)
from t	tille clogu	ires to	P/P C/0	sures.	Print Lo	of repu	vt.			. ,	
			consistence and a second of the second of th	*****			Endo	t day	lidio-Sa	wedt :	7-13-04
15 7-14-04											<u>l</u>
Lot Report:	Print Lot	Report t	or Lot	- 04-37	238-1	Place	in adju	nclive	rote book		<u></u>
Lot Disposit		: Print 1	of Disp	osition 1	eport &	r Lot	04-370	738-1			
					- 					ÐΊ	
		Placein	d. Jack	, netchool	i	End	lot de 1	(con	t. on page	_ 04	_)



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