6.3 TRANSFER OF RUBBER STOPPERS:

Transfer the ready for sterilization rubber stoppers from warehouse to the unit preparation area through the static pass box (CSP/104) of equipment wash room (CSLG 014).

6.4 STERILIZATION OF RUBBER STOPPERS AS PER SOP No. SOP/CSP/037:

Cycle started at: 21:48 Cycle Completed at: 23:47

Date	Load No.	Load Pattern No.	No.of Bags	Total qty of rubber stoppers	Sterilization Hold Time		Done by##	Ckd. By##
					From	To		
14/10/08	05	6	7	7000	22:39	23:09	Sanjeev	[illegible]

(Graph attached on the reverse side of page)

6.5 STORAGE OF STERILIZED RUBBER STOPPERS (NMT 48 HOURS AFTER STERILIZATION):

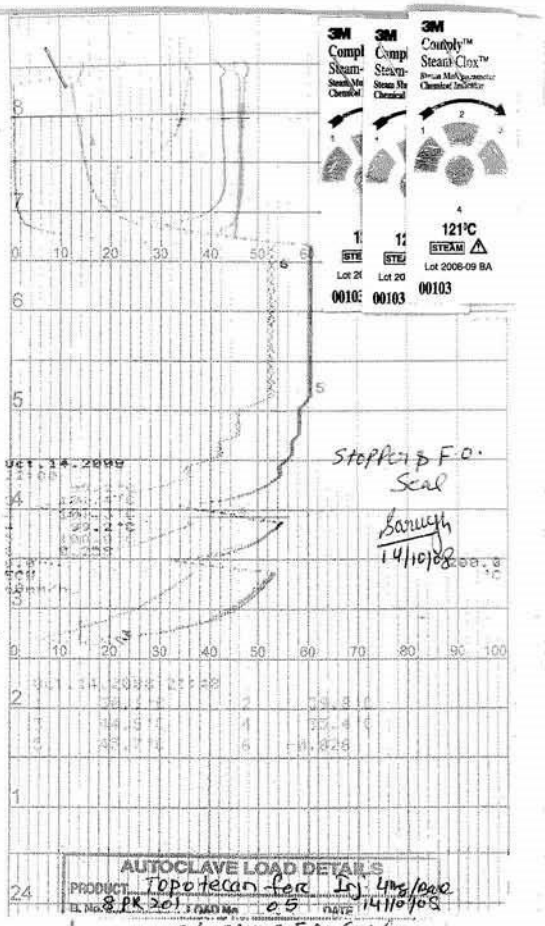
Procedure	Eq. Id. No.	SOP No.	Date	Storage Time*		Done by##	Ckd. By##
				From	To		
Store the sterilized Rubber stoppers under LAF in cooling zone.	CSP/035	SOP/CSP/072	14/10/08	23:47	---	Shambhu	14/10/08
			15/10/08	---	21:45	Sanjeev	15/10/08

* Hold time starts after completion of sterilization to end of filling.

##Production

QA Signature [illegible]

Load No -05



MFG.BY :MACHIN FABRIK
CUSTOMER :M/S DABUR PHARMA LTD.
EQUIPMENT :STEAM STERILIZER

BATCH DATA
STERILIZER NO :1007
BATCH NO :0
QUANTITY :1
OPERATOR CODE :1
PRINT.INTERVAL :60 SEC
DATE :14/10/08
TIME :21:48:38

PROCESS : STOPPER & FLIP OFF

SET PARAMETERS
PRE VACUUM : -0.750 BAR
PRE PRESSURE : 0.500 BAR
NO OF PRE PULSE : 3 NOS
SET POINT-1 : 110.0 DEG C
SET POINT-2 : 115.0 DEG C
SET POINT-3 : 118.0 DEG C
SP-1 HOLD TIME : 2 MIN
SP-2 HOLD TIME : 3 MIN
SP-3 HOLD TIME : 5 MIN
HEAT UP CONTROL BAND : 0.2 DEG C
STER HOLD TEMP : 121.5 DEG C
STER HOLD TIME : 30 MIN
TEMP CONTROL BAND : 0.2 DEG C
OVERSHOOT TEMP : 124.0 DEG C
STER COUNT STOP TEMP : 120.9 DEG C
STER COUNT RESET TEMP : 120.8 DEG C
POST VACUUM : -0.750 BAR
POST PRESSURE : -0.100 BAR
POST VAC HOLD TIME : 30 MIN
NO OF POST PULSE : 1 NOS
EXHAUST ON TIME : 5 SEC
EXHAUST OFF TIME : 50 SEC
PROCESS END PRESSURE : -0.050 BAR
CHAM PRESSURE HIGH : 1.500 BAR

* Only Rubber stoppers load has been taken.
14/10/08

MFG.BY :MACHIN FABRIK
CUSTOMER :M/S DABUR PHARMA LTD.
DATE :14/10/08
TIME :21:49:19
EQUIPMENT :STEAM STERILIZER
PROCESS :STOPPER & FLIP OFF SEAL

TIME	T1 DEG C	T2 DEG C	T3 DEG C	T4 DEG C	T5 DEG C	PRES BAR	STATUS
21:49:19	030.4	039.7	045.0	035.9	046.0	-0.021	PROCESS ON
21:49:21	030.3	039.8	045.1	036.0	046.1	-0.031	PRE VACUUM
21:50:20	029.8	037.4	043.1	033.0	044.0	-0.644	PRE VACUUM
21:50:47	029.6	036.9	042.4	032.1	043.4	-0.767	PRE PRESSURE
21:51:20	029.9	051.9	050.3	055.4	051.5	-0.586	PRE PRESSURE
21:52:20	030.0	066.1	063.0	068.0	065.2	-0.448	PRE PRESSURE
21:53:21	030.0	074.6	072.1	074.5	073.0	-0.327	PRE PRESSURE
21:54:21	030.1	080.8	078.9	080.8	079.1	-0.215	PRE PRESSURE
21:55:21	043.8	085.9	084.7	083.3	083.6	-0.104	PRE PRESSURE
21:56:20	066.1	090.4	089.4	087.4	088.2	00.008	PRE PRESSURE
21:57:22	089.4	093.9	093.7	091.0	092.1	00.085	PRE PRESSURE
21:58:21	094.8	096.5	096.4	095.4	095.0	00.151	PRE PRESSURE
21:59:20	098.1	098.9	098.9	098.7	097.8	00.218	PRE PRESSURE
22:00:21	100.9	101.2	101.3	099.6	100.3	00.284	PRE PRESSURE
22:01:22	103.2	103.2	103.4	101.2	102.4	00.348	PRE PRESSURE
22:02:21	105.3	105.0	105.2	104.2	104.4	00.411	PRE PRESSURE
22:03:22	107.1	106.8	106.9	107.4	106.1	00.473	PRE PRESSURE
22:03:49	107.8	107.5	107.6	108.2	106.9	00.499	PRE VACUUM
22:04:21	096.7	097.7	098.4	098.6	096.5	-0.201	PRE VACUUM
22:05:20	078.2	078.8	079.9	079.9	078.6	-0.593	PRE VACUUM
22:06:17	065.2	065.8	066.8	067.1	065.9	-0.759	PRE PRESSURE
22:07:23	080.0	081.7	081.6	084.5	081.8	-0.397	PRE PRESSURE
22:08:21	086.5	091.1	091.4	090.9	091.2	-0.177	PRE PRESSURE
22:09:22	093.1	097.1	097.4	096.7	097.1	-0.003	PRE PRESSURE
22:10:21	102.0	100.9	101.2	100.8	100.8	00.116	PRE PRESSURE
22:11:22	104.9	103.9	104.1	104.2	103.8	00.230	PRE PRESSURE
22:12:23	107.4	106.4	106.6	106.9	106.3	00.335	PRE PRESSURE
22:13:22	109.5	108.6	108.8	109.0	108.4	00.430	PRE PRESSURE
22:14:12	110.9	110.0	110.2	110.6	110.0	00.496	PRE VACUUM
22:14:21	109.8	109.1	109.5	109.2	108.6	00.273	PRE VACUUM
22:15:23	089.9	091.0	091.4	091.8	090.6	-0.360	PRE VACUUM

22:16:22	074.8	075.6	075.9	076.3	076.0	-0.649	PRE VACUUM
22:17:03	065.2	067.2	069.1	067.3	073.1	-0.736	PRE PRESSURE
22:17:23	069.9	070.3	070.9	074.0	075.3	-0.617	PRE PRESSURE
22:18:22	087.7	085.9	085.9	086.5	086.2	-0.295	PRE PRESSURE
22:19:23	095.9	095.3	095.7	095.3	095.4	-0.046	PRE PRESSURE
22:20:21	102.0	100.7	101.1	100.9	100.6	00.119	PRE PRESSURE
22:21:23	105.7	104.5	104.9	105.0	104.5	00.265	PRE PRESSURE
22:22:23	108.7	107.6	107.9	108.2	107.5	00.393	PRE PRESSURE
22:23:15	111.0	109.9	110.1	110.5	109.8	00.496	HEAT UP
22:24:23	109.8	109.2	109.5	109.9	109.2	00.443	HEAT UP
22:25:23	110.1	109.5	109.7	110.1	109.4	00.461	HEAT UP
22:26:22	112.6	111.6	111.9	112.3	111.7	00.589	HEAT UP
22:27:23	114.8	113.8	114.0	114.4	113.8	00.695	HEAT UP
22:28:24	115.2	114.3	114.7	115.0	114.3	00.685	HEAT UP
22:29:23	115.2	114.4	114.7	115.0	114.3	00.686	HEAT UP
22:30:23	115.0	114.3	114.6	115.0	114.3	00.674	HEAT UP
22:31:24	116.9	115.9	116.2	116.7	116.0	00.821	HEAT UP
22:32:23	118.0	117.2	117.5	117.8	117.1	00.869	HEAT UP
22:33:24	118.2	117.4	117.7	118.0	117.3	00.852	HEAT UP
22:35:24	117.9	117.2	117.5	117.9	117.2	00.855	HEAT UP
22:36:25	118.0	117.3	117.6	118.0	117.3	00.877	HEAT UP
22:37:24	118.9	118.0	118.2	118.7	118.0	00.936	HEAT UP
22:38:25	120.7	119.7	120.0	120.5	119.8	01.041	HEAT UP
22:39:24	122.1	121.1	121.5	121.8	121.1	01.128	HEAT UP
22:39:47	122.6	121.7	121.9	122.3	121.6	01.163	STER HOLD
22:40:25	122.5	121.7	122.0	122.3	121.6	01.152	STER HOLD
22:41:24	122.3	121.6	121.9	122.3	121.5	01.124	STER HOLD
22:42:25	122.5	121.7	122.0	122.4	121.6	01.123	STER HOLD
22:43:24	122.6	121.8	122.1	122.5	121.7	01.161	STER HOLD
22:44:26	122.4	121.6	121.9	122.3	121.6	01.145	STER HOLD
22:45:25	122.4	121.5	121.9	122.3	121.5	01.118	STER HOLD
22:46:26	122.5	121.7	122.0	122.4	121.6	01.119	STER HOLD
22:47:24	122.6	121.8	122.0	122.5	121.7	01.141	STER HOLD
22:48:25	122.5	121.7	122.0	122.5	121.6	01.161	STER HOLD
22:49:26	122.3	121.6	121.9	122.3	121.5	01.133	STER HOLD

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22:50:25	122.4	121.7	122.0	122.3	121.6	01.117	STER HOLD
22:51:26	122.6	121.8	122.1	122.5	121.7	01.143	STER HOLD
22:52:25	122.5	121.8	122.0	122.5	121.7	01.166	STER HOLD
22:53:26	122.3	121.7	121.9	122.3	121.5	01.128	STER HOLD
22:54:27	122.5	121.7	122.0	122.4	121.6	01.120	STER HOLD
22:55:25	122.7	121.8	122.0	122.5	121.7	01.141	STER HOLD
22:56:26	122.6	121.8	122.0	122.5	121.7	01.166	STER HOLD
22:57:27	122.3	121.7	121.9	122.3	121.5	01.141	STER HOLD
22:58:25	122.5	121.7	122.0	122.4	121.6	01.123	STER HOLD
22:59:26	122.7	121.8	122.1	122.5	121.7	01.145	STER HOLD
23:00:27	122.6	121.7	122.0	122.5	121.7	01.164	STER HOLD
23:01:26	122.4	121.7	122.0	122.4	121.6	01.149	STER HOLD
23:02:27	122.4	121.7	122.0	122.3	121.5	01.123	STER HOLD
23:03:28	122.6	121.8	122.1	122.5	121.7	01.134	STER HOLD
23:04:26	122.7	121.8	122.1	122.5	121.7	01.160	STER HOLD
23:05:27	122.4	121.7	122.0	122.4	121.6	01.147	STER HOLD
23:06:28	122.5	121.7	122.0	122.3	121.5	01.118	STER HOLD
23:07:29	122.7	121.8	122.1	122.5	121.7	01.141	STER HOLD
23:08:28	122.5	121.8	122.0	122.5	121.6	01.164	STER HOLD
23:09:29	122.4	121.7	122.0	122.3	121.5	01.116	STER HOLD
23:09:45	122.6	121.8	122.0	122.5	121.7	01.166	POST VACUUM
23:10:28	106.5	108.7	109.5	109.2	107.7	00.138	POST VACUUM
23:11:29	087.9	090.2	090.2	090.9	091.1	-0.401	POST VACUUM
23:12:28	072.2	075.3	084.6	076.8	090.9	-0.668	POST VACUUM
23:13:00	065.3	068.8	085.0	071.3	091.1	-0.746	VACUUM HOLD
23:13:27	060.4	064.6	086.5	066.4	091.1	-0.790	VACUUM HOLD
23:14:28	052.1	062.2	089.3	060.7	091.2	-0.850	VACUUM HOLD
23:15:29	046.4	072.8	090.9	053.3	091.4	-0.882	VACUUM HOLD
23:16:28	042.5	077.9	091.8	046.6	091.7	-0.902	VACUUM HOLD
23:17:29	039.7	081.1	092.6	043.8	092.1	-0.913	VACUUM HOLD
23:18:28	037.8	082.9	093.2	043.1	092.4	-0.919	VACUUM HOLD
23:19:29	036.3	084.2	093.6	043.6	092.7	-0.924	VACUUM HOLD
23:20:29	035.3	085.2	093.9	043.5	092.9	-0.928	VACUUM HOLD

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[illegible]	[illegible]	085.7	094.1	042.8	093.1	-0.930	VACUUM HOLD
23:22:29	033.7	085.9	094.2	043.0	093.3	-0.932	VACUUM HOLD
23:23:30	033.1	086.0	094.3	042.6	093.4	-0.933	VACUUM HOLD
23:24:31	032.5	085.9	094.3	043.5	093.5	-0.935	VACUUM HOLD
23:25:30	032.0	085.8	094.3	044.2	093.6	-0.935	VACUUM HOLD
23:26:30	031.6	085.7	094.2	043.9	093.8	-0.937	VACUUM HOLD
23:27:29	031.1	085.7	094.1	047.1	093.9	-0.937	VACUUM HOLD
23:28:30	030.4	085.6	094.0	054.8	093.3	-0.938	VACUUM HOLD
23:29:30	030.5	085.5	093.9	059.5	093.0	-0.938	VACUUM HOLD
23:30:30	030.2	085.4	093.7	062.8	093.3	-0.939	VACUUM HOLD
23:31:29	029.9	085.3	093.7	065.0	093.7	-0.940	VACUUM HOLD
23:32:30	029.5	085.3	093.6	066.6	094.0	-0.940	VACUUM HOLD
23:33:31	029.2	085.2	093.5	067.8	094.2	-0.940	VACUUM HOLD
23:34:30	028.8	085.2	093.4	068.6	094.4	-0.941	VACUUM HOLD
23:35:31	028.6	085.1	093.2	069.3	094.5	-0.942	VACUUM HOLD
23:36:32	028.3	085.1	093.2	069.8	094.7	-0.942	VACUUM HOLD
23:37:32	027.9	085.1	093.1	070.3	094.8	-0.942	VACUUM HOLD
23:38:30	027.6	085.1	093.1	070.7	094.8	-0.942	VACUUM HOLD
23:39:31	027.4	085.0	093.0	071.2	094.9	-0.942	VACUUM HOLD
23:40:32	027.0	084.8	093.0	071.6	095.0	-0.942	VACUUM HOLD
23:41:33	026.8	084.7	093.0	072.0	095.1	-0.943	VACUUM HOLD
23:42:31	026.6	084.6	093.0	072.3	095.1	-0.942	VACUUM HOLD
23:43:01	026.5	084.5	092.9	072.5	095.2	-0.943	POST PRESSURE
23:43:32	028.6	084.8	092.5	073.8	095.3	-0.793	POST PRESSURE
23:44:33	029.5	086.0	091.0	073.2	096.7	-0.485	POST PRESSURE
23:45:31	030.4	085.9	090.5	071.8	096.8	-0.232	POST PRESSURE
23:46:16	030.9	084.0	090.7	071.6	096.0	-0.103	VACUUM BREAK
23:46:32	031.0	083.5	090.8	071.5	095.7	-0.072	VACUUM BREAK
23:47:31	031.4	081.1	090.7	070.2	094.4	-0.050	PROCESS END

FO VALUE:- 0030.0

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14/10/08

6.6 PRE CLEANING DETAILS OF EQUIPMENTS USED FOR ONLINE FILTRATION AND FILLING:

Clean the equipment and filtration accessories with the WFI in the wash table lying in the equipment wash room (CSLG 014).

Cleaning started at: 22:00 Cleaning completed at: 23:00

Date: 14/10/08

S.No.	Equipment Name	Equipment Id. No.	Previous Product Detail	Done By##	Ckd. By##
1.	SS Beakers 500 mL, 1000 mL	---	Cytarabine inj. 8LA204		
2.	*Platinum Cured silicon tubes	---	---		
3.	Cartridge Filter Holder with stand	CSP/113	Cytarabine inj 8LA204		
4.	**50 mm disc type Vent filter	---	—		
5.	Buffer Bottle	---	Cytarabine inj 8LA 204		
6.	SS forceps	---	Cytarabine inj 8LA204		
7.	SS filling needle	---	Cytarabine inj 8LA204		
8.	SS syringe set	---	Cytarabine inj 8LA204		
9.	Stopper hopper, Stopper rail, chute	---	Cytarabine inj 8LA204		
10.	Needle holding plate	---	Cytarabine inj 8LA204		
11.	Nylon Fasteners	---	---		
12.	Stopper head set	---	Cytarabine inj. 8LA204		
13.	TC with Nozzle	---	Cytarabine inj 8LA204		
14.	Manifold	---	Cytarabine inj 8LA204		
15.	SS clamps, gaskets and nozzles	---	Cytarabine inj 8LA204		

**These equipments to be used product dedicated.

* To be Used Batch Specific.

##Production

QA Signature

6.7 FINAL CLEANING OF EQUIPMENT AND ACCESSORIES FOR ONLINE FILTRATION AND FILLING:

A. R. No. Of WFI: 02WF08000748 Date: 14/10/08

Note: Final cleaning and rinsing of the washed equipments should be done with WFI under LAF No.: CSP/059 in unit preparation room (CSLG017).

Cleaning Started at: 22:00 Cleaning Completed at: 23:10

S.No.	Equipment Name	Equipment Id. No.	SOP No.	Qty.	Done By##	Ckd. By##
1.	SS Beakers 500 mL, 1000 mL	---	SOP/CSP/006	01 + 01	Sarwan	[illegible]
2.	*Platinum Cured silicon tubes	---	SOP/CSP/006	04 + 04 + 03	Sarwan	[illegible]
3.	Cartridge Filter Holder with stand	CSP/113	SOP/CSP/006	01	Sarwan	[illegible]
4.	**50 mm disc type Vent filter	---	SOP/CSP/006	01	Sarwan	[illegible]
5.	Buffer Bottle	---	SOP/CSP/006	01	Sarwan	[illegible]
6.	SS forceps	---	SOP/CSP/006	06	Sarwan	[illegible]
7.	SS filling needle	---	SOP/CSP/006	04	Sarwan	[illegible]
8.	SS syringe set	---	SOP/CSP/006	04 (1 set)	Sarwan	[illegible]
9.	Stopper hopper, Stopper rail, chute	---	SOP/CSP/006	01 + 01	Sarwan	[illegible]
10.	Needle holding plate	---	SOP/CSP/006	01	Sarwan	[illegible]
11.	Nylon Fasteners	---	SOP/CSP/006	15	Sarwan	[illegible]
12.	Stopper head set	---	SOP/CSP/006	02	Sarwan	[illegible]
13.	Sealing head set with plate	---	SOP/CSP/006	–	Sarwan	[illegible]
14.	TC with Nozzle	---	SOP/CSP/006	06	Sarwan	[illegible]
15.	Manifold	---	SOP/CSP/006	01	Sarwan	[illegible]
16.	SS clamps, gaskets and nozzles	---	SOP/CSP/006	06 + 06 + 06	Sarwan	[illegible]

**These equipments to be used product dedicated.

* To be Used Batch Specific

##Production

QA Signature [illegible]

6.8 FILTER HOLDER PREPARATION:

A. R. No. Of WFI: 02WF08000748 Date: 14/10/08

Note: Preparation of Cartridge filter holder should be done under LAF No.: CSP/059

S. No.	Procedure	SOP No.	Time		Observations	Done by##	Ckd. By##
			From	To			
1.	Assemble 4 inch cartridge filter holder under LAF	SOP/CSP/022	21:26	21:30	Cartridge filter housing Eq. Id. No. CSP/113	Sanvesh	[illegible]
2.	Arrangement of sterilization grade filter: Supplier: Millipore Type: LAGL04TP6 MOC: PVDF Porosity: 0.22 µ Place the filter in cartridge filter holder and Note down the Filter Serial No.	---	21:31	21:35	Filter Serial No.: C7NN15708 0607	Sanvesh	[illegible]
3.	Carry out Pre integrity of the cartilage filter and note the observation in Step 6.9	SOP/CSP/023	23:07	23:27	53.9 PSI	Sohan	[illegible]
4.	Carry out the sterilization of the filtration equipments and accessories. Record the details in table of step 6.11.	SOP/CSP/037	15/10/08 09:20	11:25	OK	Ravinder	[illegible]

##Production

QA Signature [illegible]

6.9 PRE INTEGRITY TEST OF PRODUCT FILTER (BUBBLE POINT TEST):

- Perform the pre filter integrity of the Product filter as per SOP No. SOP/CSP/023.
- Properly wet the filter by flushing cool WFI before undergoing pre integrity test.
- Bubble point value is NLT 50 psi with WFI.

Date	Filter Catalogue No	Filter Serial No.	Cartridge Filter Holder No.	Observed Bubble Point	Result (Pass/~~Fail~~)	Done By##	Checked By##
14/10/08	C 14/10/08 LOGL04TP6	C7NN15708 0607	CSP/113	53.9	Pass	Sohan	

6.10 PRE INTEGRITY TEST OF AIR VENT FILTER (BUBBLE POINT TEST):

- Perform the pre integrity test of the Air vent filter for buffer bottle as per SOP No. SOP/CSP/023.
- Properly wet the filter by flushing 60% IPA/WFI mixture before undergoing pre integrity test.
- Bubble point value is NLT 16 psi with 60% IPA/WFI mixture.

Date	Filter Catalogue No	Filter Serial No.	Cartridge Filter Holder No.	Observed Bubble Point	Result (Pass/~~Fail~~)	Done By##	Checked By##
14/10/08	MTGR15010	F7PN0 9210 01965	–	22.48	Pass	Sohan	14/10/08

##Production

INTEGRITEST EXACTA

Instrument Serial Number:
W20678
Date:
10/14/2008
Time:
11:07:32PM
Test Serial Number:
200810142307
Test Name:
LAGL BPT
Test Revision:
2
Test Description:
BUBBLE POINT

Bubble Point Test

Filter Catalog Number:
LAGL04TP6
Test Fluid:
Water
Filter Description:
Optiseal Cartridge Filter With Durapore Membrane , 6/pack

Filter Size:
4"
Pore Size:
0.22
Housing Type:
OPTISEAL

Operator Inputs

Operator:
rai
Product Batch no.
TOPOTECAN INJ. ~~8PR201~~ 8PK 201 14/10/08
Filter Lot no.
C7NN15708
User Defined Field #3 - Optional
0607
User Defined Field #4 - Optional
CSP/113

Notes:
ONLINE FILTER PRE INT.

Test Specifications

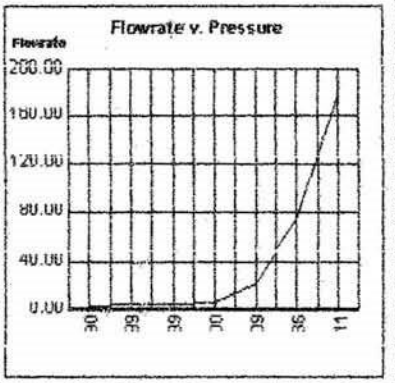
of Cartridges: 1

Minimum Bubble Point: 50.0 psig

Test Data

Gas Volume: 449 ml

Pressure psig	Flowrate ml/min
39.9	2.7
49.0	4.6
50.0	4.4
51.0	6.7
53.1	22.7
54.4	74.5
55.1	176.6



Test Results

Measured Bubble Point: 53.9 psig

Immediate Retest

Test Conclusion

PASSED

Signature: Sotan 14/10/08

Signature: 14/10/08

****

Palltronic Flowstar Test Report

14/Oct/2008 23:32:31

Serial Number	: 15342626/3.3a
Function	: BP
Test Programme	: MTGR15010-BP
Production area	: PROD-CSL
Filter line	: BUFFER BOTTLE FILTER
Product name	: TOPOTECAN FOR INJ.
Product batch no.	: 8PK201
Filter part no.	: MTGR
Filt. serial no.	: F7PN09210 01965
Housing	: ---
Wetting liquid	: 60:40 IPA.WATER
Test gas	: AIR
BP minimum	: 16.00 psi

BP value measured	: 22.48 psi
BP within limits	
Comment	: PRE-INTEGRITY
Electr. Signature	: PRADEEP
Created	14/Oct/2008 23:39:31

Sohan 14/10/08

14/10/08

****

6.11 STERILIZATION OF EQUIPMENT AND ACCESSORIES FOR ONLINE FILTRATION AND FILLING AS PER SOP No. SOP/CSP/037:

Cycle started at: 09:20 Cycle end at: 11:25

Date	Load No.	Load Pattern No.	Sterilization Hold Time		Done By##	Checked By##
			From	To		
15/10/08	02	2	10:16	10:46	Ravinder	[illegible]

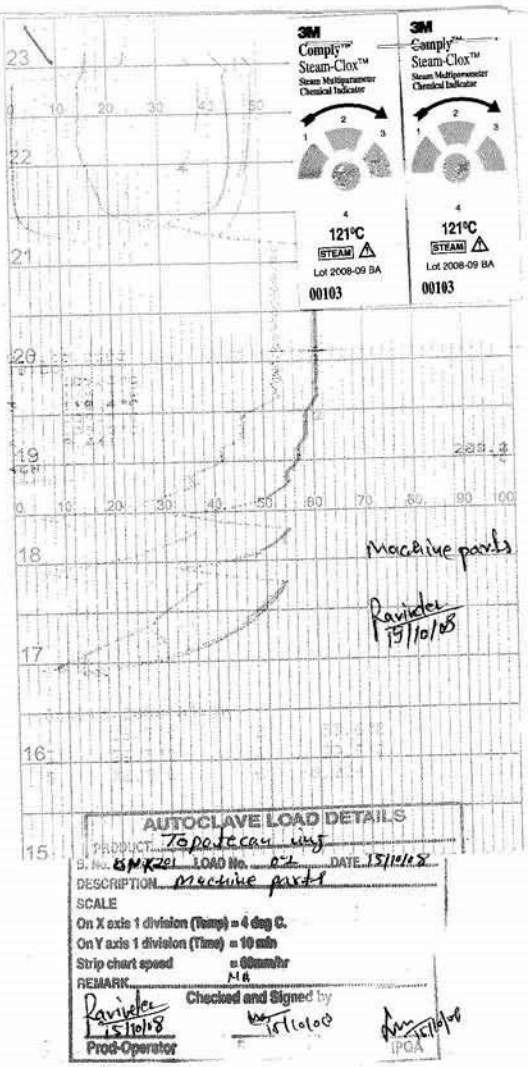
(Graph attached on the reverse side of page No.: 23)

6.12 STORAGE OF STERILIZED EQUIPMENT AND ACCESSORIES FOR ONLINE FILTRATION AND FILLING (NMT 48 HOURS AFTER STERILIZATION):

Procedure	Eq. Id. No.	SOP No.	Date	Storage Time*		Done By##	Checked By##
				From	To		
Store the sterilized equipment and accessories for on line filtration and Filling under LAF in filtration area.	CSP/036	SOP/CSP/072	15/10/08	11:25	---	Naresh	[illegible]
			15/10/08	---	21:45	Shamsher	[illegible] 15/10/08

* Hold time starts after completion of sterilization and completes at the end of activity.
##Production

Load No - 02



MFG.BY :MACHIN FABRIK
CUSTOMER :M/S DABUR PHARMA LTD.
EQUIPMENT :STEAM STERILIZER

BATCH DATA
STERILIZER NO :1007
BATCH NO :0
QUANTITY :1
OPERATOR CODE :1
PRINT INTERVAL :60 SEC
DATE :15/10/08
TIME :09:20:15

PROCESS : MACHINE PARTS

SET PARAMETERS

PRE VACUUM	: -0.750 BAR
PRE PRESSURE	: 0.500 BAR
NO OF PRE PULSE	: 3 NOS
SET POINT-1	: 110.0 DEG C
SET POINT-2	: 115.0 DEG C
SET POINT-3	: 118.0 DEG C
SP-1 HOLD TIME	: 2 MIN
SP-2 HOLD TIME	: 3 MIN
SP-3 HOLD TIME	: 5 MIN
HEAT UP CONTROL BAND	: 0.2 DEG C
STER HOLD TEMP	: 121.5 DEG C
STER HOLD TIME	: 30 MIN
TEMP CONTROL BAND	: 0.2 DEG C
OVERSHOOT TEMP	: 124.0 DEG C
STER COUNT STOP TEMP	: 120.9 DEG C
STER COUNT RESET TEMP	: 120.8 DEG C
POST VACUUM	: -0.750 BAR
POST PRESSURE	: -0.100 BAR
POST VAC HOLD TIME	: 30 MIN
NO OF POST PULSE	: 1 NOS
EXHAUST ON TIME	: 5 SEC
EXHAUST OFF TIME	: 50 SEC
PROCESS END PRESSURE	: -0.050 BAR
CHAM PRESSURE HIGH	: 1.500 BAR

MFG.BY :MACHIN FABRIK
CUSTOMER :M/S DABUR PHARMA LTD.
DATE :15/10/08
TIME :09:20:43
EQUIPMENT :STEAM STERILIZER
PROCESS :MACHINE PARTS

1

TIME	T1 DEG C	T2 DEG C	T3 DEG C	T4 DEG C	T5 DEG C	PRES BAR	STATUS
09:20:45	028.5	032.7	035.9	029.7	036.1	-0.025	PROCESS ON
09:20:47	028.5	032.7	035.9	029.7	036.1	-0.039	PRE VACUUM
09:21:41	028.0	029.9	033.2	027.0	033.4	-0.587	PRE VACUUM
09:22:20	027.8	028.4	031.8	025.6	032.0	-0.762	PRE PRESSURE
09:22:41	027.9	037.2	036.6	041.2	038.2	-0.674	PRE PRESSURE
09:23:41	028.2	053.8	050.6	056.8	052.3	-0.581	PRE PRESSURE
09:24:42	028.3	063.1	059.6	065.2	059.6	-0.496	PRE PRESSURE
09:25:41	031.2	069.8	066.4	071.6	066.1	-0.412	PRE PRESSURE
09:26:42	044.6	075.1	072.1	076.7	072.0	-0.326	PRE PRESSURE
09:27:41	060.3	079.7	077.5	081.0	077.0	-0.238	PRE PRESSURE
09:28:42	058.9	084.3	082.8	085.4	081.5	-0.142	PRE PRESSURE
09:29:41	055.8	088.0	086.9	089.2	085.9	-0.045	PRE PRESSURE
09:30:42	064.1	091.4	091.0	092.4	089.8	00.052	PRE PRESSURE
09:31:43	087.7	094.7	094.3	094.5	092.4	00.119	PRE PRESSURE
09:32:42	094.7	096.8	096.6	096.9	094.6	00.160	PRE PRESSURE
09:33:42	097.6	098.9	098.8	099.2	097.1	00.210	PRE PRESSURE
09:34:43	100.2	100.9	100.7	099.6	099.4	00.267	PRE PRESSURE
09:35:42	102.3	102.7	102.6	100.6	101.6	00.316	PRE PRESSURE
09:36:43	104.3	104.4	104.4	103.1	103.5	00.373	PRE PRESSURE
09:37:42	106.0	105.9	106.0	106.1	105.3	00.420	PRE PRESSURE
09:38:44	107.6	107.3	107.4	108.0	106.8	00.468	PRE PRESSURE
09:39:22	108.5	108.1	108.2	108.9	107.7	00.498	PRE VACUUM
09:39:43	103.2	103.4	104.3	104.7	102.7	00.005	PRE VACUUM
09:40:44	084.5	085.4	086.3	086.4	085.0	-0.472	PRE VACUUM
09:41:44	071.1	071.5	072.9	072.6	071.5	-0.694	PRE VACUUM
09:42:13	065.3	065.8	067.2	067.1	065.9	-0.758	PRE PRESSURE
09:42:43	072.0	071.3	071.7	075.2	071.6	-0.578	PRE PRESSURE
09:43:44	086.5	086.2	086.3	087.0	086.5	-0.290	PRE PRESSURE
09:44:43	091.8	094.3	094.5	093.7	094.4	-0.085	PRE PRESSURE
09:45:44	100.3	099.5	099.7	099.2	099.4	00.065	PRE PRESSURE
09:46:44	103.7	102.7	102.9	102.9	102.6	00.184	PRE PRESSURE

09:47:43	106.3	105.4	105.6	105.8	105.3	00.292	PRE PRESSURE
09:48:44	108.7	107.8	107.9	108.2	107.6	00.394	PRE PRESSURE
09:49:44	110.5	109.7	109.9	110.2	109.6	00.477	PRE PRESSURE
09:49:58	110.9	110.0	110.2	110.6	110.0	00.500	PRE VACUUM
09:50:44	097.2	098.4	098.9	100.0	098.0	-0.149	PRE VACUUM
09:51:45	083.1	083.4	083.9	087.1	083.4	-0.506	PRE VACUUM
09:52:44	069.9	071.3	072.4	080.0	070.9	-0.707	PRE VACUUM
09:53:07	065.3	067.1	068.3	079.5	066.9	-0.756	PRE PRESSURE
09:53:45	075.7	074.7	074.5	081.4	074.8	-0.526	PRE PRESSURE
09:54:43	088.6	089.3	089.3	089.8	089.3	-0.213	PRE PRESSURE
09:55:46	097.6	097.9	098.2	097.8	097.8	00.034	PRE PRESSURE
09:56:43	103.7	102.5	102.8	102.8	102.4	00.180	PRE PRESSURE
09:57:45	106.9	105.9	106.1	106.3	105.7	00.314	PRE PRESSURE
09:58:45	109.6	108.5	108.8	109.1	108.4	00.428	PRE PRESSURE
09:59:28	111.1	110.1	110.4	110.7	110.0	00.499	HEAT UP
09:59:44	110.5	109.8	110.2	110.3	109.6	00.435	HEAT UP
10:00:45	110.1	109.3	109.5	110.0	109.3	00.459	HEAT UP
10:01:44	110.5	109.6	109.8	110.3	109.6	00.478	HEAT UP
10:02:45	112.8	111.8	112.0	112.4	111.8	00.590	HEAT UP
10:03:46	114.6	113.6	113.8	114.2	113.6	00.682	HEAT UP
10:04:45	115.2	114.3	114.5	114.9	114.2	00.682	HEAT UP
10:05:45	115.3	114.3	114.7	115.0	114.3	00.708	HEAT UP
10:06:46	114.9	114.1	114.5	114.9	114.2	00.703	HEAT UP
10:07:45	116.6	115.6	115.8	116.2	115.6	00.788	HEAT UP
10:08:45	118.1	117.1	117.4	117.7	117.1	00.870	HEAT UP
10:09:46	118.1	117.2	117.5	117.8	117.1	00.841	HEAT UP
10:10:45	118.0	117.2	117.5	117.9	117.2	00.866	HEAT UP
10:11:47	118.0	117.3	117.6	118.0	117.3	00.880	HEAT UP
10:12:47	118.3	117.4	117.7	118.1	117.3	00.869	HEAT UP
10:13:46	118.5	117.6	117.9	118.4	117.6	00.909	HEAT UP
10:14:47	120.1	119.2	119.4	119.9	119.1	01.005	HEAT UP
10:15:47	121.4	120.6	120.7	121.2	120.5	01.086	HEAT UP
✓10:16:53	122.5	121.7	121.8	122.3	121.5	01.152	STER HOLD
10:17:47	122.3	121.7	121.8	122.3	121.5	01.136	STER HOLD
10:18:47	122.1	121.5	121.7	122.1	121.3	01.113	STER HOLD

3

10:19:46	122.1	121.4	121.5	122.1	121.3	01.134	STER HOLD
10:20:47	122.5	121.7	122.0	122.4	121.6	01.153	STER HOLD
10:21:48	122.3	121.5	121.9	122.3	121.5	01.131	STER HOLD
10:22:47	122.6	121.7	122.1	122.5	121.7	01.138	STER HOLD
10:23:48	122.3	121.6	121.9	122.3	121.5	01.144	STER HOLD
10:24:46	122.4	121.5	122.0	122.3	121.5	01.110	STER HOLD
10:25:47	122.5	121.8	122.0	122.5	121.7	01.159	STER HOLD
10:26:48	122.3	121.7	121.8	122.3	121.5	01.144	STER HOLD
10:27:46	122.3	121.7	121.9	122.3	121.5	01.113	STER HOLD
10:28:47	122.6	121.8	122.0	122.5	121.7	01.143	STER HOLD
10:29:48	122.3	121.7	121.9	122.3	121.5	01.145	STER HOLD
10:30:47	122.3	121.6	122.0	122.3	121.5	01.115	STER HOLD
10:31:48	122.6	121.7	122.1	122.4	121.7	01.135	STER HOLD
10:32:47	122.4	121.7	122.0	122.3	121.6	01.150	STER HOLD
10:33:49	122.3	121.6	121.9	122.3	121.5	01.136	STER HOLD
10:34:47	122.5	121.7	122.0	122.4	121.6	01.124	STER HOLD
10:35:49	122.6	121.8	122.0	122.5	121.7	01.139	STER HOLD
10:36:48	122.3	121.6	121.9	122.4	121.5	01.144	STER HOLD
10:37:49	122.3	121.6	121.9	122.3	121.5	01.126	STER HOLD
10:38:49	122.6	121.8	122.0	122.5	121.7	01.138	STER HOLD
10:39:48	122.5	121.7	122.0	122.5	121.6	01.155	STER HOLD
10:40:49	122.3	121.7	121.9	122.3	121.5	01.135	STER HOLD
10:41:50	122.5	121.8	122.0	122.4	121.6	01.124	STER HOLD
10:42:49	122.6	121.8	122.0	122.5	121.7	01.167	STER HOLD
10:43:50	122.3	121.7	121.9	122.3	121.5	01.142	STER HOLD
10:44:49	122.6	121.8	122.0	122.5	121.6	01.129	STER HOLD
10:45:50	122.6	121.9	122.0	122.6	121.7	01.160	STER HOLD
10:46:49	122.3	121.7	121.9	122.3	121.5	01.145	STER HOLD
10:46:54	122.5	121.7	122.0	122.5	121.6	01.158	POST VACUUM
10:47:50	101.6	103.9	104.4	104.6	102.9	-0.038	POST VACUUM
10:48:51	086.1	087.3	087.1	088.0	087.6	-0.442	POST VACUUM
10:49:50	074.3	075.5	077.1	075.4	085.7	-0.657	POST VACUUM
10:50:31	065.3	071.7	071.0	068.2	087.5	-0.746	VACUUM HOLD

10:50:49	067	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	VACUUM HOLD
10:51:50	053.4	063.1	060.7	056.9	089.6	-0.841	VACUUM HOLD
10:52:49	047.3	069.7	056.1	050.9	090.4	-0.881	VACUUM HOLD
10:53:50	042.9	076.9	056.5	048.9	091.3	-0.901	VACUUM HOLD
10:54:51	039.8	081.2	070.3	044.3	092.3	-0.913	VACUUM HOLD
10:55:50	038.0	083.3	078.2	043.9	093.1	-0.921	VACUUM HOLD
10:56:50	037.9	084.9	083.6	047.4	093.9	-0.926	VACUUM HOLD
10:57:51	037.2	085.8	087.1	047.6	094.6	-0.930	VACUUM HOLD
10:58:52	036.2	086.6	089.4	047.5	095.1	-0.932	VACUUM HOLD
10:59:51	035.2	086.7	090.9	054.1	095.4	-0.935	VACUUM HOLD
11:00:52	034.2	087.3	092.1	060.5	095.7	-0.936	VACUUM HOLD
11:01:52	033.4	087.7	092.8	065.4	094.8	-0.937	VACUUN HOLD
11:02:51	032.7	088.0	093.4	068.8	095.2	-0.938	VACUUM HOLD
11:03:51	032.0	088.2	093.9	071.1	095.7	-0.939	VACUUM HOLD
11:04:52	031.3	088.4	094.3	072.7	096.0	-0.940	VACUUM HOLD
11:05:53	030.6	088.4	094.5	073.8	096.3	-0.940	VACUUM HOLD
11:06:51	030.1	088.5	094.7	074.4	096.5	-0.940	VACUUM HOLD
11:07:52	029.5	088.5	094.8	074.8	096.8	-0.940	VACUUM HOLD
11:08:53	029.3	088.4	094.9	075.3	096.9	-0.940	VACUUM HOLD
11:09:53	029.5	088.4	095.0	075.7	097.1	-0.940	VACUUM HOLD
11:10:52	029.7	088.4	095.0	076.1	097.2	-0.939	VACUUM HOLD
11:11:52	029.8	088.2	095:0	076.4	097.4	-0.938	VACUUM HOLD
11:12:53	029.9	088.0	095.1	076.7	097.5	-0.936	VACUUM HOLD
11:13:53	029.9	087.8	095.1	077.0	097.7	-0.934	VACUUM HOLD
11:14:54	029.9	087.6	095.1	077.2	097.8	-0.931	VACUUM HOLD
11:15:52	029.9	087.5	095.0	077.2	097.8	-0.929	VACUUM HOLD
11:16:52	030.0	087.3	095.0	077.2	097.8	-0.928	VACUUM HOLD
11:17:54	030.0	087.1	094.9	077.2	097.8	-0.927	VACUUM HOLD
11:18:54	030.0	086.9	094.8	077.2	097.8	-0.927	VACUUM HOLD
11:19:53	030.1	086.7	094.7	077.2	097.8	-0.927	VACUUM HOLD
11:20:31	030.1	086.7	094.6	077.2	097.8	-0.927	POST PRESSURE
11:20:53	030.5	086.5	094.3	077.7	097.8	-0.828	POST PRESSURE
11:21:55	031.7	087.3	093.3	077.4	098.5	-0.519	POST PRESSURE

S

I

Dabur PHARMA
PLANT-II, BADDI

CHECKLIST FOR FILLING ROOM

QUALITY ASSURANCE DEPARTMENT

Previous Product: Cytarabine Inj. 100mg/m2 **B. No.** SLA204

Product Name: Topotecan for Inj. 4mg/vial **B. No.** SPK201

Equipment No. CSP/021 **Date** 15/10/08

CHECKLIST FOR FILLING ROOM			
Sr. No.	**Check Points**	**Remarks (ok / not ok)**	**Checked By**
1.	Ensure that the filling line room for cleanliness and no remnants of previous batch/ product left out in the room.	ok	15/10/08
2.	Check Ensure that the filling, bunging and sealing cRAB is visibly clean and no remnants of previous batch/ product left out in the room.	ok	15/10/08
3.	Ensure that pressure differential of cRAB & area within the limit.	ok	15/10/08
4.	Ensure that Equipment usage log, room cleaning and sanitization logbook are maintained and updated.	ok	15/10/08
5.	Ensure the "CLEANED" label affixed on the filling, bunging, sealing is cRAB.	ok	15/10/08
6.	Ensure the temp. and %RH is within the limit.	ok	15/10/08

QA Signature

7.0 ONLINE FILTRATION, FILLING, STOPPERING AND SEALING OPERATION:

7.1 CLEANING:

Step No.	Checks	Eq. Id. No.	SOP No.	Date	Time		Done By##	Checked By##
					From	To		
1.	Cleaning of filling, Stoppering and Sealing machine	CSP/021	SOP/CSP/031	15/10/08	11:00	11:35	Naresh	Sunil
2.	Cleaning of cRABs 2a. cRAB1 2b. cRAB2 2c. cRAB3 2d. cRAB4 2e. RAB5	 CSP/025 CSP/026 CSP/027 CSP/028 CSP/029	SOP/CSP/054	15/10/08	11:00	11:35	Naresh	Sunil

7.2 LINE CLEARANCE:

- Ensure the cleanliness of Vial Filling room.
- Ensure the line clearance as per the check list.
- Ensure that status label is properly written on door of the room and on holding tank.
- Ensure proper change over and setting is done as per the pack size.
- Ensure that the pressure differential in gauges of the cRAB is within the limit.
- Ensure that the pressure differential, temperature, relative humidity of filling room is within limit.

Date: 15/10/08

Step No.	Checks	Eq. Id. No.	SOP No.	Previous product		Ckd. by##	Verified by###
				Product Name	Batch No.		
1.	Line clearance for filling, stoppering and sealing machine	CSP/021	SOP/QAD/053	cytrabine inj 100mg/m2	8LA204	[illegible]	Sanjeevan 15/10/08

##Production

###IPQA

7.3 ENVIRONMENTAL MONITORING IN FILLING ROOM:

Frequency: At the start and at the end of activity

S. No.	Checks	SOP No.	Observations			
1.	Date	---	15/10/08	15/10/08		
2.	Time	---	15:20	21:55		
3.	Differential pressure reading on the magnehelic gauge: Filling room to Filling Corridor (Range: 0.5 –5.0 mm of water)	SOP/CSP/011	2.4	2.4		
4.	Filling room temperature (NMT 25°C)	SOP/CSP/011	22	23	NA	
5.	Filling room R.H. (NMT 60%)	SOP/CSP/011	51	56		
6.	Done by##	---	Shambhu	Shambhu		
7.	Ckd. by ##	---	[illegible]	[illegible]		

15/10/08

7.4 FILL WEIGHT CALCULATION DATA.

Specific Gravity of the Product 1.01 as per A.R. No. 02BL080000084 Dated 15/10/08

Fill volume*	Target fill Volume	Min.	Max.
Range in ml	1.957	1.898	2.015
Range in Wt. (Volume X Specific Gravity of the Product)	1.976	1.916	2.035

Calculated by [signature] 15/10/08
Production

Ckd. by [signature] 15/10/08
IPQA

* Refer page no. 3.

##Production

QA Signature [signature]

7.5 ONLINE FILTRATION, FILLING AND HALF STOPPERING OPERATION:

Date: 15/10/08 First Filtration completed at: 17:10

Filling started at: 19:50 Filling completed at: 21:45

Duration between first filtration completion time to filling completion time 4hrs 35 minuts. (NMT 48 hours)

Step No.	Checks	SOP No.	Time From	Time To	Observations	Done By##	Ckd. By##
1.	Note the reading of cRAB1 over infeed turntable on magnehelic gauge in 'ON' condition. (Limit: 10 to 16 Pascal)	SOP/CSP/054	---	---	At Start 14	Sanjeev	[illegible]
					At End 14	Shanthi	[illegible]
2.	Note the reading of cRAB1 over filling and Stoppering machine on magnehelic gauge in 'ON' condition. (Limit: 30 to 36 Pascal)	SOP/CSP/054	---	---	At Start 32	Sanjeev	[illegible]
					At End 32	Shanthi	[illegible]
3.	Note the reading of cRAB 2 for Sealing Machine on the magnehelic gauge in 'ON' condition (Limit: 14 to 20 Pascal)	SOP/CSP/054	---	---	At Start 16	Sanjeev	[illegible]
					At End 16	Shanthi	[illegible]
4.	Transfer the sterilized equipments; rubber stoppers and aluminum flip off overseal from the cooling zone LAF to the filling room in the mobile LAF. And note the reading of ΔP across HEPA on the magnehelic gauge in 'ON' condition (Limit: 10 to 15 mm of WC)	SOP/CSP/018	15:35	15:37	ΔP across HEPA 12 (mm of WC)	Sanjeev	[illegible]
5.	Ensure the Stoppering unit is assembled.	SOP/CSP/031	15:40	15:43	OK	Sanjeev	[illegible]

##Production

QA Signature [illegible]

Step No.	Checks	SOP No.	Time		Observations	Done By##	Ckd. By##
			From	To			
6.	Check the initial weight of the tank and note the reading	---	17:36	17:38	Wt = 10275 Kg	Sanjeev	[illegible]
7.	Connect the outlet of holding tank to the inlet of product filter through peristaltic pump and outlet of product filter to the inlet of buffer bottle and connect the outlet of buffer bottle to the manifold having connections for piston and filling needles using Platinum cured silicone tubes.	---	17:42	17:46	OK	Sanjeev	[illegible]
8.	Filter the solution and collect in buffer bottle.	SOP/CSP/031	17:49	17:53	OK	Sanjeev	[illegible]
9.	Before start of the filling of vials, purge the needles with the product removing the entrapped air from tubes and piston and collect the solution in SS container and discard.	SOP/CSP/031	17:56	18:01	OK	Sanjeev	[illegible]
10.	Adjust the volume of syringes as per the data obtained from step 7.4 and record the observation in the table 7.6.1.	SOP/CSP/031	19:37	19:45	OK	Shambhu	[illegible]
11.	Load the Rubber stoppers in hoppers.	SOP/CSP/031	19:30	19:32	OK	Shambhu	[illegible]

##Production

Step No.	Checks	SOP No.	Time		Observations	Done By##	Ckd. By##
			From	To			
12.	Operate the filling and Stoppering machine at validated speed and fill the solution in the vials filtering through online 0.22µ cartridge filter.	SOP/CSP/031	19:50	21:45	50 Vials per minute	Shambhu	[illegible]
13.	Check the in process Fill volume at Start and End (during process every 30 min.) of filling from each Filling head (4 vials) and record the details in table 7.6.2	---	---	---	OK	Sanjeev	[illegible]
14.	Check the final weight of the tank and note the reading (Left over solution)	---	---	---	Wt = ~~0.00~~ 12.35 Kg [illegible] 15/10/08.	Sanjeev	[illegible]
15.	Total solution consumed = Initial Wt (Step6) -Final Wt (Step14)	---	---	---	10.4 Kg	Sanjeev	[illegible]
16.	Total rejection during filling and Stoppering.	---	---	---	Vials 24 Rubber stoppers 24	Sanjeev	[illegible]
17.	Send the rejected vials for deactivation and crushing.	SOP/CSP/069	---	---	24 Vials	Sanjeev	[illegible]
18.	Filled vials rejected at filling As per table 7.8	---	---	---	24 Vials	Sanjeev	[illegible]

##Production

7.6 INPROCESS CHECKS:

7.6.1 INITIAL FILL WEIGHT AND STOPPERING CHECK:

Specific Gravity of the Product 1·01 as per A.R. No. 02BL08000084 Dated 15/10/08

Fill volume*	Target fill Volume	Min.	Max.
Range in ml	15/10/08 ~~1·956~~ 1·957	1·898	2·015
Range in Wt. (Volume X Specific Gravity of the Product)	1·976	1·916	2·035

Date	Time	Filled Weight (g)				Initial Half Stoppering		Done By##	Ckd. By##
		N_1	N_2	N_3	N_4	S_1	S_2		
15/10/08	19:37	1·708	1·732	1·753	1·795	OK	OK	Shambhu	
15/10/08	19:45	1·864	1·873	1·938	1·997	OK	OK	Shambhu	
			N/A						

N_1 = nozzle 1, N_2 = nozzle 2, N_3 = nozzle 3, N_4 = nozzle 4, S_1= Stoppering head 1, S_2= Stoppering head 2

(Weights of filled vials sheet attached on the reverse side of page No.: 29) 15/10/08

* Refers page no. 3.

##Production

PRODUCT NAME :- TOPOTECAN INJ. 4 MG/2ML.

PRODUCT. BATCH.NO: 8P/4201.

INITIAL FILL WEIGHT. A.J. CHECKS.

Weighing 15.10.2008 19:37	
1.708	[illegible] g
	[illegible] g
1.732	12.632 g
1.753	12.318 g
1.785	10.370 g
	10.216 g
	10.224 g
15/10/08	10.223 g
	15/10/08

Weighing 15.10.2008 19:45	
1.964	12.342 g
1.973	12.245 g
	12.385 g
1.938	12.899 g
1.997	10.370 g
	10.176 g
15/10/08	10.367 g
	15/10/08
	10.852 g

7.6.2 IN PROCESS FILL WEIGHT CHECK:

Specific Gravity of the Product: 1.01

Frequency: Start and End of filling (during process every 30 min.)

Date: 15/10/08

Filling started at: 19:50 Filling completed at: 21:45

Total filling time: 1 Hr 55 minuts

Date	Time	Filled Weight (g)				Initial Half Stoppering		Done By##	Ckd. By##
		N_1	N_2	N_3	N_4	S_1	S_2		
15/10/08	19:50	2.000	2.011	2.027	1.956	OK	OK	Shambhu	[illegible]
15/10/08	20:20	1.992	1.983	1.965	2.019	OK	OK	Shambhu	[illegible]
15/10/08	21:15	1.945	1.995	1.956	2.000	OK	OK	Shambhu	[illegible]
15/10/08	21:45	1.993	1.959	1.929	1.952	OK	OK	Shambhu	[illegible]
				N/A					

(Attach the In process fill weight graph on reverse of this page.)

N_1 = nozzle 1, N_2 = nozzle 2, N_3 = nozzle 3, N_4 = nozzle 4, S_1= Stoppering head 1, S_2= Stoppering head 2

15/10/08

##Production

PRODUCT NAME: TOPOTECAN INJ. 4MG/2ML.
BATCH NO : 8PK201.

IN PROCESS FILL WEIGHT CHECKS

	12.283 g
2.000	10.283 g
	12.250 g
2.011	[illegible] g
	[illegible] g
2.027	[illegible] g
	12.212 g
1.956	10.256 g

15/10/08 15/10/08

	12.151 g
1.992	10.159 g
	12.335 g
1.983	[illegible] g
	[illegible] g
1.965	10.161 g
	12.240 g
2.019	10.221 g

15/10/08 15/10/08

	12.227 g
1.945	10.282 g
	12.855 g
1.995	10.860 g
	[illegible] g
1.956	[illegible] g
	12.102 g
2.000	10.102 g

15/10/08 15/10/08

	12.369 g
1.993	10.376 g
	12.862 g
1.959	10.193 g
	[illegible] g
1.929	[illegible] g
	12.181 g
1.952	10.229 g

15/10/08 15/10/08

Product Name	**Topotecan for Injection 4 mg (base)/vial**		
Batch Number	BPK 201		
Batch size	12 L	**Batch Filling Code**	IO720004
Department	Production (CSL)	**BFR No.**	BFR/CSL/TOP/001
Shelf life	24 Months (Provisional)	**Version No.**	00

7.7 INTERVENTIONS OBSERVED DURING FILLING:

Date	Time		Interventions	Tray No.	Ckd. By##
	From	To			
15/10/08	20:30	21:13	M/C stopped for dunner break	03	

N/A

15/10/08

7.8 FILLED VIAL REJECTION DETAILS

Time	No of vials	Type of Rejection	Ckd. By##
19:37	04	Initial fill wt. check	
19:45	04	Initial fill wt. check	
19:50	04	Inprocess fill wt. check	
20:20	04	Inprocess fill wt. check.	
21:15	04	Inprocess fill wt. check	
21:45	04	Inprocess fill wt. check	

N/A

15/10/08

##Production

7.9 POST INTEGRITY TEST OF AIR VENT FILTER (WATER INTRUSION TEST/BUBBLE POINT TEST):

- Perform the post integrity test of the Air vent filter of holding tank as per SOP No SOP/CSP/023.
- Flow rate should be NMT 0.12mL/minute.
- Bubble point value of this filter is NLT 20psi with IPA.

Date	Filter Catalogue No.	Filter Serial No.	Cartridge Filter Holder No.	Flow Rate (mL/min.) / ~~Bubble Point Pressure (psi)~~ **	Result (Pass/~~Fail~~)	Done By##	Ckd. By##
15/10/08	SLK7002PFRP	FP9649 0387	CSP/016	0.10 ml/min	Pass	Sohan	15/10/08

7.10 POST INTEGRITY TEST OF PRODUCT FILTER (BUBBLE POINT TEST):

- Perform the post integrity test of the Product filter as per SOP No. SOP/CSP/023.
- Properly flush the filter with cool WFI before undergoing post integrity test.
- Bubble point value is NLT 50 psi with WFI.

Date	Filter Catalogue No	Filter Serial No.	Cartridge Filter Holder No.	Observed Bubble Point	Result (Pass/~~Fail~~)	Done By##	Checked By##
15/10/08	LAGL04TPG	C7MN15708 0607	CSP/113	57.29	Pass	Sohan	15/10/08

7.11 POST INTEGRITY TEST OF AIR VENT FILTER (BUBBLE POINT TEST):

- Perform the post integrity test of the Air vent filter for buffer bottle as per SOP No SOP/CSP/023.
- Properly wet the filter by flushing 60% IPA/WFI mixture before undergoing post integrity test.
- Bubble point value is NLT 16 psi with 60% IPA/WFI mixture.

Date	Filter Catalogue No	Filter Serial No.	Cartridge Filter Holder No.	Observed Bubble Point	Result (Pass/~~Fail~~)	Done By##	Checked By##
15/10/08	MTGR15010 - BP	F7PN092 10 01965	–	22.48	Pass	Sohan	15/10/08

Note: In case of any technical problem with the integrity test apparatus, the integrity should be performed manually as per SOP No. SOP/CSP/023

** Strike off which is not applicable

(Attach the print out of the process on the backside of the page)

Production

IPQA

QA Signature

****

Palltronic Flowstar Test Report

15/Oct/2008 22:57:09

Serial Number	: 15342626/3.3a
Function	: BP
Test Programme	: MTGR15010-BP
Production area	: PROD-CSL
Filter line	: BUFFER BOTTLE FILTER
Product name	: TOPOTECAN FOR INJ.
Product batch no.	: 8PK201
Filter part no.	: MTGR
Filt. serial no.	: F7PN09210 01965
Housing	: -----
Wetting liquid	: 60:40 IPA:WATER
Test gas	: AIR
BP minimum	: 16.00 psi

BP value measured : 22.48 psi

BP within limits

Comment : POST-INTEGRITY

Electr. Signature : PRADEEP
Created 15/Oct/2008 23:04:11

Sohan 15/10/08

****

****

Palltronic Flowstar Test Report

15/Oct/2008 22:30:51

Serial Number	: 15342626/3.3a
Function	: BP
Test Programme	: LAGL04TP6
Production area	: PROD-CSL
Filter line	: ONLINE FILTER
Product name	: TOPOTECAN FOR INJ.
Product batch no.	: 8PK201
Filter part no.	: LAGL04TP6 ✓
Filt. serial no.	: C7MN15708 0607
Housing	: CSP/113
Wetting liquid	: WATER
Test gas	: AIR
BP minimum	: 50.00 psi

BP value measured	: 57.29 psi ✓
BP within limits	
Comment	: POST-INTEGRITY
Electr. Signature	: PRADEEP
Created	15/Oct/2008 22:46:32

15/10/08

15/10/08

Sohan 15/10/08

****

****

Palltronic Flowstar Test Report

15/Oct/2008 23:07:12

Serial Number	: 15342626/3.3a
Function	: WIT
Test Programme	: SLK7002PFRP-WIT ✓
Production area	: PROD-CSL
Filter line	: AIR VENT FILTER
Product name	: TOPOTECAN FOR INJ.
Product batch no.	: 8NJ201
Filter part no.	: SLK7002PFRP ✓
Filt. serial no.	: FP9649 0387
Housing	: CSP/016
Test pressure	: 36.25 psi
Test time	: 236 sec (Auto)
Max. flow	: 0.12 ml/min

Flow	: 0.10 ml/min ✓
Flow within limits	
Comment	: POST-INTEGRITY HOLDING TANK
Electr. Signature	: PRADEEP
Created	15/Oct/2008 23:19:11

Pradeep 15/10/08

15/10/08

Sohan 15/10/08

****

7.12 POST CLEANING OF EQUIPMENTS AND ACCESSORIES FOR ONLINE FILTRATION AND FILLING:

Clean the equipments and accessories for online filtration and filling with the WFI in the wash table lying in the equipment wash room (CSLG 014).

Cleaning started at: 22:58 (15/10/08) Cleaning completed at: 23:58

S.No.	Equipment Name	Equipment Id. No.	SOP No.	Qty.	Done By##	Ckd. By##
1.	SS Beakers 500 mL, 1000 mL	---	SOP/CSP/006	01+01		
2.	Cartridge Filter Holder with stand		SOP/CSP/006	01		
3.	**50 mm disc type Vent filter	---	SOP/CSP/006	01		
4.	Buffer Bottle	---	SOP/CSP/006	02		
5.	SS forceps	---	SOP/CSP/006	08		
6.	SS filling needle	---	SOP/CSP/006	04		
7.	SS syringe set	---	SOP/CSP/006	04		
8.	Stopper hopper, Stopper rail, chute	---	SOP/CSP/006	01+01 01+01		
9.	Needle holding plate	---	SOP/CSP/006	01		
10.	Nylon Fasteners	---	SOP/CSP/006	–		
11.	Stopper head set	---	SOP/CSP/006	02		
12.	TC with Nozzle	---	SOP/CSP/006	–		
13.	Manifold	---	SOP/CSP/006	01		
14.	SS clamps, gaskets and nozzles	---	SOP/CSP/006	06+06+06		

** These equipments to be used product dedicated

##Production

QA Signature

8.0 LYOPHILIZATION

8.1 Perform the vacuum leak test as per SOP No. SOP/CSP/032

Date : 14/10/08 Time : 03:05

Vacuum Achieved : 54 bar. Hold Time : 60 min. Vacuum Drop : 24 bar

Result : PASS / ~~FAIL~~

Note:- Allowable pressure rise in system should not be more than 6 μ bars.

The system should pass the leak rate not more than 0.01 mbar/litre/sec.

8.2 CIP of Lyophilizer

8.2.1 Line Clearance for CIP

S.No.	Checks	Room No.	SOP No.	Date	Previous Product		Ckd by##	Verified by###
					Product Name	Batch no.		
1.	Line Clearance of lyophilizer	CSLG/034	SOP/QAD/053	13/10/08	Topotecan Placebo	—	[signature]	[signature] 13/10/08

8.2.2 Ensure the CIP of lyophilizer is complete using WFI as per SOP No. SOP/CSP/032.

8.2.3 A.R. No. of WFI 02WF080000748

8.2.4 Record the details of the operation in the table below.

Date	Details	Eq. Id. No.	Cleaning		Done by##	Checked by##
			Started at	Completed at		
14/10/08	Lyophiliser	CSP/040	06:29	08:08	[signature]	[signature]

(Attach the print out of the process on the reverse side of page)

##Production

Leak Rate Test Process Report

Initiator:	SUP	**Start Time:**	14/10/2008 3:05:14
Batch Name:	LRT20081014030514	**End Time:**	14/10/2008 5:25:53

PARAMETERS:

Test vacuum:	6	ubar
Test time:	60	Min.
Drying pressure:	100	ubar
Drying time:	30	Min.
Max time to reach dry pressure:	60	Min.
Retry number:	3	

RESULT:

No.: 1

Actual Pressure Rise: 2 ubar Test Result: Success

14/10/08

14/10/08

14/10/08

Leak Rate Test Process Report

Initiator:	SUP	**Start Time:**	14/10/2008 3:05:14
Batch Name:	LRT20081014030514	**End Time:**	14/10/2008 5:25:53

Date	Time	Description
Alarm:	Total: 3	
14/10/2008	3:05:39	Compressor 1 cooling water low flowrate
14/10/2008	3:20:02	Vacuum pump 1 failure
14/10/2008	3:20:10	PT301 pump vacuum probe fail
Audit:	Total: 5	
14/10/2008	3:05:15	Vacuum leakage test is enabled by Sup.
14/10/2008	3:20:23	SUP logged in as Application User by Sup.
14/10/2008	3:20:29	A_PUMPVACPROBEFAIL ALARM is acknowledged by Sup.
14/10/2008	3:20:29	A_VP1FAIL ALARM is acknowledged by Sup.
14/10/2008	3:20:29	A_COM1COOLWATERLOWPRES ALARM is acknowledged by Sup.

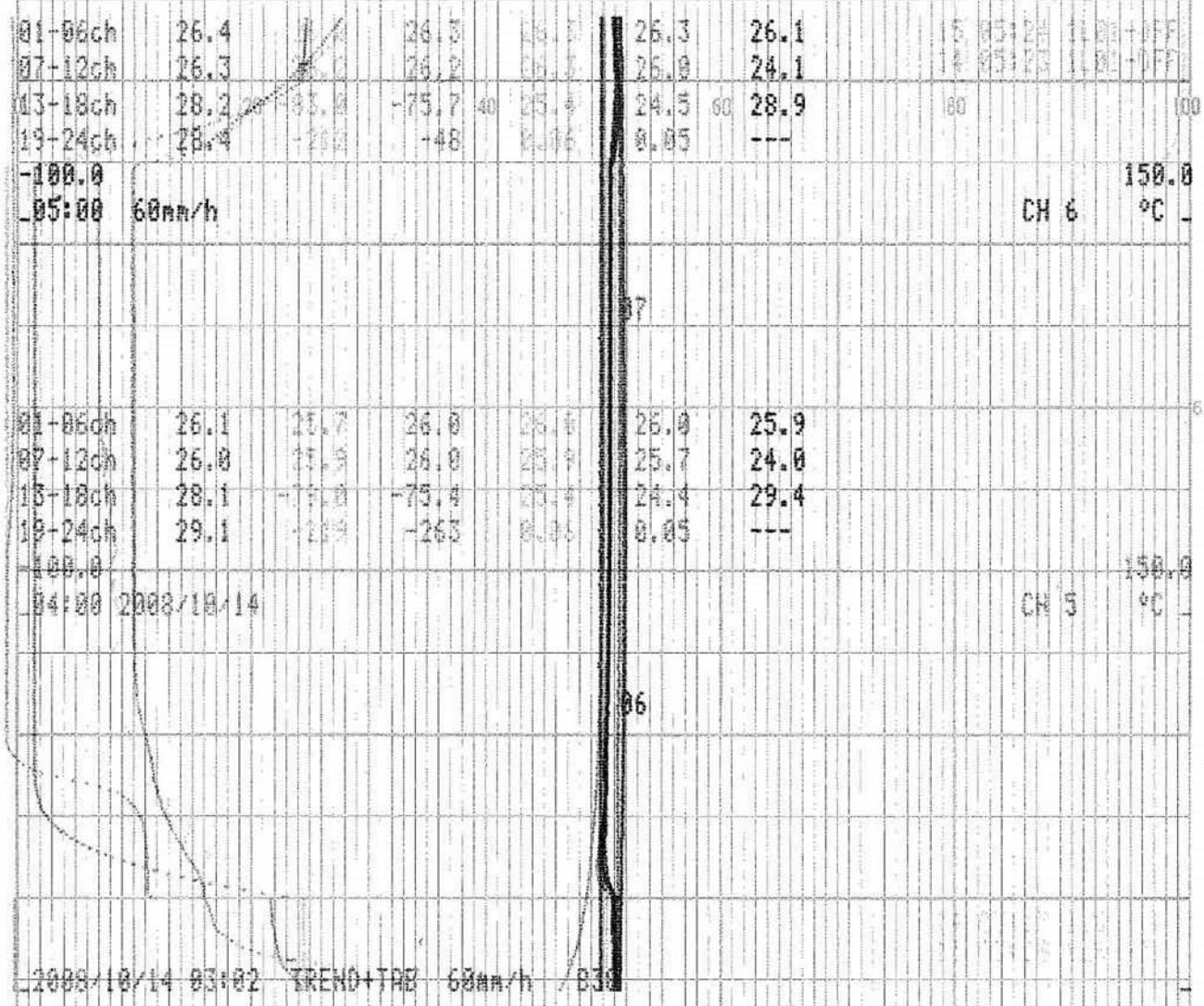
14/10/08

Raj
14/10/08
14/10/08

Vacuum Leak Test

Pass Rej 14/10/08

14/10/08



CIP Process Report

Initiator:	SUP	**Start Time:**	14/10/2008 6:29:16
Batch Name:	CIP20081014062916	**End Time:**	14/10/2008 8:08:23

PARAMETERS:

Chamber Wash Time:	2	Min.
Condenser Wash Time:	2	Min.
Drain time between mainfolds:	60	Sec.
Number of washes:	2	
Final drain time:	5	Min.
System drying time:	30	Min.
Flooding time:	1	Min.
Flooding Number :	1	

14/10/08

14/10/08

14/10/08

CIP Process Report

Initiator:	SUP	**Start Time:**	14/10/2008 6:29:16
Batch Name:	CIP20081014062916	**End Time:**	14/10/2008 8:08:23

Date	Time	Description
Alarm:	Total: 1	
14/10/2008	6:51:13	Compressor 1 cooling water low flowrate
Audit:	Total: 3	
14/10/2008	6:29:17	CIP cycle is enabled by Sup.
14/10/2008	6:51:57	SUP logged in as Application User by Sup.
14/10/2008	6:52:01	A_COM1COOLWATERLOWPRES ALARM is acknowledged by Sup.

14/10/08

14/10/08

14/10/08

Manufactured By : Adam Fabriwerks Pvt. Ltd.
Equipment : WIP Module
Client : Dabur Pharma Ltd. Unit II, Baddi
SIP OF WIP VESSEL SELECTED
Operator : A
Date : 13/10/2008 Time : 9:51

Sterilization Temperature : 123.0 degC
Stop Temperature : 122.0 degC
Reset Temperature : 121.0 degC
Sterilization Time : 30 mins

TIME	STER TIME (mins:secs)	VESSEL TEMP (degC)	VES OUTLET TEMP (degC)	PROCESS STATUS
9:51	0:0	37.0	36.6	WAITING FOR TEMP.
9:52	0:0	62.6	46.8	WAITING FOR TEMP.
9:53	0:0	69.8	57.6	WAITING FOR TEMP.
9:54	0:0	74.2	66.2	WAITING FOR TEMP.
9:55	0:0	77.8	73.0	WAITING FOR TEMP.
9:56	0:0	82.4	78.6	WAITING FOR TEMP.
9:57	0:0	86.8	84.2	WAITING FOR TEMP.
9:58	0:0	91.4	89.2	WAITING FOR TEMP.
9:59	0:0	94.6	93.2	WAITING FOR TEMP.
10:00	0:0	99.2	98.2	WAITING FOR TEMP.
10:01	0:0	103.2	102.6	WAITING FOR TEMP.
10:02	0:0	107.0	106.6	WAITING FOR TEMP.
10:03	0:0	110.0	110.0	WAITING FOR TEMP.
10:04	0:0	112.4	112.6	WAITING FOR TEMP.
10:05	0:0	114.2	114.8	WAITING FOR TEMP.
10:06	0:0	115.6	116.6	WAITING FOR TEMP.
10:07	0:0	116.4	117.8	WAITING FOR TEMP.
10:08	0:0	117.6	118.6	WAITING FOR TEMP.
10:09	0:0	118.0	119.2	WAITING FOR TEMP.
10:10	0:0	118.0	119.2	WAITING FOR TEMP.
10:11	0:0	118.8	120.2	WAITING FOR TEMP.
10:12	0:0	119.0	120.2	WAITING FOR TEMP.
10:13	0:0	119.4	120.8	WAITING FOR TEMP.
10:14	0:0	119.6	121.0	WAITING FOR TEMP.
10:15	0:0	119.6	121.0	WAITING FOR TEMP.
10:16	0:0	120.2	121.8	WAITING FOR TEMP.
10:17	0:0	120.4	121.8	WAITING FOR TEMP.
10:18	0:0	120.6	122.0	WAITING FOR TEMP.
10:19	0:0	120.8	122.2	WAITING FOR TEMP.
10:20	0:0	121.0	122.4	WAITING FOR TEMP.
10:21	0:0	121.2	122.6	WAITING FOR TEMP.
10:22	0:5	121.4	123.0	STER. TIMER RUNNING
10:23	1:5	121.4	122.8	STER. TIMER RUNNING
10:24	2:5	121.4	122.8	STER. TIMER RUNNING
10:25	3:5	121.4	122.8	STER. TIMER RUNNING
10:26	4:5	121.4	123.0	STER. TIMER RUNNING
10:27	5:5	121.4	123.0	STER. TIMER RUNNING
10:28	6:5	121.4	122.8	STER. TIMER RUNNING
10:29	7:5	121.4	122.8	STER. TIMER RUNNING
10:30	8:5	121.6	123.0	STER. TIMER RUNNING
10:31	9:5	121.4	123.0	STER. TIMER RUNNING
10:32	10:5	121.4	123.0	STER. TIMER RUNNING
10:33	11:5	121.4	122.8	STER. TIMER RUNNING

10:33	11:5	121.4	122.8	STER. TIMER RUNNING
10:34	12:5	121.6	123.0	STER. TIMER RUNNING
10:35	13:5	121.4	123.0	STER. TIMER RUNNING
10:36	14:5	121.4	123.0	STER. TIMER RUNNING
10:37	15:5	121.4	123.0	STER. TIMER RUNNING
10:38	16:5	121.4	122.8	STER. TIMER RUNNING
10:39	17:5	121.4	123.0	STER. TIMER RUNNING
10:40	18:5	121.4	123.0	STER. TIMER RUNNING
10:41	19:5	121.4	123.0	STER. TIMER RUNNING
10:42	20:5	121.4	123.0	STER. TIMER RUNNING
10:43	21:5	121.4	123.0	STER. TIMER RUNNING
10:44	22:5	121.4	123.0	STER. TIMER RUNNING
10:45	23:5	121.4	123.0	STER. TIMER RUNNING
10:46	24:5	121.4	123.0	STER. TIMER RUNNING
10:47	25:5	121.4	123.0	STER. TIMER RUNNING
10:48	26:5	121.4	123.0	STER. TIMER RUNNING
10:49	27:5	121.4	123.0	STER. TIMER RUNNING
10:50	28:5	121.4	123.0	STER. TIMER RUNNING
10:51	29:5	121.4	123.0	STER. TIMER RUNNING

13/10/2008 10:52 SIP Of WIP Vessel Process Completed Successfully

DONE BY 13/10/08 13/10/08 13/10/08

CHECKED BY 13/10/08

.nufactured By : Adam Fabriwerks Pvt. Ltd.
ıuipment : WIP Module
.ient : Dabur Pharma Ltd. Unit II, Baddi
›erator : A
.P VESSEL RINSE CYCLE SELECTED
.te : 13/10/2008 Time : 9:00

'I Quantity : 500 Ltrs

ME	WFI QTY.	VESSEL TEMP (degC)	PROCESS STATUS
01	0	24.6	WIP VESSEL RINSE IN PROCESS
02	80	24.4	WIP VESSEL RINSE IN PROCESS
03	140	24.2	WIP VESSEL RINSE IN PROCESS
04	196	24.2	WIP VESSEL RINSE IN PROCESS
05	240	24.0	WIP VESSEL RINSE IN PROCESS
06	284	24.0	WIP VESSEL RINSE IN PROCESS
07	320	24.0	WIP VESSEL RINSE IN PROCESS
08	364	24.0	WIP VESSEL RINSE IN PROCESS
09	400	23.8	WIP VESSEL RINSE IN PROCESS
10	436	23.8	WIP VESSEL RINSE IN PROCESS
11	468	24.0	WIP VESSEL RINSE IN PROCESS
12	500	24.0	WIP WATER LEVEL REACHED
12	500	24.0	WIP DRAIN IN PROCESS
13	276	24.0	WIP DRAIN IN PROCESS
14	180	23.8	WIP DRAIN IN PROCESS
15	84	23.8	WIP DRAIN IN PROCESS
16	0	23.6	WIP DRAIN IN PROCESS
17	0	23.6	WIP DRAIN IN PROCESS
/10/2008	9:17	Rinse Cycle Process Completed Successfully	

ONE BY 13/10/08 13/10/08 CHECKED BY 13/10/08

Manufactured By : Adam Fabriwerks Pvt. Ltd.
Equipment : WIP Module
Client : Dabur Pharma Ltd. Unit II, Baddi
WIP OF LYOPHILISER SELECTED
Operator : A
Date : 14/10/2008 Time : 4:49

WFI Quantity : 2000 Ltrs
Temperature : 70.0 degC
Delay For Drain : 15 secs

TIME	WFI QTY.	VESSEL TEMP (degC)	PROCESS STATUS
4:49	0	55.8	WATER LEVEL MAKEUP IN PROCESS
4:50	0	48.4	WATER LEVEL MAKEUP IN PROCESS
4:51	0	43.4	WATER LEVEL MAKEUP IN PROCESS
4:52	0	39.6	WATER LEVEL MAKEUP IN PROCESS
4:53	116	37.0	WATER LEVEL MAKEUP IN PROCESS
4:54	204	35.6	WATER LEVEL MAKEUP IN PROCESS
4:55	260	34.0	WATER LEVEL MAKEUP IN PROCESS
4:56	312	33.0	WATER LEVEL MAKEUP IN PROCESS
4:57	364	32.6	WATER LEVEL MAKEUP IN PROCESS
4:58	404	32.8	WATER LEVEL MAKEUP IN PROCESS
4:59	448	32.8	WATER LEVEL MAKEUP IN PROCESS
5:00	492	36.2	WATER LEVEL MAKEUP IN PROCESS
5:01	532	36.2	WATER LEVEL MAKEUP IN PROCESS
5:02	560	35.8	WATER LEVEL MAKEUP IN PROCESS
5:03	604	35.4	WATER LEVEL MAKEUP IN PROCESS
5:04	644	35.0	WATER LEVEL MAKEUP IN PROCESS
5:05	676	34.6	WATER LEVEL MAKEUP IN PROCESS
5:06	716	34.2	WATER LEVEL MAKEUP IN PROCESS
5:07	748	34.0	WATER LEVEL MAKEUP IN PROCESS
5:08	792	33.6	WATER LEVEL MAKEUP IN PROCESS
5:09	828	33.4	WATER LEVEL MAKEUP IN PROCESS
5:10	864	33.2	WATER LEVEL MAKEUP IN PROCESS
5:11	900	33.0	WATER LEVEL MAKEUP IN PROCESS
5:12	944	32.8	WATER LEVEL MAKEUP IN PROCESS
5:13	980	32.6	WATER LEVEL MAKEUP IN PROCESS
5:14	1020	32.4	WATER LEVEL MAKEUP IN PROCESS
5:15	1048	32.4	WATER LEVEL MAKEUP IN PROCESS
5:16	1096	32.2	WATER LEVEL MAKEUP IN PROCESS
5:17	1128	32.0	WATER LEVEL MAKEUP IN PROCESS
5:18	1152	31.8	WATER LEVEL MAKEUP IN PROCESS
5:19	1188	31.8	WATER LEVEL MAKEUP IN PROCESS
5:20	1236	31.6	WATER LEVEL MAKEUP IN PROCESS
5:21	1272	31.4	WATER LEVEL MAKEUP IN PROCESS
5:22	1308	31.4	WATER LEVEL MAKEUP IN PROCESS
5:23	1344	31.2	WATER LEVEL MAKEUP IN PROCESS
5:24	1380	31.2	WATER LEVEL MAKEUP IN PROCESS
5:25	1416	31.2	WATER LEVEL MAKEUP IN PROCESS
5:26	1456	31.0	WATER LEVEL MAKEUP IN PROCESS
5:27	1488	31.0	WATER LEVEL MAKEUP IN PROCESS
5:28	1528	30.8	WATER LEVEL MAKEUP IN PROCESS
5:29	1560	30.8	WATER LEVEL MAKEUP IN PROCESS
5:30	1600	30.6	WATER LEVEL MAKEUP IN PROCESS
5:31	1636	30.6	WATER LEVEL MAKEUP IN PROCESS
5:32	1672	30.6	WATER LEVEL MAKEUP IN PROCESS
5:33	1712	30.6	WATER LEVEL MAKEUP IN PROCESS
5:34	1744	30.4	WATER LEVEL MAKEUP IN PROCESS
5:35	1784	30.4	WATER LEVEL MAKEUP IN PROCESS
5:36	1820	30.4	WATER LEVEL MAKEUP IN PROCESS
5:37	1856	30.2	WATER LEVEL MAKEUP IN PROCESS
5:38	1892	30.2	WATER LEVEL MAKEUP IN PROCESS
5:39	1928	30.2	WATER LEVEL MAKEUP IN PROCESS
5:40	1964	30.2	WATER LEVEL MAKEUP IN PROCESS
5:41	2000	30.2	WIP WATER LEVEL REACHED
5:41	1960	30.2	WATER LEVEL MAKEUP IN PROCESS

5:42	2240	30.2	WAITING FOR TEMP.
5:43	2116	30.8	WAITING FOR TEMP.
5:44	1988	31.8	WAITING FOR TEMP.
5:45	1960	31.6	WAITING FOR TEMP.
5:46	1968	33.0	WAITING FOR TEMP.
5:47	1956	33.0	WAITING FOR TEMP.
5:48	1972	35.0	WAITING FOR TEMP.
5:49	1984	36.2	WAITING FOR TEMP.
5:50	1960	37.0	WAITING FOR TEMP.
5:51	1996	38.0	WAITING FOR TEMP.
5:52	1968	39.8	WAITING FOR TEMP.
5:53	1980	40.8	WAITING FOR TEMP.
5:54	1984	41.4	WAITING FOR TEMP.
5:55	1980	43.2	WAITING FOR TEMP.
5:56	1968	44.2	WAITING FOR TEMP.
5:57	2000	45.0	WAITING FOR TEMP.
5:58	1964	46.4	WAITING FOR TEMP.
5:59	1996	47.0	WAITING FOR TEMP.
6:00	1972	48.8	WAITING FOR TEMP.
6:01	1984	49.0	WAITING FOR TEMP.
6:02	1984	50.2	WAITING FOR TEMP.
6:03	2024	50.6	WAITING FOR TEMP.
6:04	2004	52.6	WAITING FOR TEMP.
6:05	1960	53.8	WAITING FOR TEMP.
6:06	1984	54.4	WAITING FOR TEMP.
6:07	2016	55.8	WAITING FOR TEMP.
6:08	2060	56.2	WAITING FOR TEMP.
6:09	2040	57.4	WAITING FOR TEMP.
6:10	2004	59.0	WAITING FOR TEMP.
6:11	2024	59.6	WAITING FOR TEMP.
6:12	2016	61.0	WAITING FOR TEMP.
6:13	2072	62.0	WAITING FOR TEMP.
6:14	2036	62.8	WAITING FOR TEMP.
6:15	2036	64.0	WAITING FOR TEMP.
6:16	2028	65.0	WAITING FOR TEMP.
6:17	2056	65.8	WAITING FOR TEMP.
6:18	2080	67.2	WAITING FOR TEMP.
6:19	2040	67.8	WAITING FOR TEMP.
6:20	2000	67.6	WAITING FOR TEMP.
6:21	1896	69.2	WAITING FOR TEMP.
6:21	1896	70.0	WIP WATER TEMP. REACHED
6:22	1876	70.0	WATER RECIRCULATION
6:23	1892	71.0	WATER RECIRCULATION
6:24	1912	71.0	WATER RECIRCULATION
6:25	1944	71.4	WATER RECIRCULATION
6:26	1928	71.4	WATER RECIRCULATION
6:27	1924	71.6	WATER RECIRCULATION
6:28	1920	71.6	WATER RECIRCULATION
6:29	1920	71.6	WATER RECIRCULATION
6:30	1924	71.6	WATER RECIRCULATION
6:31	1916	71.6	WATER RECIRCULATION
6:32	1920	71.6	WATER RECIRCULATION
6:33	1920	71.6	WATER RECIRCULATION
6:34	1916	71.6	WATER RECIRCULATION
6:35	1920	71.6	WATER RECIRCULATION
6:36	1916	71.6	WATER RECIRCULATION
6:37	1920	71.8	WATER RECIRCULATION
6:38	1920	71.8	WATER RECIRCULATION
6:39	1916	71.8	WATER RECIRCULATION
6:40	1916	71.8	WATER RECIRCULATION
6:41	1912	71.8	WATER RECIRCULATION
6:41	1912	71.8	WIP PROCESS STARTED
6:42	1580	71.8	WIP IN PROCESS
6:43	1736	71.8	WATER RECIRCULATION
6:44	1724	71.8	WIP PROCESS STARTED
6:44	1544	71.8	WIP IN PROCESS
6:45	1440	71.8	WIP PROCESS STARTED
6:45	1360	71.8	WIP IN PROCESS
6:46	1228	71.6	WIP IN PROCESS
6:47	1092	71.8	WIP IN PROCESS
6:48	1284	71.6	WATER RECIRCULATION
6:49	1252	71.6	WIP PROCESS STARTED
6:49	1060	[illegible]	WIP IN PROCESS

6:49	1060	71.6	WIP IN PROCESS
6:50	872	71.6	WIP IN PROCESS
6:51	768	71.6	WIP IN PROCESS
6:52	848	71.6	WIP IN PROCESS
6:53	968	71.6	WATER RECIRCULATION
6:54	944	71.6	WIP PROCESS STARTED
6:54	716	71.6	WIP IN PROCESS
6:55	568	71.6	WIP IN PROCESS
6:56	744	71.4	WATER RECIRCULATION
6:57	720	71.4	WIP PROCESS STARTED
6:57	556	71.4	WIP IN PROCESS
6:58	556	71.4	WIP IN PROCESS
6:59	524	71.4	WIP IN PROCESS
7:00	476	71.4	WIP IN PROCESS
7:01	560	71.4	WATER RECIRCULATION
7:02	548	71.4	WIP PROCESS STARTED
7:02	308	71.4	WIP IN PROCESS
7:03	416	71.2	WIP IN PROCESS
7:04	340	70.8	WIP IN PROCESS
7:05	300	70.6	WIP IN PROCESS
7:06	400	70.8	WATER RECIRCULATION
7:07	372	70.8	WATER RECIRCULATION
7:08	360	70.8	WATER RECIRCULATION
7:09	356	70.8	WATER RECIRCULATION
7:10	348	70.8	WATER RECIRCULATION
7:11	352	70.8	WATER RECIRCULATION
7:12	348	70.8	WATER RECIRCULATION
7:13	352	70.8	WATER RECIRCULATION
7:14	356	70.8	WATER RECIRCULATION
7:15	288	70.8	WIP DRAIN IN PROCESS
7:16	224	70.4	WIP DRAIN IN PROCESS
7:17	204	70.2	WIP DRAIN IN PROCESS
7:18	168	70.0	WIP DRAIN IN PROCESS
7:19	124	70.0	WIP DRAIN IN PROCESS
7:20	76	69.6	WIP DRAIN IN PROCESS
7:21	8	69.4	WIP DRAIN IN PROCESS
7:22	0	69.2	WIP DRAIN IN PROCESS

14/10/2008 7:23 WIP Of Lyophiliser Process Completed Successfully

DONE BY 14/10/08

14/10/08

CHECKED BY 14/10/08

8.3 FILTER INTEGRITY TEST

8.3.1PRE INTEGRITY TEST OF AIR VENT FILTER (HYDRO CORR TEST/BUBBLE POINT TEST)

- Prior to startup of the SIP, perform the pre filter integrity of the vent filter to be used on Lyophilizer as per SOP No. SOP/CSP/023 and record the details in the table below.
- Flow rate should be NMT 0.7mL/minute in case of 5 inch cartridge filter MDI.
- Flow rate should be NMT 0.2mL/minute in case of 4 inch cartridge filter Millipore.
- Bubble point value is NLT 16 psi with 70:30 IPA:WFI.

Date	Filter Catalogue No.	Filter Serial No.	Cartridge Filter Holder No.	Flow Rate (mL/min.) / ~~Bubble Point Pressure~~ (Psi) **	Result (Pass/~~Fail~~)	Done By##	Ckd. By##
13/10/08	CGMNG7312/ 0189	0189	BM7AN0008K CSP/086	0.05ml/min	Passed	Raj	[illegible]
14/10/08	CPTF5301AS5101	CT0198-4	M3707 50003	0.14 ml/min	Passed	Raj	[illegible]
14/10/08	CPTF5301AS5101	CT0198-3	M3707 50015	0.13 ml/min	Passed	Raj	[illegible]

(Attach the print out of the process on the reverse side of page.)

** Strike off which is not applicable.

QA Signature [illegible]

INTEGRITEST EXACTA

Instrument Serial Number:
W20678
Date:
10/13/2008
Time:
9:42:28PM
Test Serial Number:
200810132142
Test Name:
LAGR HYDROCORR
Test Revision:
3
Test Description:
LAGR 4", PTFE, 0.2micron, 6/pk
HydroCorr Test

Filter Catalog Number:
LAGR04TP6
Test Fluid:
Water
Filter Description:
Optiseal Cartridge Filter With Aervent Membrane , 6/pack

Filter Size:
4"
Pore Size:
0.2
Housing Type:
optiseal

Operator Inputs

Operator:
raj
Product Batch no.
TOPTECAN
Filter Lot no.
C6MN97312
User Defined Field #3 - Optional
0189
User Defined Field #4 - Optional
PRE INT. H.N. CSP/086

Notes:
NITROGEN LINE FILTER

Test Specifications

HydroCorr Test Pressure:	38.0 psig
Test Time:	20.00 min
HydroCorr Specification:	0.20 ml/min
# of Cartridges:	1

# of Cartridges: 1

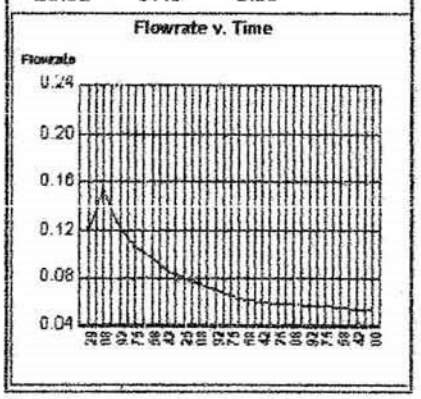
System Specification: 0.20 ml/min

Test Data

Gas Volume: 207 ml

Actual Test Pressure: 37.9 psig

Time min	Pressure psig	Flowrate ml/min
5.29	37.8	0.12
6.08	37.7	0.15
6.92	37.7	0.12
7.75	37.7	0.11
8.58	37.7	0.10
9.42	37.7	0.09
10.25	37.6	0.08
11.08	37.6	0.07
11.92	37.6	0.07
12.75	37.6	0.07
13.58	37.6	0.06
14.42	37.6	0.06
15.25	37.5	0.06
16.08	37.5	0.06
16.92	37.5	0.06
17.75	37.5	0.06
18.58	37.5	0.06
19.42	37.5	0.05
20.00	37.5	0.05



Test Results

Flowrate: 0.05 ml/min

Constant Pressure Flowrate: 0.05 ml/min

Immediate Retest

Test Conclusion

PASSED

Signature: Raj 13/10/08

Signature: 13/10/08

13/10/08

INTEGRITEST EXACTA

Instrument Serial Number:
W20678
Date:
10/14/2008
Time:
5:30:05AM
Test Serial Number:
200810140530
Test Name:
Lyo Vent filter
Test Revision:
2
Test Description:
MDI

HydroCorr Test

Filter Catalog Number:
CPTF5301A0SS101
Test Fluid:
WFI
Filter Description:

Filter Size:
5"
Pore Size:
0.2
Housing Type:
5"

Operator Inputs

Operator:
rai
Product Batch no.
TOPOTECAN
Filter Lot no.
CPTF 5301A0SS101
User Defined Field #3 - Optional
CT0198-04
User Defined Field #4 - Optional
PRE INT. H.N. M370750003

Notes:
AIR LINE FILTER

Test Specifications

HydroCorr Test Pressure:	38.0 psig
Test Time:	20.00 min

HydroCorr Specification: 0.70 ml/min

# of Cartridges: 1

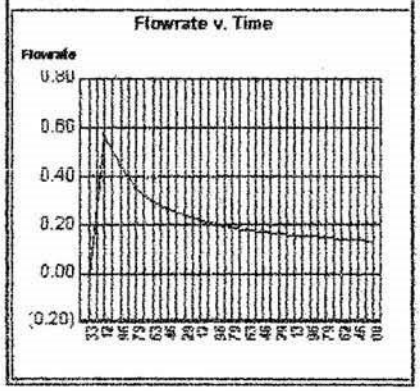
System Specification: 0.70 ml/min

Test Data

Gas Volume: 555 ml

Actual Test Pressure: 37.9 psig

Time min	Pressure psig	Flowrate ml/min
5.33	37.8	-0.01
6.12	37.8	0.57
6.96	37.8	0.44
7.79	37.7	0.36
8.63	37.7	0.30
9.46	37.7	0.27
10.29	37.7	0.24
11.12	37.7	0.22
11.96	37.6	0.20
12.79	37.6	0.19
13.63	37.6	0.18
14.46	37.6	0.17
15.29	37.6	0.16
16.13	37.6	0.16
16.96	37.5	0.15
17.79	37.5	0.15
18.62	37.5	0.14
19.46	37.5	0.14
20.00	37.5	0.14



Test Results

Flowrate: 0.14 ml/min

Constant Pressure Flowrate: 0.14 ml/min

Test Conclusion

PASSED

Signature: 14/10/08

Signature: 14/10/08

INTEGRITEST EXACTA

Instrument Serial Number:
W20678
Date:
10/14/2008
Time:
5:59:49AM
Test Serial Number:
200810140559
Test Name:
Lyo Vent filter
Test Revision:
2
Test Description:
MDI

HydroCorr Test

Filter Catalog Number:
CPTF5301A0SS101
Test Fluid:
WFI
Filter Description:

Filter Size:
5"
Pore Size:
0.2
Housing Type:
5"

Operator Inputs

Operator:
raj
Product Batch no.
TOPOPTECAN
Filter Lot no.
CPTF5301A0SS101
User Defined Field #3 - Optional
CT 0198-03
User Defined Field #4 - Optional
PRE INT. H.N.M370750015

Notes:
AIR LINE FILTER

Test Specifications

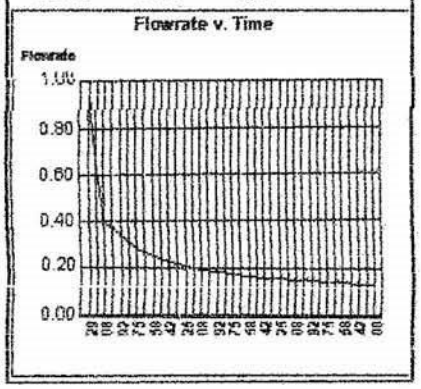
HydroCorr Test Pressure:	38.0 psig
Test Time:	20.00 min
HydroCorr Specification:	0.70 ml/min

# of Cartridges:	1
System Specification:	0.70 ml/min

Test Data

Gas Volume:	542 ml
Actual Test Pressure:	37.9 psig

Time min	Pressure psig	Flowrate ml/min
5.29	37.8	0.93
6.08	37.8	0.41
6.92	37.8	0.34
7.75	37.8	0.28
8.58	37.7	0.25
9.42	37.7	0.22
10.25	37.7	0.20
11.08	37.7	0.19
11.92	37.7	0.18
12.75	37.6	0.17
13.58	37.6	0.16
14.42	37.6	0.16
15.25	37.6	0.15
16.08	37.6	0.15
16.92	37.6	0.15
17.75	37.6	0.14
18.58	37.6	0.14
19.42	37.5	0.14
20.00	37.5	0.13



Test Results

Flowrate:	0.13 ml/min
Constant Pressure Flowrate:	0.13 ml/min

Test Conclusion

PASSED

Signature: 14/10/08 14/10/08

Signature: 14/10/08

8.4 SIP OF LYOPHILIZER

8.4.1 LINE CLEARANCE FOR SIP

S.No.	Checks	Room No.	SOP No.	Date	Previous Product		Ckd. by##	Verified by###
					Product Name	Batch no.		
1.	Line Clearance of lyophilizer.	CSLG/034	SOP/QAD/053	14/10/08	Topotecan Placebo	—	[illegible]	[illegible]

8.4.1.1 perform the SIP as per SOP No.SOP/CSP/032 and record the details in the table below.
SIP Cycle Started at: 17:57, Completed at: 22:10

Date	Details	Eq. Id. No.	SIP Details			Done by##	Ckd. by##
			Sterilization Temperature	Ster.Hold Started at	Ster. Hold Completed at		
14/10/08	Lyophilise	CSP/040	121°c	19:17	19:47	Raj	[illegible]

(Attach the print out of the process on the reverse side of page.)

8.4.2 STERILIZED LYOPHILIZER HOLD TIME (NMT 48HOURS AFTER STERILIZATION)

Procedure	Room No.	SOP No.	Date	Time		Done by##	Ckd. by##
				From	To		
Sterilized lyophilizer hold time	CSLG/034	---	14/10/08	22:10	—	Raj	[illegible]
			15/10/08	—	17:30	Shambhu	[illegible]

##Production

###IPQA

SIP Process Report

Initiator:	SUP	**Start Time:**	14/10/2008 17:57:16
Batch Name:	SIP20081014175716	**End Time:**	14/10/2008 22:10:23

PARAMETERS:

Sterilization temperature:	121	"C
Sterilization pressure:	2.2	BarA
Sterilization time:	30	Min.
Number of purges:	2	
Pre-evacuation pressure:	0.35	BarA
Steam discharge pressure:	1.02	BarA
Filter drying time:	15	Min.
System drying time:	45	Min.
Condenser cooling time:	10	Min.
Shelf cooling time:	15	Min.
Time to reach setpoint:	120	Min.
Time below setpoint once reached:	30	Min.
Total steaming time after setpoint reached:	240	Min.

14/10/08

14/10/08

14/10/08

SIP Process Report

Initiator:	SUP	**Start Time:**	14/10/2008 17:57:16
Batch Name:	SIP20081014175716	**End Time:**	14/10/2008 22:10:23

Date	Time	Step No.	Step Type	Chamber Pressure (BarA)	Condenser Pressure (BarA)	Cham. Drain Temp. ("C)	Cond. Drain Temp. ("C)	Filter Drain Temp. 1 ("C)	Filter Drain Temp. 2 ("C)
14/10/2008	17:57:22	1	Retract Ram	1.03	0.92	24.6	24.9	26.6	26.3
14/10/2008	17:58:29	2	Lock Doors	0.99	1.00	24.6	24.9	26.5	26.1
14/10/2008	18:02:16			0.36	0.36	22.8	28.1	26.5	26.3
14/10/2008	18:02:26	3	Purge	0.34	0.34	22.7	28.0	26.6	26.2
14/10/2008	18:07:16			0.49	0.50	78.1	77.9	100.4	98.9
14/10/2008	18:12:16			0.59	0.61	83.6	83.6	101.6	100.6
14/10/2008	18:17:16			0.74	0.74	89.4	88.4	103.4	102.3
14/10/2008	18:22:16			0.88	0.89	93.5	93.3	105.3	104.4
14/10/2008	18:27:16			1.01	1.03	98.9	97.0	107.6	106.6
14/10/2008	18:32:16			0.41	0.44	71.6	75.4	76.6	76.6
14/10/2008	18:37:16			0.49	0.52	78.3	78.1	100.6	99.3
14/10/2008	18:42:16			0.69	0.72	88.1	87.8	102.8	101.7
14/10/2008	18:47:16			0.89	0.92	95.1	94.8	105.6	104.4
14/10/2008	18:50:19	4	Steaming	1.02	1.05	99.0	99.0	107.4	106.8
14/10/2008	18:52:16			1.09	1.11	97.6	98.6	119.4	119.3
14/10/2008	18:57:16			1.30	1.32	99.7	100.1	120.7	120.4
14/10/2008	19:02:16			1.51	1.54	110.2	110.6	122.3	122.0
14/10/2008	19:07:16			1.73	1.77	114.8	114.9	123.7	123.3
14/10/2008	19:12:16			1.95	1.99	118.6	118.8	125.4	125.1
14/10/2008	19:17:16			2.15	2.19	121.7	121.9	127.1	126.7
14/10/2008	19:22:16			2.15	2.18	121.7	121.8	126.2	125.6
14/10/2008	19:27:16			2.13	2.17	121.5	121.5	123.4	123.3
14/10/2008	19:32:16			2.14	2.18	121.6	121.8	122.3	122.8
14/10/2008	19:37:16			2.17	2.20	121.8	122.1	126.1	125.8
14/10/2008	19:42:16			2.12	2.16	121.5	121.7	122.0	122.0
14/10/2008	19:47:00	5	Steam Dischar	2.15	2.18	121.6	121.8	125.6	125.4
14/10/2008	19:47:16			2.09	2.13	121.4	121.6	124.0	124.3
14/10/2008	19:52:16			1.34	1.38	109.2	109.3	108.9	110.9
14/10/2008	19:57:16			1.06	1.09	102.4	102.9	100.6	101.1
14/10/2008	20:00:41	6	Filter Drying	1.02	1.05	99.8	101.1	98.8	98.5
14/10/2008	20:02:16			1.05	1.08	91.8	98.4	71.0	84.6
14/10/2008	20:07:16			1.07	1.10	77.9	91.3	57.2	76.6
14/10/2008	20:12:16			1.07	1.10	70.3	82.8	56.6	70.7
14/10/2008	20:15:02	7	System Drying	1.01	1.04	67.2	78.2	56.7	67.3
14/10/2008	20:17:16			0.69	0.71	89.2	96.5	88.2	88.3
14/10/2008	20:22:16			0.36	0.39	84.1	95.1	70.2	71.8
14/10/2008	20:27:16			0.19	0.21	77.9	91.6	53.1	55.3
14/10/2008	20:32:16			0.13	0.15	72.6	87.2	40.9	44.4
14/10/2008	20:37:16			0.12	0.14	67.1	80.6	35.9	37.7
14/10/2008	20:42:16			0.12	0.13	61.9	73.8	34.7	35.4
14/10/2008	20:47:16			0.12	0.13	57.8	67.8	34.1	34.4
14/10/2008	20:52:16			0.12	0.13	54.3	62.3	33.7	33.6
14/10/2008	20:57:16			0.12	0.13	51.2	57.8	33.5	33.1
14/10/2008	21:02:16			0.12	0.13	48.7	54.0	33.1	33.0
14/10/2008	21:07:08	8	Cond. Cooling	0.11	0.12	46.4	50.8	33.1	32.8
14/10/2008	21:07:16			0.12	0.13	46.3	50.7	32.9	32.8
14/10/2008	21:12:16			0.07	0.08	44.2	46.7	32.8	32.6
14/10/2008	21:17:16			0.07	0.08	42.3	43.5	32.7	32.4
14/10/2008	21:22:16			0.07	0.08	40.6	41.5	32.3	32.0
14/10/2008	21:25:03	9	Shelf Cooling	0.06	0.08	39.7	40.3	32.2	31.9
14/10/2008	21:27:16			0.07	0.08	39.0	39.7	32.0	31.8
14/10/2008	21:32:16			0.07	0.08	37.6	38.0	31.7	31.5

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14/10/08

SIP Process Report

Initiator:	SUP	**Start Time:**	14/10/2008 17:57:16
Batch Name:	SIP20081014175716	**End Time:**	14/10/2008 22:10:23

Date	Time	Step No.	Step Type	Chamber Pressure (BarA)	Condenser Pressure (BarA)	Cham. Drain Temp. ("C)	Cond. Drain Temp. ("C)	Filter Drain Temp. 1 ("C)	Filter Drain Temp. 2 ("C)
14/10/2008	21:37:16			0.07	0.08	36.5	37.0	31.6	31.2
14/10/2008	21:42:16			0.07	0.08	35.6	35.9	31.1	30.9
14/10/2008	21:47:16			0.07	0.08	34.6	35.2	30.8	30.7
14/10/2008	21:52:16			0.07	0.08	33.9	34.5	30.7	30.1
14/10/2008	21:57:16			0.07	0.08	33.2	33.9	30.4	30.0
14/10/2008	21:57:59	10	Unlock Doors	0.06	0.08	33.0	33.8	30.3	30.0
14/10/2008	21:58:03	11	Final Aeration	0.06	0.08	33.1	33.8	30.3	30.0
14/10/2008	22:02:16			0.49	0.49	32.5	33.3	30.2	29.8
14/10/2008	22:10:23			0.98	0.99	31.6	32.4	29.9	29.6

14/10/08 14/10/08 14/10/08

SIP Process Report

Initiator:	SUP	**Start Time:**	14/10/2008 17:57:16
Batch Name:	SIP20081014175716	**End Time:**	14/10/2008 22:10:23

Date	Time	Description
Alarm:	Total: 3	
14/10/2008	19:14:33	PT101 chamber vacuum probe fail
14/10/2008	19:14:49	PT101 chamber vacuum probe fail
14/10/2008	21:48:52	Shelf temperature low deviation
Audit:	Total: 10	
14/10/2008	18:30:32	SUP logged in as Application User by Sup.
14/10/2008	18:36:57	SUP logged in as Application User by Sup.
14/10/2008	18:42:23	SUP logged in as Application User by Sup.
14/10/2008	18:54:51	SUP logged in as Application User by Sup.
14/10/2008	19:15:57	SUP logged in as Application User by Sup.
14/10/2008	19:16:04	A_CHAMVACPROBEFAIL ALARM is acknowledged by Sup.
14/10/2008	20:47:43	SUP logged in as Application User by Sup.
14/10/2008	21:48:41	SUP logged in as Application User by Sup.
14/10/2008	21:49:02	A_SHELFTEMPLD ALARM is acknowledged by Sup.
14/10/2008	22:10:16	SUP logged in as Application User by Sup.

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14/10/08

Kai 14/10/08

Ken 14/10/08

01-06ch	91.1	91.1	90.8	91.1	
07-12ch	91.0	91.0	90.7	84.2	
13-18ch	102.2	102.8	93.9	32.8	
19-24ch	32.9	26	4.11	---	

100.0 — 158.0 — 21:00 60mm/h — CH 4 — °C

01-06ch	100.1	100.0	100.2	100.1	
07-12ch	100.1	100.1	99.9	98.9	
13-18ch	114.9	101.3	98.1	64.7	
19-24ch	81.4	15	1.07	---	

100.0 — 158.0 — CH 4 — °C

01-06ch	111.8	111.8	111.8	111.7	
07-12ch	111.9	111.9	104.7	74.3	
13-18ch	107.6	111.6	110.1	122.1	
19-24ch	121.7	-1	0.58	---	

100.0 — 158.0 — 19:00 60mm/h — CH 4 — °C

590cm

0 20 40 60 80 100

2009/10/14 17:57 TREND+TAB 60mm/h B39 [illegible]

8.5 LOADING OF LYOPHILIZER

Loading is done as per SOP No. SOP/CSP/032

Date	SOP No.	No. of Tray in Shelf	Quantity	Time		Done by ##	Ckd. by ##
				From	To		
15/10/08		1 X 6	48.40	18:10	22:20	Shambhu	15/10/08

8.6 LYOPHILIZATION CYCLE

Start the lyophilization cycle as per SOP No. SOP/CSP/032

Recipe Name: -

Date	SOP No.	Cycle started at		Cycle end at		Done by ##	Ckd. by ##
		Date	Time	Date	Time		
16/10/08	SOP/CSP/032	16/10/08	00:41	18/10/08	18:32	Arvind	16/10/08

(Attach the print out of the process on the reverse side of page.)

Production

9.0 CLEANING OF ALUMINUM FLIP-OFF OVER SEALS:

9.1 LINE CLEARANCE:

- Ensure the cleanliness of equipment wash area.
- Ensure no remains of previous product are there.
- Ensure that proper status label is attached on machine.

Date: ~~14/10/08~~ 17/10/08 17/10/08

Step No.	Checks	Eq. Id. No.	SOP No.	Previous product		Ckd. by##	Verified by###
				Product Name	Batch No.		
1.	Line clearance for washing of aluminum seals	CSP/129	SOP/QAD/053	Cytarabine inj BP/ 100 mg/ml	8LA204		17/10/08

9.2 CLEANING:

Cleaning of aluminum flip-off over seals done as per SOP No. SOP/CSP/053.

A.R. No. Of WFI*: 02WF08000757

Date	Quantity	Cleaning Time		Quantity		Done by##	Ckd. By##
		Started at	Completed at	No. of good seals	No. of Rejected seals		
17/10/08 ~~14/10/08~~ 17/10/08	6300	15:45	16:25	6295	05		

* Return loop A. R. No to be mentioned

Production

###IPQA

QA Signature

Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Vacuum Control Parameters:

Vacuum high limit:	3	uBarA	Vacuum preAlarm:	500	uBarA
Vacuum low limit:	3	uBarA	Vacuum alarm:	700	uBarA

Step No	Step Type	Temperature ("C)	Vacuum (ubar)	Time	
				HH:MM	MM:SS
1	Loading	10.0	--	--	--
2	Freezing	-10.0	--	0 : 20	--
3	Freezing	-10.0	--	0 : 30	--
4	Freezing	-15.0	--	0 : 5	--
5	Freezing	-15.0	--	1 : 0	--
6	Freezing	-25.0	--	0 : 10	--
7	Freezing	-25.0	--	1 : 0	--
8	Freezing	-40.0	--	0 : 15	--
9	Freezing	-40.0	--	3 : 0	--
10	Evacuation	--	200	--	--
11	Drying	-28.0	200	0 : 10	--
12	Drying	-28.0	200	1 : 30	--
13	Drying	-20.0	200	0 : 8	--
14	Drying	-20.0	200	1 : 30	--
15	Drying	-12.0	150	0 : 8	--
16	Drying	-12.0	150	4 : 0	--
17	Drying	-6.0	150	0 : 6	--
18	Drying	-6.0	150	11 : 0	--
19	Drying	0.0	100	0 : 6	--
20	Drying	0.0	100	11 : 0	--
21	Drying	7.0	80	0 : 7	--
22	Drying	7.0	80	3 : 0	--
23	Drying	15.0	80	0 : 8	--
24	Drying	15.0	80	3 : 0	--
25	Drying	30.0	60	0 : 15	--
26	Drying	30.0	60	8 : 0	--
27	Drying	45.0	60	0 : 15	--
28	Drying	45.0	60	12 : 0	--
29	Moisture Test	--	300	--	30 : 60
30	Pre-Aeration	--	--	--	--
31	Stoppering	--	--	--	0 : 0
32	Aeration	--	--	--	--
33	Storage	25.0	--	0 : 0	--

The time setpoint at the step of moisture test denotes respectively the repeat time in unit of minutes,and test time in unit of second.

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18/10/08

Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
16/10/2008	0:43:36	1	Loading	9.6	10.0	10.6	36.9	36.9	1000	--
16/10/2008	0:44:31	2	Freezing	10.4	10.0	9.1	36.9	36.9	1000	--
16/10/2008	0:46:52			6.6	7.6	8.9	36.9	37.2	1000	--
16/10/2008	0:51:52			1.5	2.6	4.3	36.9	37.2	1000	--
16/10/2008	0:56:52			-1.2	-2.4	-1.8	36.9	37.2	1000	--
16/10/2008	1:01:52			-6.8	-7.4	-6.3	36.9	36.7	1000	--
16/10/2008	1:04:26	3	Freezing	-10.7	-10.0	-7.6	36.6	36.7	1000	--
16/10/2008	1:06:52			-9.6	-9.9	-9.6	36.9	36.7	1000	--
16/10/2008	1:11:52			-9.4	-9.9	-10.7	36.9	36.7	1000	--
16/10/2008	1:16:52			-10.7	-9.9	-9.9	36.9	36.7	1000	--
16/10/2008	1:21:52			-9.6	-9.9	-11.1	36.9	36.7	1000	--
16/10/2008	1:26:52			-10.4	-9.9	-10.4	36.4	36.7	1000	--
16/10/2008	1:31:52			-9.7	-9.9	-10.8	36.4	36.7	1000	--
16/10/2008	1:34:27	4	Freezing	-9.7	-10.0	-11.3	36.3	36.3	1000	--
16/10/2008	1:36:52			-12.6	-12.4	-11.3	36.4	36.7	1000	--
16/10/2008	1:39:25	5	Freezing	-14.7	-14.9	-13.4	36.2	36.3	1000	--
16/10/2008	1:41:52			-14.7	-14.9	-15.4	36.4	36.2	1000	--
16/10/2008	1:46:52			-15.2	-14.9	-15.3	36.4	36.2	1000	--
16/10/2008	1:51:52			-15.6	-14.9	-15.3	36.4	36.2	1000	--
16/10/2008	1:56:52			-14.4	-14.9	-16.3	36.4	36.2	1000	--
16/10/2008	2:01:52			-15.1	-14.9	-15.5	36.4	36.2	1000	--
16/10/2008	2:06:52			-15.7	-14.9	-15.5	35.9	36.2	1000	--
16/10/2008	2:11:52			-14.7	-14.9	-16.2	35.9	36.2	1000	--
16/10/2008	2:16:52			-14.5	-14.9	-16.2	35.9	36.2	1000	--
16/10/2008	2:21:52			-15.8	-14.9	-15.2	35.9	35.7	1000	--
16/10/2008	2:26:52			-15.0	-14.9	-16.2	35.9	35.7	1000	--
16/10/2008	2:31:52			-14.6	-14.9	-16.1	35.9	35.7	1000	--
16/10/2008	2:36:52			-15.7	-14.9	-15.3	35.9	35.7	1000	--
16/10/2008	2:39:26	6	Freezing	-14.7	-15.0	-15.8	35.6	35.5	1000	--
16/10/2008	2:41:52			-17.2	-17.4	-17.0	35.9	35.7	1000	--
16/10/2008	2:46:52			-22.0	-22.4	-20.8	35.9	35.7	1000	--
16/10/2008	2:49:25	7	Freezing	-24.5	-24.9	-23.6	35.5	35.5	1000	--
16/10/2008	2:51:52			-25.0	-24.9	-24.5	35.4	35.7	1000	--
16/10/2008	2:56:52			-24.3	-24.9	-25.6	35.4	35.7	1000	--
16/10/2008	3:01:52			-24.9	-24.9	-25.8	35.4	35.2	1000	--
16/10/2008	3:06:52			-25.6	-24.9	-25.5	35.4	35.2	1000	--
16/10/2008	3:11:52			-24.6	-24.9	-25.1	35.4	35.2	1000	--
16/10/2008	3:16:52			-24.3	-24.9	-26.0	35.4	35.2	1000	--
16/10/2008	3:21:52			-25.1	-24.9	-25.9	35.4	35.2	1000	--
16/10/2008	3:26:52			-25.6	-24.9	-25.2	35.4	35.2	1000	--
16/10/2008	3:31:52			-25.1	-24.9	-25.1	35.4	35.2	1000	--
16/10/2008	3:36:52			-24.7	-24.9	-25.7	34.9	35.2	1000	--
16/10/2008	3:41:52			-24.4	-24.9	-25.8	34.9	35.2	1000	--
16/10/2008	3:46:52			-25.5	-24.9	-26.0	34.9	35.2	1000	--
16/10/2008	3:49:28	8	Freezing	-24.6	-25.0	-25.9	34.8	34.8	1000	--
16/10/2008	3:51:52			-26.8	-27.4	-26.4	34.9	34.7	1000	--
16/10/2008	3:56:52			-31.7	-32.4	-31.0	34.9	34.7	1000	--
16/10/2008	4:01:52			-35.1	-37.4	-34.6	34.9	34.7	1000	--
16/10/2008	4:06:52			-37.6	-40.0	-37.3	34.9	34.7	1000	--
16/10/2008	4:11:52			-38.1	-40.0	-38.5	34.9	34.7	1000	--
16/10/2008	4:13:55	9	Freezing	-39.0	-40.0	-39.1	34.6	34.5	1000	--
16/10/2008	4:16:52			-40.0	-40.0	-40.3	34.9	34.7	1000	--
16/10/2008	4:21:52			-39.6	-40.0	-40.3	34.9	34.7	1000	--
16/10/2008	4:26:52			-39.6	-40.0	-40.8	34.9	34.7	1000	--

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
16/10/2008	4:31:52			-40.1	-40.0	-40.8	34.4	34.7	1000	--
16/10/2008	4:36:52			-39.9	-40.0	-40.3	34.4	34.7	1000	--
16/10/2008	4:41:52			-39.2	-40.0	-40.8	34.4	34.2	1000	--
16/10/2008	4:46:52			-40.1	-40.0	-40.1	34.4	34.2	1000	--
16/10/2008	4:51:52			-39.2	-40.0	-40.3	34.4	34.2	1000	--
16/10/2008	4:56:52			-40.3	-40.0	-40.9	34.4	34.2	1000	--
16/10/2008	5:01:52			-39.6	-40.0	-40.3	34.4	34.2	1000	--
16/10/2008	5:06:52			-39.5	-40.0	-40.9	34.4	34.2	1000	--
16/10/2008	5:11:52			-39.9	-40.0	-40.2	34.4	34.2	1000	--
16/10/2008	5:16:52			-39.2	-40.0	-41.0	34.4	34.2	1000	--
16/10/2008	5:21:52			-40.2	-40.0	-40.8	34.4	34.2	1000	--
16/10/2008	5:26:52			-39.4	-40.0	-40.2	33.9	34.2	1000	--
16/10/2008	5:31:52			-40.2	-40.0	-40.7	33.9	34.2	1000	--
16/10/2008	5:36:52			-39.6	-40.0	-40.3	33.9	34.2	1000	--
16/10/2008	5:41:52			-39.5	-40.0	-41.1	33.9	34.2	1000	--
16/10/2008	5:46:52			-40.0	-40.0	-40.3	33.9	33.7	1000	--
16/10/2008	5:51:52			-39.2	-40.0	-40.8	33.9	33.7	1000	--
16/10/2008	5:56:52			-40.1	-40.0	-40.2	33.9	33.7	1000	--
16/10/2008	6:01:52			-39.2	-40.0	-40.8	33.9	33.7	1000	--
16/10/2008	6:06:52			-40.3	-40.0	-40.8	33.9	33.7	1000	--
16/10/2008	6:11:52			-39.2	-40.0	-40.7	33.9	33.7	1000	--
16/10/2008	6:16:52			-40.1	-40.0	-40.3	33.9	33.7	1000	--
16/10/2008	6:21:52			-39.4	-40.0	-40.3	33.4	33.7	1000	--
16/10/2008	6:26:52			-40.3	-40.0	-40.7	33.4	33.7	1000	--
16/10/2008	6:31:52			-39.6	-40.0	-40.7	33.4	33.7	1000	--
16/10/2008	6:36:52			-39.7	-40.0	-40.7	33.4	33.2	1000	--
16/10/2008	6:41:52			-40.0	-40.0	-40.7	33.4	33.2	1000	--
16/10/2008	6:46:52			-39.2	-40.0	-40.7	33.4	33.2	1000	--
16/10/2008	6:51:52			-39.8	-40.0	-40.2	33.4	33.2	1000	--
16/10/2008	6:56:52			-39.4	-40.0	-40.9	33.4	33.2	1000	--
16/10/2008	7:01:52			-40.1	-40.0	-40.2	33.4	33.2	1000	--
16/10/2008	7:06:52			-39.1	-40.0	-40.5	33.4	33.2	1000	--
16/10/2008	7:11:52			-40.1	-40.0	-40.3	32.9	33.2	1000	--
16/10/2008	7:13:52	10	Evacuation	-39.4	-40.0	-40.2	33.0	32.9	1000	200
16/10/2008	7:16:52			-39.4	-40.0	-40.2	30.6	14.6	1000	200
16/10/2008	7:21:52			-39.5	-40.0	-40.2	19.3	-46.7	1000	200
16/10/2008	7:26:52			-39.3	-40.0	-40.2	-24.3	-50.9	1000	200
16/10/2008	7:31:52			-39.4	-40.0	-40.2	-33.9	-47.5	1000	200
16/10/2008	7:36:52			-39.4	-40.0	-40.7	-43.6	-56.8	1000	200
16/10/2008	7:41:52			-39.6	-40.0	-40.7	-56.1	-60.9	1000	200
16/10/2008	7:46:52			-39.7	-40.0	-40.7	-55.5	-68.6	1000	200
16/10/2008	7:51:52			-39.4	-40.0	-40.7	-60.2	-72.7	389	200
16/10/2008	7:53:23	11	Drying	-39.7	-39.5	-40.8	-60.8	-74.5	205	200
16/10/2008	7:56:52			-36.2	-35.5	-38.1	-64.4	-75.2	213	200
16/10/2008	8:01:52			-30.1	-29.7	-33.5	-68.2	-76.6	316	200
16/10/2008	8:06:52			-28.0	-28.0	-29.8	-71.5	-77.9	437	200
16/10/2008	8:11:52			-27.8	-28.0	-29.3	-70.1	-79.6	491	200
16/10/2008	8:16:52			-27.9	-28.0	-29.3	-45.8	-63.9	322	200
16/10/2008	8:19:35	12	Drying	-28.5	-28.0	-30.0	-43.2	-44.8	202	200
16/10/2008	8:21:52			-27.0	-28.0	-29.1	-55.6	-55.6	203	200
16/10/2008	8:26:52			-27.9	-28.0	-29.0	-63.8	-66.2	208	200
16/10/2008	8:31:52			-27.8	-28.0	-29.0	-72.4	-74.5	208	200
16/10/2008	8:36:52			-29.5	-28.0	-30.7	-73.1	-58.9	338	200
16/10/2008	8:41:52			-27.7	-28.0	-28.9	-74.1	-71.9	212	200

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
16/10/2008	8:46:52			-29.8	-28.0	-30.6	-71.5	-54.7	383	200
16/10/2008	8:51:52			-27.6	-28.0	-28.3	-73.4	-70.5	213	200
16/10/2008	8:56:52			-27.7	-28.0	-28.9	-73.8	-77.5	213	200
16/10/2008	9:01:52			-27.4	-28.0	-28.9	-72.6	-79.3	215	200
16/10/2008	9:06:52			-27.7	-28.0	-28.9	-67.8	-79.8	216	200
16/10/2008	9:11:52			-27.7	-28.0	-28.9	-67.9	-79.8	217	200
16/10/2008	9:16:52			-29.5	-28.0	-30.4	-67.6	-59.1	434	200
16/10/2008	9:21:52			-27.4	-28.0	-28.2	-64.6	-70.4	202	200
16/10/2008	9:26:52			-27.6	-28.0	-28.7	-63.3	-76.4	202	200
16/10/2008	9:31:52			-27.6	-28.0	-28.7	-64.4	-79.2	201	200
16/10/2008	9:36:52			-27.6	-28.0	-28.7	-64.9	-79.2	198	200
16/10/2008	9:41:52			-27.8	-28.0	-28.7	-64.3	-79.2	201	200
16/10/2008	9:46:52			-27.9	-28.0	-28.7	-65.4	-79.2	197	200
16/10/2008	9:51:52			-27.6	-28.0	-28.7	-65.9	-80.2	205	200
16/10/2008	9:56:52			-27.7	-28.0	-28.7	-65.8	-80.2	270	200
16/10/2008	10:01:52			-27.5	-28.0	-28.7	-66.4	-80.2	203	200
16/10/2008	10:06:05	13	Drying	-27.3	-28.0	-28.7	-66.1	-80.1	202	200
16/10/2008	10:06:52			-27.4	-27.2	-28.7	-65.9	-80.2	193	200
16/10/2008	10:11:52			-22.0	-22.2	-25.0	-68.1	-80.2	200	200
16/10/2008	10:14:05	14	Drying	-20.9	-20.0	-23.3	-69.0	-80.6	200	200
16/10/2008	10:16:52			-19.9	-20.0	-20.9	-68.7	-80.2	202	200
16/10/2008	10:21:52			-19.9	-20.0	-20.9	-69.2	-80.2	197	200
16/10/2008	10:26:52			-19.6	-20.0	-20.9	-72.5	-80.2	196	200
16/10/2008	10:31:52			-19.6	-20.0	-20.9	-76.2	-80.7	204	200
16/10/2008	10:36:52			-19.5	-20.0	-20.9	-73.3	-81.2	193	200
16/10/2008	10:41:52			-19.7	-20.0	-20.9	-71.5	-81.2	204	200
16/10/2008	10:46:52			-19.6	-20.0	-20.9	-69.2	-80.7	198	200
16/10/2008	10:51:52			-19.7	-20.0	-20.4	-69.8	-80.7	192	200
16/10/2008	10:56:52			-19.6	-20.0	-20.4	-68.8	-80.2	202	200
16/10/2008	11:01:52			-19.7	-20.0	-20.4	-65.4	-80.2	193	200
16/10/2008	11:06:52			-19.6	-20.0	-20.4	-67.3	-80.2	204	200
16/10/2008	11:11:52			-19.6	-20.0	-20.4	-65.8	-80.2	193	200
16/10/2008	11:16:52			-19.9	-20.0	-20.4	-67.3	-80.2	204	200
16/10/2008	11:21:52			-19.6	-20.0	-20.4	-66.8	-80.2	197	200
16/10/2008	11:26:52			-19.7	-20.0	-20.4	-64.4	-80.2	192	200
16/10/2008	11:31:52			-19.5	-20.0	-20.4	-65.7	-80.2	205	200
16/10/2008	11:36:52			-19.6	-20.0	-20.4	-66.2	-80.2	199	200
16/10/2008	11:41:52			-19.5	-20.0	-20.4	-66.0	-80.2	201	200
16/10/2008	11:44:11	15	Drying	-19.5	-20.0	-20.6	-67.3	-80.0	201	150
16/10/2008	11:46:52			-17.2	-17.3	-19.7	-67.6	-80.2	149	150
16/10/2008	11:51:52			-13.1	-12.5	-14.9	-66.2	-79.7	149	150
16/10/2008	11:52:15	16	Drying	-12.9	-12.0	-14.7	-66.7	-79.6	152	150
16/10/2008	11:56:52			-11.7	-12.0	-13.2	-67.3	-79.7	156	150
16/10/2008	12:01:52			-11.7	-12.0	-12.7	-66.0	-79.7	156	150
16/10/2008	12:06:52			-11.5	-12.0	-12.7	-68.0	-79.7	156	150
16/10/2008	12:11:52			-11.5	-12.0	-12.7	-65.5	-79.7	155	150
16/10/2008	12:16:52			-11.5	-12.0	-12.7	-67.4	-79.7	154	150
16/10/2008	12:21:52			-11.8	-12.0	-12.7	-67.9	-79.7	155	150
16/10/2008	12:26:52			-11.7	-12.0	-12.7	-65.3	-79.7	154	150
16/10/2008	12:31:52			-11.6	-12.0	-12.7	-66.4	-79.7	152	150
16/10/2008	12:36:52			-11.6	-12.0	-12.7	-66.9	-79.7	151	150
16/10/2008	12:41:52			-11.6	-12.0	-12.7	-66.9	-79.7	149	150
16/10/2008	12:46:52			-11.6	-12.0	-12.7	-66.1	-79.7	146	150
16/10/2008	12:51:52			-11.4	-12.0	-12.7	-66.6	-79.7	145	150

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
16/10/2008	12:56:52			-11.9	-12.0	-12.7	-65.6	-79.7	145	150
16/10/2008	13:01:52			-11.6	-12.0	-12.7	-67.2	-79.7	146	150
16/10/2008	13:06:52			-11.4	-12.0	-12.7	-74.2	-80.2	145	150
16/10/2008	13:11:52			-11.6	-12.0	-12.7	-75.2	-80.2	146	150
16/10/2008	13:16:52			-11.6	-12.0	-12.7	-76.9	-80.7	151	150
16/10/2008	13:21:52			-11.4	-12.0	-12.7	-72.5	-80.7	155	150
16/10/2008	13:26:52			-11.5	-12.0	-12.7	-69.8	-80.7	155	150
16/10/2008	13:31:52			-11.7	-12.0	-12.7	-69.4	-80.7	157	150
16/10/2008	13:36:52			-11.5	-12.0	-12.7	-67.9	-80.2	157	150
16/10/2008	13:41:52			-11.5	-12.0	-12.7	-67.8	-80.2	156	150
16/10/2008	13:46:52			-11.7	-12.0	-12.7	-66.7	-79.7	154	150
16/10/2008	13:51:52			-11.5	-12.0	-12.7	-68.5	-79.7	147	150
16/10/2008	13:56:52			-11.6	-12.0	-12.7	-67.8	-79.7	144	150
16/10/2008	14:01:52			-11.5	-12.0	-12.7	-69.0	-79.7	157	150
16/10/2008	14:06:52			-11.8	-12.0	-12.7	-69.0	-79.7	157	150
16/10/2008	14:11:52			-11.6	-12.0	-12.7	-70.0	-80.2	157	150
16/10/2008	14:16:52			-11.6	-12.0	-12.7	-69.0	-80.2	156	150
16/10/2008	14:21:52			-11.7	-12.0	-12.7	-70.7	-80.2	154	150
16/10/2008	14:26:52			-11.5	-12.0	-12.7	-71.6	-80.2	154	150
16/10/2008	14:31:52			-11.7	-12.0	-12.7	-67.8	-80.2	155	150
16/10/2008	14:36:52			-11.7	-12.0	-12.7	-68.3	-80.2	155	150
16/10/2008	14:41:52			-11.6	-12.0	-12.7	-71.9	-80.2	154	150
16/10/2008	14:46:52			-11.5	-12.0	-12.7	-71.9	-80.2	153	150
16/10/2008	14:51:52			-11.6	-12.0	-12.7	-72.4	-80.2	153	150
16/10/2008	14:56:52			-11.6	-12.0	-12.7	-72.4	-80.2	153	150
16/10/2008	15:01:52			-11.7	-12.0	-12.7	-75.0	-80.2	153	150
16/10/2008	15:06:52			-11.5	-12.0	-12.7	-70.4	-80.2	152	150
16/10/2008	15:11:52			-11.6	-12.0	-12.7	-69.6	-80.2	152	150
16/10/2008	15:16:52			-11.5	-12.0	-12.7	-70.6	-80.7	155	150
16/10/2008	15:21:52			-11.7	-12.0	-12.7	-66.0	-80.7	154	150
16/10/2008	15:26:52			-11.6	-12.0	-12.7	-67.3	-80.7	154	150
16/10/2008	15:31:52			-11.7	-12.0	-12.7	-67.8	-80.2	155	150
16/10/2008	15:36:52			-11.4	-12.0	-12.7	-66.0	-80.2	154	150
16/10/2008	15:41:52			-11.7	-12.0	-12.7	-67.6	-80.2	155	150
16/10/2008	15:46:52			-11.6	-12.0	-12.7	-68.1	-80.2	156	150
16/10/2008	15:51:52			-11.6	-12.0	-12.7	-67.7	-80.2	155	150
16/10/2008	15:52:21	17	Drying	-11.7	-12.0	-12.5	-68.3	-80.3	152	150
16/10/2008	15:56:52			-8.2	-7.4	-10.0	-69.5	-80.2	156	150
16/10/2008	15:58:28	18	Drying	-5.6	-6.0	-8.2	-69.2	-80.5	153	150
16/10/2008	16:01:52			-5.2	-6.1	-6.9	-68.4	-80.2	150	150
16/10/2008	16:06:52			-5.8	-6.1	-6.9	-71.2	-80.2	145	150
16/10/2008	16:11:52			-5.8	-6.1	-6.9	-77.5	-80.7	157	150
16/10/2008	16:16:52			-5.6	-6.1	-6.4	-78.0	-80.7	148	150
16/10/2008	16:21:52			-5.6	-6.1	-6.4	-78.6	-81.2	148	150
16/10/2008	16:26:52			-5.8	-6.1	-6.4	-77.1	-81.2	154	150
16/10/2008	16:31:52			-5.6	-6.1	-6.4	-77.6	-81.2	147	150
16/10/2008	16:36:52			-5.6	-6.1	-6.4	-77.6	-81.2	154	150
16/10/2008	16:41:52			-5.7	-6.1	-6.4	-78.3	-81.2	149	150
16/10/2008	16:46:52			-5.6	-6.1	-6.4	-77.0	-81.2	150	150
16/10/2008	16:51:52			-5.4	-6.1	-6.4	-75.2	-81.2	154	150
16/10/2008	16:56:52			-5.5	-6.1	-6.4	-71.2	-81.2	145	150
16/10/2008	17:01:52			-5.6	-6.1	-6.4	-70.1	-81.2	157	150
16/10/2008	17:06:52			-5.6	-6.1	-6.4	-70.6	-81.2	144	150
16/10/2008	17:11:52			-5.5	-6.1	-6.4	-70.6	-80.1	157	150

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
16/10/2008	17:16:52			-5.8	-6.1	-6.4	-67.3	-79.6	150	150
16/10/2008	17:21:52			-5.7	-6.1	-6.4	-66.4	-79.6	152	150
16/10/2008	17:26:52			-5.7	-6.1	-6.4	-67.4	-79.6	153	150
16/10/2008	17:31:52			-5.6	-6.1	-6.4	-65.2	-79.6	145	150
16/10/2008	17:36:52			-5.4	-6.1	-6.4	-65.9	-79.6	157	150
16/10/2008	17:41:52			-5.5	-6.1	-6.4	-66.9	-79.6	146	150
16/10/2008	17:46:52			-5.6	-6.1	-6.4	-66.9	-79.6	157	150
16/10/2008	17:51:52			-5.5	-6.1	-6.4	-68.1	-80.1	149	150
16/10/2008	17:56:52			-5.4	-6.1	-6.4	-68.8	-80.1	148	150
16/10/2008	18:01:52			-5.4	-6.1	-6.4	-65.2	-80.1	154	150
16/10/2008	18:06:52			-5.7	-6.1	-6.4	-66.9	-80.1	146	150
16/10/2008	18:11:52			-5.7	-6.1	-6.4	-67.5	-80.1	156	150
16/10/2008	18:16:52			-5.5	-6.1	-6.4	-66.2	-80.1	147	150
16/10/2008	18:21:52			-5.6	-6.1	-6.4	-65.5	-80.1	156	150
16/10/2008	18:26:52			-5.6	-6.1	-6.4	-66.6	-80.1	152	150
16/10/2008	18:31:52			-5.6	-6.1	-6.4	-65.8	-80.1	146	150
16/10/2008	18:36:52			-5.6	-6.1	-6.4	-66.3	-72.8	213	150
16/10/2008	18:41:52			-5.7	-6.1	-6.4	-65.3	-74.3	146	150
16/10/2008	18:46:52			-5.6	-6.1	-6.4	-66.5	-74.5	253	150
16/10/2008	18:51:52			-5.7	-6.1	-6.4	-67.5	-74.0	150	150
16/10/2008	18:56:52			-5.6	-6.1	-6.4	-68.0	-75.4	150	150
16/10/2008	19:01:52			-5.4	-6.1	-6.4	-68.7	-75.4	153	150
16/10/2008	19:06:52			-5.6	-6.1	-6.4	-66.0	-74.7	145	150
16/10/2008	19:11:52			-5.7	-6.1	-6.4	-68.3	-75.4	157	150
16/10/2008	19:16:52			-5.5	-6.1	-6.4	-69.0	-75.4	150	150
16/10/2008	19:21:52			-5.8	-6.1	-6.4	-69.5	-75.9	146	150
16/10/2008	19:26:52			-5.6	-6.1	-6.4	-69.5	-75.4	156	150
16/10/2008	19:31:52			-5.6	-6.1	-6.4	-69.0	-76.1	150	150
16/10/2008	19:36:52			-5.5	-6.1	-6.4	-69.0	-74.7	145	150
16/10/2008	19:41:52			-5.6	-6.1	-6.4	-65.7	-74.2	158	150
16/10/2008	19:46:52			-5.6	-6.1	-6.4	-67.2	-75.7	152	150
16/10/2008	19:51:52			-5.7	-6.1	-6.4	-69.9	-75.1	149	150
16/10/2008	19:56:52			-5.7	-6.1	-6.4	-67.9	-75.2	145	150
16/10/2008	20:01:52			-5.7	-6.1	-6.4	-68.3	-75.9	152	150
16/10/2008	20:06:52			-5.6	-6.1	-6.4	-69.4	-75.8	154	150
16/10/2008	20:11:52			-5.6	-6.1	-6.4	-70.5	-76.3	157	150
16/10/2008	20:16:52			-5.7	-6.1	-6.4	-68.3	-75.7	157	150
16/10/2008	20:21:52			-5.5	-6.1	-6.4	-68.7	-76.3	154	150
16/10/2008	20:26:52			-5.5	-6.1	-6.4	-69.2	-75.7	157	150
16/10/2008	20:31:52			-5.7	-6.1	-6.4	-69.8	-75.7	157	150
16/10/2008	20:36:52			-5.5	-6.1	-6.4	-66.8	-76.7	148	150
16/10/2008	20:41:52			-5.8	-6.1	-6.4	-67.3	-75.9	146	150
16/10/2008	20:46:52			-5.4	-6.1	-6.4	-65.4	-75.4	155	150
16/10/2008	20:51:52			-5.8	-6.1	-6.4	-67.3	-75.5	146	150
16/10/2008	20:56:52			-5.5	-6.1	-6.4	-69.1	-76.5	154	150
16/10/2008	21:01:52			-5.7	-6.1	-6.4	-68.5	-75.5	144	150
16/10/2008	21:06:52			-5.5	-6.1	-6.4	-69.6	-76.6	154	150
16/10/2008	21:11:52			-5.7	-6.1	-6.4	-65.9	-77.2	156	150
16/10/2008	21:16:52			-5.6	-6.1	-6.4	-67.0	-77.2	156	150
16/10/2008	21:21:52			-5.6	-6.1	-6.4	-67.0	-79.0	147	150
16/10/2008	21:26:52			-5.4	-6.1	-6.4	-66.9	-77.1	151	150
16/10/2008	21:31:52			-5.5	-6.1	-6.4	-65.6	-76.6	147	150
16/10/2008	21:36:52			-5.5	-6.1	-6.4	-65.5	-76.6	158	150
16/10/2008	21:41:52			-5.7	-6.1	-6.4	-66.5	-76.5	154	150

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
16/10/2008	21:46:52			-5.7	-6.1	-6.4	-67.7	-77.1	144	150
16/10/2008	21:51:52			-5.4	-6.1	-6.4	-66.4	-77.1	155	150
16/10/2008	21:56:52			-5.4	-6.1	-6.4	-68.3	-77.6	159	150
16/10/2008	22:01:52			-5.7	-6.1	-6.4	-68.3	-79.4	147	150
16/10/2008	22:06:52			-5.5	-6.1	-6.4	-65.2	-79.9	159	150
16/10/2008	22:11:52			-5.7	-6.1	-6.4	-67.1	-79.9	159	150
16/10/2008	22:16:52			-5.7	-6.1	-6.4	-66.9	-78.4	150	150
16/10/2008	22:21:52			-5.8	-6.1	-6.4	-66.8	-78.9	159	150
16/10/2008	22:26:52			-5.4	-6.1	-6.4	-67.4	-78.9	159	150
16/10/2008	22:31:52			-5.4	-6.1	-6.4	-66.9	-79.4	148	150
16/10/2008	22:36:52			-5.7	-6.1	-6.4	-67.0	-78.9	204	150
16/10/2008	22:41:52			-5.6	-6.1	-6.4	-68.2	-79.9	149	150
16/10/2008	22:46:52			-5.7	-6.1	-6.4	-68.7	-79.0	153	150
16/10/2008	22:51:52			-5.8	-6.1	-6.4	-68.7	-79.0	160	150
16/10/2008	22:56:52			-5.4	-6.1	-6.4	-74.7	-79.5	143	150
16/10/2008	23:01:52			-5.4	-6.1	-6.4	-77.2	-79.5	153	150
16/10/2008	23:06:52			-5.8	-6.1	-6.4	-71.6	-80.5	149	150
16/10/2008	23:11:52			-5.7	-6.1	-6.4	-71.1	-81.5	146	150
16/10/2008	23:16:52			-5.6	-6.1	-6.4	-69.8	-80.5	150	150
16/10/2008	23:21:52			-5.5	-6.1	-6.4	-70.3	-79.7	147	150
16/10/2008	23:26:52			-5.5	-6.1	-6.4	-67.7	-79.2	152	150
16/10/2008	23:31:52			-5.6	-6.1	-6.4	-68.7	-80.9	148	150
16/10/2008	23:36:52			-5.7	-6.1	-6.4	-66.9	-80.9	150	150
16/10/2008	23:41:52			-5.7	-6.1	-6.4	-67.8	-80.9	153	150
16/10/2008	23:46:52			-5.5	-6.1	-6.4	-66.8	-80.8	151	150
16/10/2008	23:51:52			-5.5	-6.1	-6.4	-68.3	-80.2	148	150
16/10/2008	23:56:52			-5.4	-6.1	-6.4	-67.3	-81.3	148	150
17/10/2008	0:01:52			-5.6	-6.1	-6.4	-68.4	-82.3	148	150
17/10/2008	0:06:52			-5.4	-6.1	-6.4	-68.9	-82.3	148	150
17/10/2008	0:11:52			-5.5	-6.1	-6.4	-66.8	-82.3	149	150
17/10/2008	0:16:52			-5.5	-6.1	-6.4	-68.5	-82.3	150	150
17/10/2008	0:21:52			-5.7	-6.1	-6.4	-67.1	-82.3	150	150
17/10/2008	0:26:52			-5.7	-6.1	-6.4	-68.9	-82.3	150	150
17/10/2008	0:31:52			-5.6	-6.1	-6.4	-68.9	-82.8	152	150
17/10/2008	0:36:52			-5.5	-6.1	-6.4	-68.9	-82.8	152	150
17/10/2008	0:41:52			-5.5	-6.1	-6.4	-67.9	-83.3	149	150
17/10/2008	0:46:52			-5.5	-6.1	-6.4	-69.1	-82.8	148	150
17/10/2008	0:51:52			-5.6	-6.1	-6.4	-68.4	-82.8	150	150
17/10/2008	0:56:52			-5.6	-6.1	-6.4	-69.5	-82.8	150	150
17/10/2008	1:01:52			-5.5	-6.1	-6.4	-69.5	-82.8	152	150
17/10/2008	1:06:52			-5.5	-6.1	-6.4	-67.7	-82.8	153	150
17/10/2008	1:11:52			-5.6	-6.1	-6.4	-67.6	-82.3	146	150
17/10/2008	1:16:52			-5.6	-6.1	-6.4	-68.8	-82.3	146	150
17/10/2008	1:21:52			-5.6	-6.1	-6.4	-68.2	-82.3	146	150
17/10/2008	1:26:52			-5.6	-6.1	-6.4	-68.0	-82.3	147	150
17/10/2008	1:31:52			-5.5	-6.1	-6.4	-66.2	-82.3	147	150
17/10/2008	1:36:52			-5.6	-6.1	-6.4	-68.1	-82.3	150	150
17/10/2008	1:41:52			-5.5	-6.1	-6.4	-68.7	-82.3	151	150
17/10/2008	1:46:52			-5.6	-6.1	-6.4	-66.4	-81.8	150	150
17/10/2008	1:51:52			-5.6	-6.1	-6.4	-67.9	-81.8	149	150
17/10/2008	1:56:52			-5.7	-6.1	-6.4	-68.4	-81.8	150	150
17/10/2008	2:01:52			-5.7	-6.1	-6.4	-69.1	-81.8	151	150
17/10/2008	2:06:52			-5.6	-6.1	-6.4	-67.3	-81.8	151	150
17/10/2008	2:11:52			-5.5	-6.1	-6.4	-68.3	-81.8	152	150

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
17/10/2008	2:16:52			-5.4	-6.1	-6.4	-68.2	-81.8	153	150
17/10/2008	2:21:52			-5.5	-6.1	-6.4	-69.0	-81.8	154	150
17/10/2008	2:26:52			-5.5	-6.1	-6.4	-69.5	-81.3	153	150
17/10/2008	2:31:52			-5.5	-6.1	-6.4	-66.6	-81.3	152	150
17/10/2008	2:36:52			-5.4	-6.1	-6.4	-68.7	-81.3	152	150
17/10/2008	2:41:52			-5.5	-6.1	-6.4	-69.2	-80.3	150	150
17/10/2008	2:46:52			-5.4	-6.1	-6.4	-66.1	-80.3	152	150
17/10/2008	2:51:52			-5.5	-6.1	-6.4	-68.0	-80.8	154	150
17/10/2008	2:56:52			-5.6	-6.1	-6.4	-68.5	-80.8	152	150
17/10/2008	3:01:52			-5.4	-6.1	-6.4	-66.5	-80.8	152	150
17/10/2008	3:05:23	19	Drying	-5.8	-6.0	-6.2	-68.4	-80.9	150	150
17/10/2008	3:06:52			-5.4	-4.7	-6.4	-68.8	-80.8	121	100
17/10/2008	3:11:36	20	Drying	0.3	0.0	-2.4	-69.1	-80.9	102	100
17/10/2008	3:11:52			0.3	-0.1	-1.5	-69.4	-80.8	101	100
17/10/2008	3:16:52			0.2	-0.1	-0.9	-71.4	-80.8	104	100
17/10/2008	3:21:52			0.2	-0.1	-0.3	-72.8	-80.8	97	100
17/10/2008	3:26:52			0.4	-0.1	-0.3	-72.9	-80.8	102	100
17/10/2008	3:31:52			0.4	-0.1	-0.3	-73.5	-80.8	105	100
17/10/2008	3:36:52			0.5	-0.1	-0.3	-71.0	-80.8	97	100
17/10/2008	3:41:52			0.3	-0.1	-0.3	-69.7	-80.8	102	100
17/10/2008	3:46:52			0.3	-0.1	-0.3	-70.7	-80.8	104	100
17/10/2008	3:51:52			0.3	-0.1	-0.3	-70.7	-80.8	98	100
17/10/2008	3:56:52			0.4	-0.1	-0.3	-70.7	-80.8	101	100
17/10/2008	4:01:52			0.4	-0.1	-0.3	-68.1	-80.8	102	100
17/10/2008	4:06:52			0.5	-0.1	-0.3	-70.0	-80.8	103	100
17/10/2008	4:11:52			0.5	-0.1	-0.3	-69.2	-80.8	104	100
17/10/2008	4:16:52			0.5	-0.1	-0.3	-69.2	-80.3	103	100
17/10/2008	4:21:52			0.3	-0.1	-0.3	-70.2	-80.3	102	100
17/10/2008	4:26:52			0.5	-0.1	-0.3	-71.3	-80.3	97	100
17/10/2008	4:31:52			0.3	-0.1	-0.3	-71.8	-80.3	96	100
17/10/2008	4:36:52			0.5	-0.1	-0.3	-71.8	-80.3	98	100
17/10/2008	4:41:52			0.5	-0.1	-0.3	-72.4	-80.3	97	100
17/10/2008	4:46:52			0.3	-0.1	-0.3	-71.0	-80.8	96	100
17/10/2008	4:51:52			0.6	-0.1	-0.3	-72.1	-80.8	99	100
17/10/2008	4:56:52			0.3	-0.1	-0.3	-68.7	-80.8	101	100
17/10/2008	5:01:52			0.2	-0.1	-0.3	-69.8	-81.3	104	100
17/10/2008	5:06:52			0.3	-0.1	-0.3	-70.3	-81.3	103	100
17/10/2008	5:11:52			0.4	-0.1	-0.3	-69.2	-81.3	101	100
17/10/2008	5:16:52			0.5	-0.1	-0.3	-68.9	-81.3	100	100
17/10/2008	5:21:52			0.3	-0.1	-0.3	-69.5	-81.3	97	100
17/10/2008	5:26:52			0.5	-0.1	-0.3	-68.5	-81.3	102	100
17/10/2008	5:31:52			0.5	-0.1	-0.3	-70.0	-81.3	104	100
17/10/2008	5:36:52			0.3	-0.1	-0.3	-69.3	-81.3	104	100
17/10/2008	5:41:52			0.5	-0.1	-0.3	-70.2	-81.3	100	100
17/10/2008	5:46:52			0.5	-0.1	-0.3	-69.1	-81.3	97	100
17/10/2008	5:51:52			0.2	-0.1	-0.3	-70.3	-81.3	103	100
17/10/2008	5:56:52			0.3	-0.1	-0.3	-70.3	-81.3	103	100
17/10/2008	6:01:52			0.5	-0.1	-0.3	-68.2	-81.3	102	100
17/10/2008	6:06:52			0.4	-0.1	-0.3	-69.9	-81.3	99	100
17/10/2008	6:11:52			0.5	-0.1	-0.3	-69.9	-81.3	101	100
17/10/2008	6:16:52			0.4	-0.1	-0.3	-69.6	-80.8	104	100
17/10/2008	6:21:52			0.3	-0.1	-0.3	-70.6	-80.8	101	100
17/10/2008	6:26:52			0.5	-0.1	-0.3	-68.6	-81.3	96	100
17/10/2008	6:31:52			0.5	-0.1	-0.3	-70.5	-81.3	104	100

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
17/10/2008	6:36:52			0.5	-0.1	-0.3	-69.1	-81.3	103	100
17/10/2008	6:41:52			0.4	-0.1	-0.3	-69.0	-81.3	100	100
17/10/2008	6:46:52			0.3	-0.1	-0.3	-69.5	-81.3	102	100
17/10/2008	6:51:52			0.4	-0.1	-0.3	-70.0	-81.3	104	100
17/10/2008	6:56:52			0.4	-0.1	-0.3	-68.1	-81.3	100	100
17/10/2008	7:01:52			0.6	-0.1	-0.3	-69.4	-81.3	101	100
17/10/2008	7:06:52			0.5	-0.1	-0.3	-69.9	-81.3	104	100
17/10/2008	7:11:52			0.4	-0.1	-0.3	-68.3	-80.8	101	100
17/10/2008	7:16:52			0.3	-0.1	-0.3	-70.5	-80.8	102	100
17/10/2008	7:21:52			0.5	-0.1	-0.3	-69.6	-81.3	102	100
17/10/2008	7:26:52			0.5	-0.1	-0.3	-71.0	-81.3	98	100
17/10/2008	7:31:52			0.2	-0.1	-0.3	-70.5	-81.8	103	100
17/10/2008	7:36:52			0.4	-0.1	-0.3	-71.2	-81.8	99	100
17/10/2008	7:41:52			0.5	-0.1	-0.3	-70.2	-81.8	104	100
17/10/2008	7:46:52			0.3	-0.1	-0.3	-72.2	-81.8	101	100
17/10/2008	7:51:52			0.5	-0.1	-0.3	-72.7	-81.8	102	100
17/10/2008	7:56:52			0.5	-0.1	-0.3	-73.3	-81.8	102	100
17/10/2008	8:01:52			0.3	-0.1	-0.3	-73.8	-81.3	101	100
17/10/2008	8:06:52			0.7	-0.1	-0.3	-69.3	-81.3	102	100
17/10/2008	8:11:52			0.3	-0.1	-0.3	-70.5	-81.3	102	100
17/10/2008	8:16:52			0.3	-0.1	-0.3	-69.4	-81.3	102	100
17/10/2008	8:21:52			0.3	-0.1	-0.3	-69.2	-81.3	101	100
17/10/2008	8:26:52			0.5	-0.1	-0.3	-70.3	-81.3	102	100
17/10/2008	8:31:52			0.5	-0.1	-0.3	-70.3	-81.3	103	100
17/10/2008	8:36:52			0.3	-0.1	-0.3	-68.7	-81.3	101	100
17/10/2008	8:41:52			0.4	-0.1	-0.3	-70.6	-81.3	104	100
17/10/2008	8:46:52			0.5	-0.1	-0.3	-71.4	-81.3	101	100
17/10/2008	8:51:52			0.5	-0.1	-0.3	-72.0	-81.3	103	100
17/10/2008	8:56:52			0.5	-0.1	-0.3	-72.0	-81.3	101	100
17/10/2008	9:01:52			0.3	-0.1	-0.3	-72.5	-81.3	104	100
17/10/2008	9:06:52			0.5	-0.1	-0.3	-73.0	-80.8	98	100
17/10/2008	9:11:52			0.5	-0.1	-0.3	-73.7	-80.8	103	100
17/10/2008	9:16:52			0.6	-0.1	-0.3	-70.1	-80.8	97	100
17/10/2008	9:21:52			0.5	-0.1	-0.3	-71.3	-80.3	103	100
17/10/2008	9:26:52			0.5	-0.1	-0.3	-71.8	-80.8	101	100
17/10/2008	9:31:52			0.5	-0.1	-0.3	-69.5	-80.8	102	100
17/10/2008	9:36:52			0.5	-0.1	-0.3	-70.8	-81.3	104	100
17/10/2008	9:41:52			0.5	-0.1	-0.3	-70.3	-81.3	99	100
17/10/2008	9:46:52			0.5	-0.1	-0.3	-70.4	-81.3	104	100
17/10/2008	9:51:52			0.5	-0.1	-0.3	-70.9	-81.3	98	100
17/10/2008	9:56:52			0.3	-0.1	-0.3	-68.6	-81.3	102	100
17/10/2008	10:01:52			0.2	-0.1	-0.3	-70.1	-81.3	104	100
17/10/2008	10:06:52			0.3	-0.1	-0.3	-70.6	-81.3	98	100
17/10/2008	10:11:52			0.3	-0.1	-0.3	-68.1	-81.3	104	100
17/10/2008	10:16:52			0.5	-0.1	-0.3	-69.7	-80.8	96	100
17/10/2008	10:21:52			0.6	-0.1	-0.3	-70.2	-79.8	102	100
17/10/2008	10:26:52			0.5	-0.1	-0.3	-70.3	-80.9	101	100
17/10/2008	10:31:52			0.5	-0.1	-0.3	-71.9	-80.9	101	100
17/10/2008	10:36:52			0.5	-0.1	-0.3	-70.6	-80.9	103	100
17/10/2008	10:41:52			0.6	-0.1	-0.3	-70.4	-80.9	96	100
17/10/2008	10:46:52			0.6	-0.1	-0.3	-70.9	-81.4	102	100
17/10/2008	10:51:52			0.5	-0.1	-0.3	-68.9	-81.4	104	100
17/10/2008	10:56:52			0.3	-0.1	-0.3	-70.1	-81.4	100	100
17/10/2008	11:01:52			0.3	-0.1	-0.3	-68.6	-81.4	101	100

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
17/10/2008	11:06:52			0.5	-0.1	-0.3	-69.1	-81.4	104	100
17/10/2008	11:11:52			0.3	-0.1	-0.3	-69.6	-80.9	98	100
17/10/2008	11:16:52			0.6	-0.1	-0.3	-69.6	-80.9	103	100
17/10/2008	11:21:52			0.6	-0.1	-0.3	-68.8	-80.9	96	100
17/10/2008	11:26:52			0.2	-0.1	-0.3	-70.0	-80.9	102	100
17/10/2008	11:31:52			0.3	-0.1	-0.3	-67.8	-80.9	103	100
17/10/2008	11:36:52			0.5	-0.1	-0.3	-68.8	-80.9	100	100
17/10/2008	11:41:52			0.4	-0.1	-0.3	-69.3	-80.9	104	100
17/10/2008	11:46:52			0.4	-0.1	-0.3	-68.6	-80.9	96	100
17/10/2008	11:51:52			0.5	-0.1	-0.3	-70.4	-80.9	102	100
17/10/2008	11:56:52			0.5	-0.1	-0.3	-70.4	-80.9	102	100
17/10/2008	12:01:52			0.5	-0.1	-0.3	-68.2	-80.9	100	100
17/10/2008	12:06:52			0.5	-0.1	-0.3	-70.1	-81.4	104	100
17/10/2008	12:11:52			0.6	-0.1	-0.3	-70.6	-81.4	96	100
17/10/2008	12:16:52			0.6	-0.1	-0.3	-72.3	-81.4	102	100
17/10/2008	12:21:52			0.5	-0.1	-0.3	-72.3	-81.4	103	100
17/10/2008	12:26:52			0.5	-0.1	-0.3	-72.6	-81.9	99	100
17/10/2008	12:31:52			0.5	-0.1	-0.3	-71.7	-81.9	104	100
17/10/2008	12:36:52			0.5	-0.1	-0.3	-71.0	-81.9	96	100
17/10/2008	12:41:52			0.3	-0.1	-0.3	-69.7	-81.9	102	100
17/10/2008	12:46:52			0.3	-0.1	-0.3	-71.2	-81.9	103	100
17/10/2008	12:51:52			0.5	-0.1	-0.3	-68.6	-81.9	100	100
17/10/2008	12:56:52			0.4	-0.1	-0.3	-70.2	-81.9	104	100
17/10/2008	13:01:52			0.6	-0.1	-0.3	-70.2	-81.9	96	100
17/10/2008	13:06:52			0.5	-0.1	-0.3	-69.8	-81.4	102	100
17/10/2008	13:11:52			0.5	-0.1	-0.3	-70.2	-80.9	103	100
17/10/2008	13:16:52			0.5	-0.1	-0.3	-70.7	-80.9	101	100
17/10/2008	13:21:52			0.3	-0.1	-0.3	-70.7	-80.9	104	100
17/10/2008	13:26:52			0.3	-0.1	-0.3	-70.4	-81.4	98	100
17/10/2008	13:31:52			0.3	-0.1	-0.3	-70.9	-81.4	102	100
17/10/2008	13:36:52			0.5	-0.1	-0.3	-68.5	-81.4	104	100
17/10/2008	13:41:52			0.3	-0.1	-0.3	-69.8	-81.4	99	100
17/10/2008	13:46:52			0.5	-0.1	-0.3	-71.6	-81.4	102	100
17/10/2008	13:51:52			0.5	-0.1	-0.3	-73.7	-81.9	104	100
17/10/2008	13:56:52			0.3	-0.1	-0.3	-76.4	-81.9	99	100
17/10/2008	14:01:52			0.3	-0.1	-0.3	-73.5	-81.9	104	100
17/10/2008	14:06:52			0.4	-0.1	-0.3	-73.0	-81.9	96	100
17/10/2008	14:11:45	21	Drying	0.6	0.1	-0.1	-70.1	-81.4	102	80
17/10/2008	14:11:52			0.5	0.2	-0.3	-70.0	-81.4	103	100
17/10/2008	14:16:52			4.9	5.2	2.9	-69.9	-81.4	79	80
17/10/2008	14:18:39	22	Drying	6.4	7.0	5.4	-69.6	-81.4	84	80
17/10/2008	14:21:52			7.2	6.9	6.4	-69.9	-81.4	79	80
17/10/2008	14:26:52			7.2	6.9	6.4	-69.6	-80.9	85	80
17/10/2008	14:31:52			7.4	6.9	6.9	-71.2	-80.9	82	80
17/10/2008	14:36:52			7.5	6.9	6.9	-69.4	-81.4	78	80
17/10/2008	14:41:52			7.3	6.9	6.9	-70.5	-81.4	81	80
17/10/2008	14:46:52			7.4	6.9	6.9	-70.5	-81.4	85	80
17/10/2008	14:51:52			7.3	6.9	6.9	-69.8	-81.4	81	80
17/10/2008	14:56:52			7.4	6.9	6.9	-69.3	-81.4	77	80
17/10/2008	15:01:52			7.5	6.9	6.9	-70.3	-81.4	83	80
17/10/2008	15:06:52			7.5	6.9	6.9	-68.9	-81.4	85	80
17/10/2008	15:11:52			7.3	6.9	6.9	-70.1	-81.4	81	80
17/10/2008	15:16:52			7.5	6.9	6.9	-71.1	-80.9	79	80
17/10/2008	15:21:52			7.4	6.9	6.9	-68.2	-80.9	78	80

Arvind K. 18/10/08

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
17/10/2008	15:26:52			7.2	6.9	6.9	-70.1	-80.9	85	80
17/10/2008	15:31:52			7.6	6.9	6.9	-70.1	-80.9	82	80
17/10/2008	15:36:52			7.2	6.9	6.9	-69.1	-80.9	80	80
17/10/2008	15:41:52			7.4	6.9	6.9	-70.2	-80.9	77	80
17/10/2008	15:46:52			7.4	6.9	6.9	-68.4	-80.9	78	80
17/10/2008	15:51:52			7.4	6.9	6.9	-70.1	-80.9	86	80
17/10/2008	15:56:52			7.4	6.9	6.9	-70.1	-80.9	85	80
17/10/2008	16:01:52			7.3	6.9	6.9	-71.3	-80.9	81	80
17/10/2008	16:06:52			7.2	6.9	6.9	-69.0	-80.9	78	80
17/10/2008	16:11:52			7.5	6.9	6.9	-70.3	-80.9	80	80
17/10/2008	16:16:52			7.3	6.9	6.9	-69.4	-80.4	85	80
17/10/2008	16:21:52			7.5	6.9	6.9	-71.0	-80.9	82	80
17/10/2008	16:26:52			7.3	6.9	6.9	-71.5	-80.9	80	80
17/10/2008	16:31:52			7.4	6.9	6.9	-69.4	-80.9	76	80
17/10/2008	16:36:52			7.5	6.9	6.9	-70.5	-80.9	86	80
17/10/2008	16:41:52			7.3	6.9	6.9	-71.0	-80.9	85	80
17/10/2008	16:46:52			7.3	6.9	6.9	-71.0	-80.9	82	80
17/10/2008	16:51:52			7.3	6.9	6.9	-70.4	-80.9	80	80
17/10/2008	16:56:52			7.6	6.9	6.9	-71.5	-80.9	77	80
17/10/2008	17:01:52			7.2	6.9	6.9	-70.1	-80.9	84	80
17/10/2008	17:06:52			7.4	6.9	6.9	-70.6	-80.9	84	80
17/10/2008	17:11:52			7.4	6.9	6.9	-70.0	-80.9	82	80
17/10/2008	17:16:52			7.5	6.9	6.9	-70.5	-80.9	78	80
17/10/2008	17:18:52	23	Drying	7.4	7.0	6.9	-69.8	-80.8	83	80
17/10/2008	17:21:52			10.3	10.0	9.0	-71.1	-80.9	77	80
17/10/2008	17:26:52			14.6	15.0	12.4	-72.4	-80.9	86	80
17/10/2008	17:26:58	24	Drying	14.7	15.0	12.8	-72.5	-80.9	82	80
17/10/2008	17:31:52			15.4	15.0	14.8	-73.6	-80.9	83	80
17/10/2008	17:36:52			15.4	15.0	14.8	-74.1	-80.9	80	80
17/10/2008	17:41:52			15.4	15.0	15.3	-76.0	-81.4	77	80
17/10/2008	17:46:52			15.5	15.0	15.3	-75.4	-81.4	81	80
17/10/2008	17:51:52			15.5	15.0	15.3	-75.4	-81.4	85	80
17/10/2008	17:56:52			15.2	15.0	15.3	-75.4	-81.4	85	80
17/10/2008	18:01:52			15.2	15.0	15.3	-70.5	-81.4	84	80
17/10/2008	18:06:52			15.4	15.0	15.3	-71.7	-81.4	82	80
17/10/2008	18:11:52			15.4	15.0	15.3	-72.2	-81.4	79	80
17/10/2008	18:16:52			15.4	15.0	15.3	-71.7	-81.4	77	80
17/10/2008	18:21:52			15.4	15.0	15.3	-70.6	-81.4	76	80
17/10/2008	18:26:52			15.3	15.0	15.3	-71.1	-81.4	81	80
17/10/2008	18:31:52			15.3	15.0	15.3	-70.5	-81.4	86	80
17/10/2008	18:36:52			15.3	15.0	15.3	-70.0	-81.4	86	80
17/10/2008	18:41:52			15.5	15.0	15.3	-71.1	-81.4	183	80
17/10/2008	18:46:52			15.4	15.0	15.3	-69.3	-80.9	87	80
17/10/2008	18:51:52			15.5	15.0	15.3	-71.8	-80.9	84	80
17/10/2008	18:56:52			15.3	15.0	15.3	-70.9	-81.4	84	80
17/10/2008	19:01:52			15.3	15.0	15.3	-70.2	-82.0	84	80
17/10/2008	19:06:52			15.5	15.0	15.3	-72.2	-82.5	82	80
17/10/2008	19:11:52			15.3	15.0	15.3	-72.2	-82.5	81	80
17/10/2008	19:16:52			15.3	15.0	15.3	-73.9	-82.5	80	80
17/10/2008	19:21:52			15.4	15.0	15.3	-70.2	-82.5	79	80
17/10/2008	19:26:52			15.5	15.0	15.3	-70.8	-82.5	78	80
17/10/2008	19:31:52			15.5	15.0	15.3	-70.2	-82.5	78	80
17/10/2008	19:36:52			15.4	15.0	15.3	-71.2	-82.5	77	80
17/10/2008	19:41:52			15.7	15.0	15.3	-71.2	-82.5	76	80

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
17/10/2008	19:46:52			15.3	15.0	15.3	-69.6	-82.0	76	80
17/10/2008	19:51:52			15.5	15.0	15.3	-71.9	-82.0	76	80
17/10/2008	19:56:52			15.5	15.0	15.3	-71.1	-82.0	80	80
17/10/2008	20:01:52			15.4	15.0	15.3	-70.1	-82.0	79	80
17/10/2008	20:06:52			15.5	15.0	15.3	-71.4	-82.0	82	80
17/10/2008	20:11:52			15.3	15.0	15.3	-72.4	-82.0	86	80
17/10/2008	20:16:52			15.3	15.0	15.3	-72.4	-82.0	86	80
17/10/2008	20:21:52			15.4	15.0	15.3	-71.9	-82.0	85	80
17/10/2008	20:26:52			15.3	15.0	15.3	-71.4	-81.5	84	80
17/10/2008	20:31:49	25	Drying	15.2	15.0	15.4	-70.1	-81.8	82	60
17/10/2008	20:31:52			15.4	15.1	15.3	-70.2	-81.5	83	80
17/10/2008	20:36:52			19.7	20.1	17.9	-72.3	-81.5	58	60
17/10/2008	20:41:52			24.1	25.1	23.5	-73.6	-81.5	66	60
17/10/2008	20:46:45	26	Drying	29.5	30.0	28.4	-75.2	-81.7	59	60
17/10/2008	20:46:52			29.6	29.9	28.4	-74.9	-82.0	59	60
17/10/2008	20:51:52			30.2	29.9	31.1	-74.9	-82.0	63	60
17/10/2008	20:56:52			30.1	29.9	30.6	-74.4	-82.0	65	60
17/10/2008	21:01:52			30.1	29.9	30.6	-72.3	-82.0	62	60
17/10/2008	21:06:52			30.1	29.9	30.6	-72.8	-82.0	60	60
17/10/2008	21:11:52			30.4	29.9	30.6	-72.8	-82.0	58	60
17/10/2008	21:16:52			30.4	29.9	31.1	-73.8	-82.0	58	60
17/10/2008	21:21:52			30.2	29.9	31.1	-71.5	-82.0	57	60
17/10/2008	21:26:52			30.5	29.9	31.1	-72.3	-82.0	56	60
17/10/2008	21:31:52			30.3	29.9	31.1	-72.3	-82.0	57	60
17/10/2008	21:36:52			30.5	29.9	31.1	-71.8	-82.0	57	60
17/10/2008	21:41:52			30.4	29.9	31.1	-73.4	-82.0	59	60
17/10/2008	21:46:52			30.5	29.9	31.1	-70.4	-82.0	61	60
17/10/2008	21:51:52			30.4	29.9	31.1	-71.6	-81.5	63	60
17/10/2008	21:56:52			30.6	29.9	31.1	-70.5	-81.5	65	60
17/10/2008	22:01:52			30.4	29.9	31.1	-71.7	-81.5	66	60
17/10/2008	22:06:52			30.4	29.9	31.1	-72.7	-81.5	58	60
17/10/2008	22:11:52			30.2	29.9	31.1	-70.7	-81.0	58	60
17/10/2008	22:16:52			30.4	29.9	31.1	-72.0	-81.5	59	60
17/10/2008	22:21:52			30.2	29.9	31.1	-72.5	-81.5	62	60
17/10/2008	22:26:52			30.1	29.9	31.1	-70.8	-81.5	63	60
17/10/2008	22:31:52			30.4	29.9	31.1	-70.8	-81.5	66	60
17/10/2008	22:36:52			30.4	29.9	31.1	-69.8	-81.5	162	60
17/10/2008	22:41:52			30.2	29.9	31.1	-71.5	-81.0	81	60
17/10/2008	22:46:52			30.4	29.9	31.1	-72.0	-81.5	61	60
17/10/2008	22:51:52			30.4	29.9	31.1	-74.2	-82.0	62	60
17/10/2008	22:56:52			30.2	29.9	31.1	-74.7	-82.0	62	60
17/10/2008	23:01:52			30.4	29.9	31.1	-79.5	-82.0	64	60
17/10/2008	23:06:52			30.4	29.9	31.1	-79.0	-82.0	64	60
17/10/2008	23:11:52			30.6	29.9	31.1	-80.3	-82.0	64	60
17/10/2008	23:16:52			30.5	29.9	31.1	-80.8	-82.0	65	60
17/10/2008	23:21:52			30.4	29.9	31.1	-80.8	-82.0	65	60
17/10/2008	23:26:52			30.5	29.9	31.1	-81.4	-82.0	65	60
17/10/2008	23:31:52			30.2	29.9	31.1	-82.5	-82.0	65	60
17/10/2008	23:36:52			30.1	29.9	31.1	-82.4	-82.0	64	60
17/10/2008	23:41:52			30.6	29.9	31.1	-81.9	-82.0	64	60
17/10/2008	23:46:52			30.4	29.9	31.1	-81.4	-82.0	64	60
17/10/2008	23:51:52			30.3	29.9	31.1	-81.8	-82.0	63	60
17/10/2008	23:56:52			30.2	29.9	31.1	-82.3	-81.5	63	60
18/10/2008	0:01:52			30.6	29.9	31.1	-81.8	-82.0	62	60

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
18/10/2008	0:06:52			30.4	29.9	31.1	-82.3	-82.0	60	60
18/10/2008	0:11:52			30.4	29.9	31.1	-81.8	-82.0	60	60
18/10/2008	0:16:52			30.4	29.9	31.1	-81.3	-82.0	59	60
18/10/2008	0:21:52			30.6	29.9	31.1	-82.5	-82.0	58	60
18/10/2008	0:26:52			30.6	29.9	31.1	-81.3	-82.0	61	60
18/10/2008	0:31:52			30.4	29.9	31.1	-81.4	-82.0	66	60
18/10/2008	0:36:52			30.2	29.9	31.1	-81.4	-82.5	65	60
18/10/2008	0:41:52			30.2	29.9	31.1	-81.4	-83.0	64	60
18/10/2008	0:46:52			30.4	29.9	31.1	-82.0	-83.0	61	60
18/10/2008	0:51:52			30.5	29.9	31.1	-82.0	-82.5	57	60
18/10/2008	0:56:52			30.2	29.9	31.1	-82.0	-82.5	64	60
18/10/2008	1:01:52			30.1	29.9	31.1	-82.6	-81.9	64	60
18/10/2008	1:06:52			30.6	29.9	31.1	-82.6	-81.8	61	60
18/10/2008	1:11:52			30.4	29.9	31.1	-81.8	-82.3	58	60
18/10/2008	1:16:52			30.2	29.9	31.1	-82.3	-82.3	67	60
18/10/2008	1:21:52			30.4	29.9	31.1	-81.7	-82.8	65	60
18/10/2008	1:26:52			30.4	29.9	31.1	-81.7	-82.8	60	60
18/10/2008	1:31:52			30.4	29.9	31.1	-81.8	-82.8	57	60
18/10/2008	1:36:52			30.4	29.9	31.1	-81.8	-82.8	66	60
18/10/2008	1:41:52			30.1	29.9	31.1	-82.4	-82.8	63	60
18/10/2008	1:46:52			30.6	29.9	31.1	-82.9	-82.8	58	60
18/10/2008	1:51:52			30.4	29.9	31.1	-81.9	-82.8	63	60
18/10/2008	1:56:52			30.3	29.9	31.1	-81.6	-82.8	64	60
18/10/2008	2:01:52			30.3	29.9	31.1	-81.1	-82.8	61	60
18/10/2008	2:06:52			30.4	29.9	31.1	-81.1	-82.8	56	60
18/10/2008	2:11:52			30.1	29.9	31.1	-80.8	-82.8	66	60
18/10/2008	2:16:52			30.4	29.9	31.1	-81.4	-82.8	62	60
18/10/2008	2:21:52			30.4	29.9	31.1	-81.4	-82.8	57	60
18/10/2008	2:26:52			30.4	29.9	31.1	-80.5	-82.3	66	60
18/10/2008	2:31:52			30.2	29.9	31.1	-81.1	-82.3	63	60
18/10/2008	2:36:52			30.3	29.9	31.1	-81.7	-82.3	58	60
18/10/2008	2:41:52			30.4	29.9	31.1	-80.9	-82.3	66	60
18/10/2008	2:46:52			30.4	29.9	31.1	-81.4	-82.3	63	60
18/10/2008	2:51:52			30.2	29.9	31.1	-81.9	-82.3	59	60
18/10/2008	2:56:52			30.1	29.9	31.1	-81.4	-82.3	67	60
18/10/2008	3:01:52			30.4	29.9	31.1	-81.3	-82.3	63	60
18/10/2008	3:06:52			30.4	29.9	31.1	-81.3	-82.3	57	60
18/10/2008	3:11:52			30.3	29.9	31.1	-81.8	-82.3	66	60
18/10/2008	3:16:52			30.5	29.9	31.1	-82.4	-82.3	62	60
18/10/2008	3:21:52			30.4	29.9	31.1	-82.3	-82.3	57	60
18/10/2008	3:26:52			30.2	29.9	31.1	-82.3	-82.3	65	60
18/10/2008	3:31:52			30.1	29.9	31.1	-82.3	-82.3	61	60
18/10/2008	3:36:52			30.6	29.9	31.1	-82.3	-82.3	59	60
18/10/2008	3:41:52			30.4	29.9	31.1	-82.3	-82.3	64	60
18/10/2008	3:46:52			30.1	29.9	31.1	-82.3	-82.8	59	60
18/10/2008	3:51:52			30.5	29.9	31.1	-82.3	-82.8	67	60
18/10/2008	3:56:52			30.3	29.9	31.1	-81.8	-82.8	62	60
18/10/2008	4:01:52			30.2	29.9	31.1	-82.3	-82.8	57	60
18/10/2008	4:06:52			30.4	29.9	31.1	-82.3	-82.8	65	60
18/10/2008	4:11:52			30.4	29.9	31.1	-82.3	-82.8	59	60
18/10/2008	4:16:52			30.1	29.9	31.1	-82.3	-82.8	63	60
18/10/2008	4:21:52			30.4	29.9	31.1	-78.8	-82.8	63	60
18/10/2008	4:26:52			30.4	29.9	31.1	-80.0	-82.8	58	60
18/10/2008	4:31:52			30.4	29.9	31.1	-80.1	-82.8	66	60

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
18/10/2008	4:36:52			30.2	29.9	31.1	-81.3	-83.3	60	60
18/10/2008	4:41:52			30.5	29.9	31.1	-81.4	-82.8	61	60
18/10/2008	4:46:52			30.4	29.9	31.1	-80.9	-82.8	64	60
18/10/2008	4:51:52			30.4	29.9	31.1	-81.6	-82.8	58	60
18/10/2008	4:52:38	27	Drying	30.4	30.0	31.0	-81.7	-82.7	61	60
18/10/2008	4:56:52			33.1	34.1	33.4	-82.7	-82.8	67	60
18/10/2008	5:01:52			39.1	39.2	38.6	-83.2	-82.8	62	60
18/10/2008	5:06:52			43.3	44.2	42.7	-83.7	-82.8	59	60
18/10/2008	5:07:40	28	Drying	44.8	45.0	44.2	-84.0	-82.9	62	60
18/10/2008	5:11:52			45.0	45.0	46.4	-83.1	-82.8	58	60
18/10/2008	5:16:52			45.3	45.0	46.4	-81.2	-82.8	59	60
18/10/2008	5:21:52			45.1	45.0	46.4	-81.8	-82.8	64	60
18/10/2008	5:26:52			45.1	45.0	46.4	-82.8	-82.8	62	60
18/10/2008	5:31:52			45.1	45.0	46.4	-83.3	-82.8	63	60
18/10/2008	5:36:52			45.3	45.0	46.4	-83.3	-82.3	59	60
18/10/2008	5:41:52			45.2	45.0	46.4	-83.3	-82.3	65	60
18/10/2008	5:46:52			45.3	45.0	46.4	-83.3	-82.3	66	60
18/10/2008	5:51:52			45.4	45.0	46.4	-83.3	-82.3	66	60
18/10/2008	5:56:52			45.4	45.0	46.4	-83.8	-82.3	65	60
18/10/2008	6:01:52			45.4	45.0	46.4	-83.8	-82.3	66	60
18/10/2008	6:06:52			44.9	45.0	45.5	-83.8	-82.3	66	60
18/10/2008	6:11:52			44.4	45.0	46.5	-82.0	-82.3	66	60
18/10/2008	6:16:52			44.6	45.0	46.6	-78.7	-82.3	66	60
18/10/2008	6:21:52			45.9	45.0	46.2	-77.1	-82.3	66	60
18/10/2008	6:26:52			45.4	45.0	46.1	-77.1	-82.3	66	60
18/10/2008	6:31:52			44.3	45.0	46.7	-77.6	-82.3	66	60
18/10/2008	6:36:52			45.3	45.0	46.6	-77.1	-82.3	66	60
18/10/2008	6:41:52			45.8	45.0	45.6	-76.6	-81.8	66	60
18/10/2008	6:46:52			44.8	45.0	45.7	-77.1	-81.8	66	60
18/10/2008	6:51:52			44.5	45.0	46.8	-77.0	-81.8	64	60
18/10/2008	6:56:52			45.9	45.0	46.2	-76.1	-81.8	63	60
18/10/2008	7:01:52			44.9	45.0	45.5	-76.6	-81.8	62	60
18/10/2008	7:06:52			45.1	45.0	46.8	-75.5	-81.8	60	60
18/10/2008	7:11:52			45.3	45.0	46.8	-77.0	-81.8	57	60
18/10/2008	7:16:52			45.3	45.0	46.8	-78.1	-81.3	67	60
18/10/2008	7:21:52			45.3	45.0	46.8	-78.1	-81.3	66	60
18/10/2008	7:26:52			45.5	45.0	46.8	-79.8	-81.3	63	60
18/10/2008	7:31:52			45.3	45.0	46.8	-79.8	-81.3	60	60
18/10/2008	7:36:52			45.2	45.0	46.8	-81.3	-82.3	64	60
18/10/2008	7:41:52			45.3	45.0	46.8	-81.8	-82.8	65	60
18/10/2008	7:46:52			45.4	45.0	46.8	-80.7	-82.8	60	60
18/10/2008	7:51:52			45.9	45.0	46.6	-80.7	-82.8	60	60
18/10/2008	7:56:52			45.3	45.0	46.7	-80.2	-82.8	64	60
18/10/2008	8:01:52			45.4	45.0	46.7	-81.3	-82.8	59	60
18/10/2008	8:06:52			45.4	45.0	46.7	-81.8	-82.8	67	60
18/10/2008	8:11:52			45.1	45.0	46.7	-81.8	-82.8	62	60
18/10/2008	8:16:52			45.4	45.0	46.7	-81.7	-82.8	61	60
18/10/2008	8:21:52			45.6	45.0	46.7	-81.2	-82.8	63	60
18/10/2008	8:26:52			45.5	45.0	46.7	-81.2	-82.8	56	60
18/10/2008	8:31:52			45.3	45.0	46.7	-80.7	-82.1	158	60
18/10/2008	8:36:52			44.9	45.0	46.7	-80.4	-81.3	102	60
18/10/2008	8:41:52			45.3	45.0	46.8	-81.4	-81.3	57	60
18/10/2008	8:46:52			45.4	45.0	46.8	-81.9	-81.8	62	60
18/10/2008	8:51:52			45.4	45.0	46.8	-82.4	-81.6	66	60

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
18/10/2008	8:56:52			45.4	45.0	46.8	-81.4	-81.6	57	60
18/10/2008	9:01:52			45.4	45.0	46.8	-81.3	-81.6	60	60
18/10/2008	9:06:52			45.5	45.0	46.8	-81.8	-81.2	63	60
18/10/2008	9:11:52			45.4	45.0	46.8	-81.8	-81.2	67	60
18/10/2008	9:16:52			45.2	45.0	46.8	-81.2	-81.2	56	60
18/10/2008	9:21:52			45.4	45.0	46.8	-82.2	-82.2	59	60
18/10/2008	9:26:52			45.3	45.0	46.8	-82.7	-82.2	61	60
18/10/2008	9:31:52			45.5	45.0	46.8	-82.2	-82.7	64	60
18/10/2008	9:36:52			45.4	45.0	46.8	-82.2	-82.7	66	60
18/10/2008	9:41:52			45.6	45.0	46.8	-82.7	-83.2	66	60
18/10/2008	9:46:52			45.4	45.0	46.8	-81.7	-82.6	56	60
18/10/2008	9:51:52			45.4	45.0	46.8	-81.7	-82.6	58	60
18/10/2008	9:56:52			45.5	45.0	46.8	-82.2	-82.5	58	60
18/10/2008	10:01:52			45.7	45.0	46.8	-82.2	-82.5	60	60
18/10/2008	10:06:52			45.8	45.0	46.8	-82.7	-82.5	61	60
18/10/2008	10:11:52			45.9	45.0	46.8	-82.7	-82.5	61	60
18/10/2008	10:16:52			46.0	45.0	47.3	-82.7	-83.5	62	60
18/10/2008	10:21:52			46.1	45.0	47.3	-82.7	-84.0	63	60
18/10/2008	10:26:52			46.3	45.0	47.3	-82.7	-84.0	65	60
18/10/2008	10:31:52			46.4	45.0	47.3	-82.7	-84.0	65	60
18/10/2008	10:36:52			46.5	45.0	47.8	-82.2	-84.0	66	60
18/10/2008	10:41:52			46.6	45.0	47.8	-82.2	-84.0	66	60
18/10/2008	10:46:52			46.8	45.0	47.8	-81.7	-84.0	64	60
18/10/2008	10:51:52			47.1	45.0	47.8	-81.7	-83.5	57	60
18/10/2008	10:56:52			47.0	45.0	48.3	-81.7	-83.0	57	60
18/10/2008	11:01:52			47.1	45.0	48.3	-81.2	-83.0	58	60
18/10/2008	11:06:52			47.3	45.0	48.3	-81.2	-83.0	59	60
18/10/2008	11:11:52			47.4	45.0	48.3	-81.2	-83.0	60	60
18/10/2008	11:16:52			47.4	45.0	48.8	-80.7	-83.0	61	60
18/10/2008	11:21:52			47.7	45.0	48.8	-80.7	-82.5	62	60
18/10/2008	11:26:52			47.8	45.0	48.8	-80.7	-82.5	62	60
18/10/2008	11:31:52			47.8	45.0	48.8	-80.2	-83.0	63	60
18/10/2008	11:36:52			47.8	45.0	48.8	-80.2	-83.0	64	60
18/10/2008	11:41:52			47.8	45.0	49.3	-80.2	-83.0	65	60
18/10/2008	11:46:52			48.1	45.0	49.3	-79.7	-83.0	65	60
18/10/2008	11:51:52			48.1	45.0	49.3	-79.7	-83.0	66	60
18/10/2008	11:56:52			48.2	45.0	49.3	-79.7	-82.5	66	60
18/10/2008	12:01:52			48.4	45.0	49.3	-79.7	-82.5	66	60
18/10/2008	12:06:52			48.4	45.0	49.3	-79.7	-82.5	61	60
18/10/2008	12:11:52			48.4	45.0	49.8	-79.2	-82.5	56	60
18/10/2008	12:16:52			48.6	45.0	49.8	-79.2	-82.5	56	60
18/10/2008	12:21:52			48.6	45.0	49.8	-79.2	-82.0	57	60
18/10/2008	12:26:52			48.8	45.0	49.8	-78.7	-81.0	58	60
18/10/2008	12:31:52			48.9	45.0	49.8	-78.7	-82.1	57	60
18/10/2008	12:36:52			48.9	45.0	50.3	-78.7	-82.1	58	60
18/10/2008	12:41:52			48.9	45.0	50.3	-78.7	-82.1	58	60
18/10/2008	12:46:52			49.0	45.0	50.3	-78.2	-82.6	58	60
18/10/2008	12:51:52			49.2	45.0	50.3	-78.2	-82.6	60	60
18/10/2008	12:56:52			49.3	45.0	50.8	-78.2	-82.6	58	60
18/10/2008	13:01:52			49.3	45.0	50.8	-78.2	-82.6	59	60
18/10/2008	13:06:52			49.5	45.0	50.8	-78.2	-82.6	58	60
18/10/2008	13:11:52			49.5	45.0	50.8	-78.2	-82.6	58	60
18/10/2008	13:16:52			49.7	45.0	50.8	-77.7	-82.6	57	60
18/10/2008	13:21:52			49.8	45.0	51.3	-77.7	-82.6	57	60

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
18/10/2008	13:26:52			50.0	45.0	51.3	-77.7	-82.6	57	60
18/10/2008	13:31:52			50.0	45.0	51.3	-77.7	-82.1	56	60
18/10/2008	13:36:52			50.2	45.0	51.3	-77.7	-82.1	59	60
18/10/2008	13:41:52			50.2	45.0	51.3	-77.7	-82.1	63	60
18/10/2008	13:46:52			50.3	45.0	51.8	-77.7	-82.1	66	60
18/10/2008	13:51:52			50.4	45.0	51.8	-77.2	-82.1	66	60
18/10/2008	13:56:52			50.5	45.0	51.8	-77.2	-82.1	65	60
18/10/2008	14:01:52			50.6	45.0	51.8	-77.2	-82.1	63	60
18/10/2008	14:06:52			49.6	45.0	51.8	-77.2	-82.1	117	60
18/10/2008	14:11:52			48.0	45.0	50.0	-77.2	-81.6	66	60
18/10/2008	14:16:52			46.9	45.0	48.8	-77.2	-81.6	64	60
18/10/2008	14:21:52			45.7	45.0	47.3	-77.2	-81.6	61	60
18/10/2008	14:26:52			45.4	45.0	46.8	-67.1	-81.6	59	60
18/10/2008	14:31:52			45.5	45.0	46.8	-72.1	-82.1	65	60
18/10/2008	14:36:52			45.7	45.0	46.8	-75.4	-82.1	64	60
18/10/2008	14:41:52			45.9	45.0	46.8	-75.9	-82.1	58	60
18/10/2008	14:46:52			46.0	45.0	47.3	-75.9	-82.1	66	60
18/10/2008	14:51:52			46.2	45.0	47.3	-75.9	-82.1	62	60
18/10/2008	14:56:52			46.4	45.0	47.3	-75.9	-82.1	57	60
18/10/2008	15:01:52			46.6	45.0	47.8	-75.9	-82.1	65	60
18/10/2008	15:06:52			46.6	45.0	47.8	-75.9	-82.1	59	60
18/10/2008	15:11:52			46.8	45.0	47.8	-75.9	-82.1	66	60
18/10/2008	15:16:52			46.9	45.0	48.3	-75.9	-81.6	61	60
18/10/2008	15:21:52			47.1	45.0	48.3	-75.9	-81.6	62	60
18/10/2008	15:26:52			47.2	45.0	48.3	-75.9	-81.6	63	60
18/10/2008	15:31:52			47.4	45.0	48.3	-75.9	-81.6	58	60
18/10/2008	15:36:52			47.4	45.0	48.8	-75.9	-82.1	63	60
18/10/2008	15:41:52			47.6	45.0	48.8	-75.9	-82.1	57	60
18/10/2008	15:46:52			47.8	45.0	48.8	-75.9	-82.1	63	60
18/10/2008	15:51:52			48.0	45.0	49.3	-75.9	-82.1	57	60
18/10/2008	15:56:52			48.1	45.0	49.3	-75.9	-82.6	65	60
18/10/2008	16:01:52			48.1	45.0	49.3	-75.9	-82.1	57	60
18/10/2008	16:06:52			48.3	45.0	49.3	-75.9	-82.1	65	60
18/10/2008	16:11:52			48.4	45.0	49.8	-75.9	-82.1	58	60
18/10/2008	16:16:52			48.5	45.0	49.8	-75.9	-82.1	66	60
18/10/2008	16:21:52			48.7	45.0	49.8	-75.9	-82.1	58	60
18/10/2008	16:26:52			48.8	45.0	49.8	-75.9	-82.1	66	60
18/10/2008	16:31:52			49.0	45.0	49.8	-75.9	-82.1	60	60
18/10/2008	16:36:52			49.0	45.0	50.3	-75.9	-82.1	66	60
18/10/2008	16:41:52			49.0	45.0	50.3	-75.9	-82.1	60	60
18/10/2008	16:46:52			49.2	45.0	50.3	-75.9	-82.1	66	60
18/10/2008	16:51:52			49.3	45.0	50.8	-75.9	-82.1	61	60
18/10/2008	16:56:52			49.5	45.0	50.8	-75.9	-82.1	66	60
18/10/2008	17:01:52			49.6	45.0	50.8	-75.9	-82.1	61	60
18/10/2008	17:06:52			49.6	45.0	50.8	-75.9	-81.6	61	60
18/10/2008	17:11:52			49.7	45.0	50.8	-75.9	-81.6	63	60
18/10/2008	17:16:52			49.9	45.0	51.3	-75.9	-81.6	58	60
18/10/2008	17:21:52			50.2	45.0	51.3	-75.9	-81.6	63	60
18/10/2008	17:26:52			49.6	45.0	51.3	-75.9	-81.6	65	60
18/10/2008	17:31:52			48.9	45.0	50.8	-75.9	-81.6	91	60
18/10/2008	17:36:52			48.0	45.0	49.8	-75.9	-81.6	60	60
18/10/2008	17:41:52			46.7	45.0	48.6	-75.9	-82.1	66	60
18/10/2008	17:44:17	29	Moisture Test	46.0	45.0	47.6	-75.9	-82.1	63	60
18/10/2008	17:45:33	30	Pre-Aeration	45.6	45.0	47.4	-75.9	-82.1	183	--

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Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Step No.	Step Type	TE201A ("C)	Control Temp. ("C)	TE202 ("C)	TE203 ("C)	TE204 ("C)	PT101 (ubar)	Control Vacuum (ubar)
18/10/2008	17:46:52			45.1	45.0	45.6	-75.1	-66.4	1000	--
18/10/2008	17:51:52			44.9	45.0	46.4	-70.1	-60.3	1000	--
18/10/2008	17:56:52			45.1	45.0	46.4	-64.3	-57.9	1000	--
18/10/2008	18:01:52			45.0	45.0	46.4	-60.2	-56.1	1000	--
18/10/2008	18:02:58	31	Stoppering	45.2	45.0	46.3	-59.7	-56.9	1000	--
18/10/2008	18:06:16	32	Aeration	44.9	45.0	46.3	-58.0	-55.9	1000	--
18/10/2008	18:06:52			44.9	45.0	46.4	-57.7	-55.3	1000	--
18/10/2008	18:11:52			45.1	45.0	46.4	-49.2	-51.3	1000	--
18/10/2008	18:16:00	33	Storage	44.9	45.0	46.3	-38.4	-45.3	1000	--
18/10/2008	18:16:52			44.1	25.0	46.4	-38.0	-44.1	1000	--
18/10/2008	18:21:52			37.6	25.0	40.0	-35.8	-40.9	1000	--
18/10/2008	18:32:52			25.7	25.0	27.5	-31.0	-34.0	1000	--

Arrived 18/10/08
18/10/08

Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	18/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Description
Alarm:	Total: 91	
16/10/2008	4:09:19	Circulation pump 1 failure
16/10/2008	4:09:23	Circulation pump 2 failure
16/10/2008	4:09:30	Compressor 1 failure
16/10/2008	4:09:40	Compressor 2 failure
16/10/2008	4:10:37	Compressor 1 cooling water low flowrate
16/10/2008	4:10:37	Compressor 2 cooling water low flowrate
16/10/2008	6:07:53	Circulation pump 2 failure
16/10/2008	6:07:53	Circulation pump 1 failure
16/10/2008	6:08:00	Compressor 1 failure
16/10/2008	6:08:17	Compressor 1 cooling water low flowrate
16/10/2008	6:08:17	Compressor 2 cooling water low flowrate
16/10/2008	7:30:01	Vacuum pump 1 failure
16/10/2008	7:30:11	PT301 pump vacuum probe fail
16/10/2008	7:54:13	Vacuum less than low limit
16/10/2008	8:13:33	Vacuum failure pre-alarm
16/10/2008	8:20:28	Vacuum less than low limit
16/10/2008	8:25:23	Vacuum less than low limit
16/10/2008	8:32:14	FV5 gas bleed bypass valve fail
16/10/2008	8:32:25	FV5 gas bleed bypass valve fail
16/10/2008	8:33:39	FV5 gas bleed bypass valve fail
16/10/2008	8:34:07	Vacuum failure pre-alarm
16/10/2008	8:34:10	Vacuum failure alarm
16/10/2008	8:38:36	Vacuum less than low limit
16/10/2008	8:44:11	Vacuum failure pre-alarm
16/10/2008	8:44:18	Vacuum failure alarm
16/10/2008	8:49:05	Vacuum less than low limit
16/10/2008	9:14:25	FV5 gas bleed bypass valve fail
16/10/2008	9:14:45	Vacuum failure pre-alarm
16/10/2008	9:14:45	Vacuum failure alarm
16/10/2008	9:46:43	Vacuum less than low limit
16/10/2008	9:49:34	Vacuum failure pre-alarm
16/10/2008	9:52:29	Vacuum less than low limit
16/10/2008	9:54:51	Vacuum failure pre-alarm
16/10/2008	18:33:57	FV25 filter isolation valve fail
16/10/2008	18:33:57	Circulation pump 2 failure
16/10/2008	18:33:57	Circulation pump 1 failure
16/10/2008	18:33:57	FV4 aerate isolation valve fail
16/10/2008	18:33:57	FV29 chamber inlet valve 1 fail
16/10/2008	18:34:07	Compressor 2 failure
16/10/2008	18:34:14	Compressor 1 failure
16/10/2008	18:35:29	Vacuum failure pre-alarm
16/10/2008	18:41:57	Vacuum less than low limit
16/10/2008	18:45:29	Vacuum failure pre-alarm
16/10/2008	22:34:52	FV25 filter isolation valve fail
16/10/2008	22:34:52	Circulation pump 1 failure
16/10/2008	22:34:52	FV4 aerate isolation valve fail
16/10/2008	22:34:52	FV29 chamber inlet valve 1 fail
16/10/2008	22:34:56	Circulation pump 2 failure
16/10/2008	22:35:03	Compressor 1 failure
16/10/2008	22:35:11	Compressor 2 failure
16/10/2008	22:35:40	Compressor 1 cooling water low flowrate
16/10/2008	22:35:40	Compressor 2 cooling water low flowrate
16/10/2008	22:37:07	Vacuum failure pre-alarm
17/10/2008	18:39:24	Circulation pump 1 failure
17/10/2008	18:39:28	FV25 filter isolation valve fail
17/10/2008	18:39:28	Circulation pump 2 failure

Arun K 18/10/08

18/10/08

Auto Freeze Drying Process Report

Start Time:	16/10/2008 0:41:52	**Product Quantity**	4615
End Time:	16/10/2008 18:32:52	**Product Name:**	Topotecan For Injection
Initiator	SUP	**Product Model:**	
Batch Name:	AFD8PK201	**Recipe Number:**	25

Date	Time	Description
17/10/2008	18:39:28	FV4 aerate isolation valve fail
17/10/2008	18:39:28	FV29 chamber inlet valve 1 fail
17/10/2008	18:39:37	Compressor 1 failure
17/10/2008	18:39:46	Compressor 2 failure
17/10/2008	18:40:04	Compressor 1 cooling water low flowrate
17/10/2008	18:40:04	Compressor 2 cooling water low flowrate
17/10/2008	18:42:08	Vacuum failure pre-alarm
17/10/2008	22:34:14	FV25 filter isolation valve fail
17/10/2008	22:34:14	Circulation pump 1 failure
17/10/2008	22:34:14	FV4 aerate isolation valve fail
17/10/2008	22:34:14	FV29 chamber inlet valve 1 fail
17/10/2008	22:34:19	Circulation pump 2 failure
17/10/2008	22:34:23	Compressor 2 failure
17/10/2008	22:34:36	Compressor 1 failure
17/10/2008	22:34:59	Compressor 1 cooling water low flowrate
17/10/2008	22:34:59	Compressor 2 cooling water low flowrate
17/10/2008	22:36:54	Vacuum failure pre-alarm
18/10/2008	8:28:43	FV25 filter isolation valve fail
18/10/2008	8:28:43	Circulation pump 2 failure
18/10/2008	8:28:43	Circulation pump 1 failure
18/10/2008	8:28:43	FV4 aerate isolation valve fail
18/10/2008	8:28:43	FV29 chamber inlet valve 1 fail
18/10/2008	8:28:52	Compressor 1 failure
18/10/2008	8:29:05	Compressor 2 failure
18/10/2008	8:31:06	Compressor 1 cooling water low flowrate
18/10/2008	8:31:06	Compressor 2 cooling water low flowrate
18/10/2008	8:32:35	Vacuum failure pre-alarm
18/10/2008	13:25:34	Shelf temperature high deviation
18/10/2008	14:02:28	Circulation pump 1 failure
18/10/2008	14:02:32	FV25 filter isolation valve fail
18/10/2008	14:02:32	FV29 chamber inlet valve 1 fail
18/10/2008	14:03:44	Vacuum failure pre-alarm
18/10/2008	17:25:04	Circulation pump 1 failure
18/10/2008	17:25:04	FV29 chamber inlet valve 1 fail
18/10/2008	17:27:04	Vacuum failure pre-alarm

Events: Total: 1

18/10/2008	17:45:42	Pressure rise test passed. The final chamber vacuum rise in this test is :9ubar

Arvind K 18/10/08

18/10/08

9.3 STERILIZATION OF ALUMINUM FLIP-OFF OVER SEALS AS PER SOP No. SOP/CSP/037:

Cycle started at: 16:59 Cycle Completed at: 18:49

Date	Load No.	Load Pattern No.	No.of Bags	Total qty of aluminum flip off Over seals.	Sterilization Hold Time		Done by##	Ckd. By##
					From	To		
17/10/08	04	6	04	6295	17:42	18:12	Sohan	17/10/08

(Graph attached on the reverse side of page No.: 39)

9.4 STORAGE OF STERILIZED ALUMINUM FLIP-OFF OVER SEALS: (NMT 48 HOURS AFTER STERILIZATION):

Procedure	Eq. Id. No.	SOP No.	Date	Storage Time*		Done by##	Ckd. By##
				From	To		
Store the sterilized aluminum flip-off over seals under LAF in cooling zone.	CSP/035	SOP/CSP/072	17/10/08	18:50	---	Sohan	
			18/10/08	---	16:20	Sanjeev	

* Hold time starts after completion of sterilization and completes at the end of sealing.

9.5 TRANSFER OF STERILIZED ALUMINUM FLIP-OFF OVER SEALS:

Procedure	Eq. Id. No.	Date	Time		Done by##	Ckd. By##
			From	To		
Transfer the sterilized aluminum flip-off over seals from cool zone to vial washing area through the corridor in closed material transfer trolley. Load the sterilized aluminum flip-off over seals to the hopper of the sealing machine inside the unloading cRAB	CSP/030	18/10/08	16:20	16:32	Ranjeet	

Production

QA Signature

10.0 CLEANING OF UNLOADING cRAB AND SEALING MACHINE:

10.1 Cleaning of sealing Unloading cRAB is done as per SOP No. SOP/CSP/111.

Cleaning started at: 17:00 Cleaning completed at: 17:30

Date: 18/10/08

S.No.	Equipment Name	Equipment Id. No.	Previous Product Name	Batch No.	Time		Done By##	Ckd. By##
					From	To		
1.	Unloading cRAB	CSP/030	R&D Trial Batch	–	17:00	17:15	Ranjeet	18/10/08
2.	Sealing machine	CSP/171	R&D Trial Batch	–	17:16	17:30	Ranjeet	18/10/08

10.2 UNLOADING AND SEALING OF LYOPHILIZED VIALS:

10.3 LINE CLEARANCE:

Step No.	Checks	Equipment I.D	SOP No.	Date	Previous Product		Ckd. by##	Verified by###
					Product Name	Batch no.		
1.	Line Clearance of Sealing Unloading cRAB	CSP/030	SOP/QAD/053	18/10/08	R&D Trial Batch	–	18/10/08	18/10/08
2.	Line Clearance of Sealing machine	CSP/171	SOP/QAD/053	18/10/08	R&D Trial Batch	–	18/10/08	18/10/08

Production

###IPQA

QA Signature

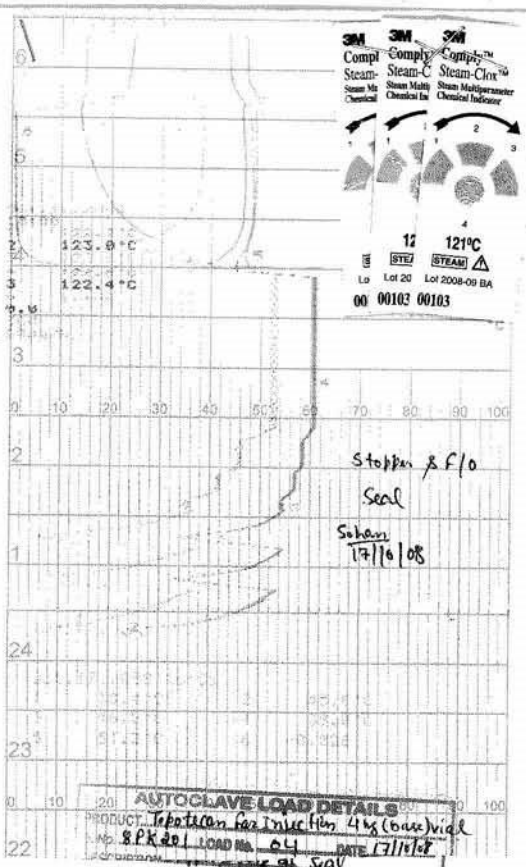
LOAD NO- 04

MFG.BY :MACHIN FABRIK
CUSTOMER :M/S DABUR PHARMA LTD.
EQUIPMENT :STEAM STERILIZER

BATCH DATA
STERILIZER NO :1007
BATCH NO :0
QUANTITY :1
OPERATOR CODE :1
PRINT INTERVAL :60 SEC
DATE :17/10/08
TIME :16:59:06

PROCESS : STOPPER & FLIP

SET PARAMETERS
PRE VACUUM : -0.750 BAR
PRE PRESSURE : 0.500 BAR
NO OF PRE PULSE : 3 NOS
SET POINT-1 : 110.0 DEG C
SET POINT-2 : 115.0 DEG C
SET POINT-3 : 118.0 DEG C
SP-1 HOLD TIME : 2 MIN
SP-2 HOLD TIME : 3 MIN
SP-3 HOLD TIME : 5 MIN
HEAT UP CONTROL BAND : 0.2 DEG C
STER HOLD TEMP : 121.5 DEG C
STER HOLD TIME : 30 MIN
TEMP CONTROL BAND : 0.2 DEG C
OVERSHOOT TEMP : 124.0 DEG C
STER COUNT STOP TEMP : 120.9 DEG C
STER COUNT RESET TEMP : 120.8 DEG C
POST VACUUM : -0.750 BAR
POST PRESSURE : -0.100 BAR
POST VAC HOLD TIME : 30 MIN
NO OF POST PULSE : 1 NOS
EXHAUST ON TIME : 5 SEC
EXHAUST OFF TIME : 50 SEC
PROCESS END PRESSURE : -0.050 BAR
CHAM PRESSURE HIGH : 1.500 BAR



AUTOCLAVE LOAD DETAILS
PRODUCT Tropotecan for Injection 4mg (base) vial
NO. 8PK201 LOAD NO. 04 DATE 17/10/08
Seal
X axis 1 division (Temp) = 4 deg C.
Y axis 1 division (Time) = 10 min
Strip chart speed = 60mm/hr
REMARK
Checked and Signed by
Sohan 17/10/08 Operator
17/10/08 Prod Officer
17/10/08 IPQA

MFG.BY :MACHIN FABRIK
CUSTOMER :M/S DABUR PHARMA LTD.
DATE :17/10/08
TIME :16:59:23
EQUIPMENT :STEAM STERILIZER
PROCESS :STOPPER & FLIP OFF SEAL

* Only Flip off Seal has been taken.

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TIME	T1 DEG C	T2 DEG C	T3 DEG C	T4 DEG C	T5 DEG C	PRES BAR	STATUS
16:59:25	030.6	046.4	048.1	039.6	052.7	-0.020	PROCESS ON
16:59:27	030.6	046.5	048.3	039.7	052.9	-0.036	PRE VACUUM
17:00:03	030.3	046.8	049.7	039.2	053.7	-0.479	PRE VACUUM
17:00:53	029.9	046.1	049.8	038.3	053.5	-0.765	PRE PRESSURE
17:01:02	030.0	047.5	050.4	045.1	054.4	-0.643	PRE PRESSURE

17:02:01	030.2	070.6	068.9	070.7	070.3	-0.385	PRE PRESSURE
17:03:02	030.2	081.5	080.3	081.4	081.4	-0.192	PRE PRESSURE
17:04:03	030.5	088.6	087.0	086.1	088.8	-0.021	PRE PRESSURE
17:05:01	090.4	093.5	092.7	091.9	093.4	00.088	PRE PRESSURE
17:06:03	096.8	097.6	097.2	096.9	097.0	00.186	PRE PRESSURE
17:07:01	100.4	100.9	100.8	101.2	100.3	00.287	PRE PRESSURE
17:08:02	103.9	103.9	103.9	104.7	103.3	00.385	PRE PRESSURE
17:09:03	106.7	106.5	106.5	107.4	105.8	00.478	PRE PRESSURE
17:09:15	107.2	107.0	107.0	107.8	106.3	00.498	PRE VACUUM
17:10:02	092.2	092.5	093.2	093.4	092.1	-0.316	PRE VACUUM
17:11:03	073.8	073.9	074.5	074.7	074.6	-0.672	PRE VACUUM
17:11:33	065.4	066.3	067.3	067.1	071.9	-0.757	PRE PRESSURE
17:12:02	074.1	072.8	073.0	074.9	075.5	-0.550	PRE PRESSURE
17:13:03	090.5	089.0	089.0	089.5	088.9	-0.220	PRE PRESSURE
17:14:02	097.9	097.1	097.3	097.6	096.8	-0.003	PRE PRESSURE
17:15:02	102.6	101.6	101.8	102.1	101.3	00.143	PRE PRESSURE
17:16:03	106.1	105.0	105.3	105.6	104.9	00.280	PRE PRESSURE
17:17:04	109.0	108.0	108.3	108.6	107.8	00.408	PRE PRESSURE
17:17:49	110.8	109.7	110.0	110.5	109.7	00.496	PRE VACUUM
17:18:03	108.3	107.9	108.4	107.9	107.5	00.201	PRE VACUUM
17:19:04	086.6	088.1	088.7	088.7	089.7	-0.442	PRE VACUUM
17:20:04	068.0	071.3	073.5	069.8	085.9	-0.733	PRE VACUUM
17:20:14	065.6	070.6	073.5	067.6	085.6	-0.757	PRE PRESSURE
17:21:04	082.1	080.5	080.8	081.5	087.2	-0.409	PRE PRESSURE
17:22:03	095.4	093.5	093.7	094.2	093.8	-0.084	PRE PRESSURE
17:23:04	102.1	100.7	101.0	101.3	100.6	00.126	PRE PRESSURE
17:24:05	106.1	104.9	105.1	105.5	104.7	00.281	PRE PRESSURE
17:25:03	109.0	108.0	108.2	108.6	107.8	00.410	PRE PRESSURE
17:25:46	110.9	109.9	110.1	110.6	109.8	00.496	HEAT UP
17:26:04	110.5	109.7	110.0	110.3	109.6	00.437	HEAT UP
17:27:03	110.1	109.4	109.6	110.1	109.2	00.459	HEAT UP
17:28:04	110.4	109.6	109.9	110.3	109.6	00.482	HEAT UP
17:29:03	113.0	111.9	112.2	112.6	111.9	00.604	HEAT UP

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17:30:05	115.0	114.0	114.3	114.8	114.0	00.710	HEAT UP
17:31:04	114.9	114.2	114.5	114.9	114.2	00.695	HEAT UP
17:32:05	114.9	114.2	114.5	115.0	114.2	00.697	HEAT UP
17:33:04	114.9	114.3	114.5	115.0	114.3	00.708	HEAT UP
17:34:05	117.2	116.1	116.5	116.9	116.2	00.827	HEAT UP
17:35:04	117.9	117.1	117.4	117.8	117.1	00.856	HEAT UP
17:36:05	117.9	117.2	117.5	117.9	117.2	00.872	HEAT UP
17:37:06	117.9	117.2	117.5	118.0	117.2	00.877	HEAT UP
17:38:04	118.0	117.3	117.6	118.0	117.3	00.881	HEAT UP
17:39:06	118.2	117.4	117.7	118.1	117.4	00.871	HEAT UP
17:40:05	118.9	117.9	118.1	118.7	117.9	00.933	HEAT UP
17:41:06	120.8	119.7	120.0	120.5	119.8	01.050	HEAT UP
17:42:05	122.1	121.1	121.3	121.8	121.1	01.125	HEAT UP
17:42:32	122.5	121.6	121.9	122.3	121.5	01.152	STER HOLD
17:43:06	122.3	121.5	121.9	122.2	121.5	01.140	STER HOLD
17:44:07	122.5	121.7	121.9	122.3	121.6	01.116	STER HOLD
17:45:06	122.5	121.7	121.9	122.5	121.6	01.162	STER HOLD
17:46:07	122.3	121.5	121.9	122.3	121.5	01.133	STER HOLD
17:47:06	122.6	121.8	122.0	122.5	121.7	01.132	STER HOLD
17:48:06	122.6	121.8	122.0	122.5	121.7	01.166	STER HOLD
17:49:08	122.4	121.6	121.9	122.3	121.5	01.148	STER HOLD
17:50:06	122.4	121.6	122.0	122.3	121.5	01.111	STER HOLD
17:51:06	122.6	121.8	122.0	122.5	121.7	01.149	STER HOLD
17:52:06	122.5	121.7	121.9	122.4	121.6	01.155	STER HOLD
17:53:07	122.3	121.6	121.9	122.3	121.5	01.133	STER HOLD
17:54:08	122.5	121.7	122.0	122.4	121.6	01.126	STER HOLD
17:55:06	122.6	121.8	122.0	122.5	121.7	01.162	STER HOLD
17:56:07	122.3	121.6	121.9	122.3	121.5	01.145	STER HOLD
17:57:08	122.5	121.7	122.0	122.3	121.6	01.121	STER HOLD
17:58:08	122.6	121.8	122.1	122.5	121.7	01.151	STER HOLD
17:59:07	122.4	121.7	121.9	122.3	121.6	01.148	STER HOLD
18:00:07	122.5	121.7	122.0	122.3	121.5	01.117	STER HOLD
18:01:08	122.6	121.8	122.0	122.4	121.6	01.131	STER HOLD

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18:02:07	122.6	121.8	122.0	122.5	121.7	01.167	STER HOLD
18:03:08	122.4	121.7	121.9	122.3	121.6	01.152	STER HOLD
18:04:08	122.3	121.7	121.9	122.3	121.5	01.127	STER HOLD
18:05:07	122.6	121.8	122.0	122.4	121.7	01.134	STER HOLD
18:06:08	122.6	121.8	122.1	122.5	121.7	01.147	STER HOLD
18:07:07	122.4	121.7	122.0	122.4	121.6	01.157	STER HOLD
18:08:09	122.3	121.7	121.9	122.3	121.5	01.134	STER HOLD
18:09:08	122.6	121.8	122.0	122.5	121.6	01.129	STER HOLD
18:10:09	122.6	121.8	122.0	122.6	121.7	01.166	STER HOLD
18:11:08	122.3	121.6	121.9	122.4	121.5	01.142	STER HOLD
18:12:09	122.5	121.7	122.0	122.5	121.5	01.118	STER HOLD
18:12:32	122.7	121.8	122.1	122.7	121.7	01.155	POST VACUUM
18:13:08	108.0	110.2	111.2	111.7	109.5	00.173	POST VACUUM
18:14:09	085.6	087.3	090.0	090.8	095.9	-0.476	POST VACUUM
18:15:08	070.5	079.8	090.3	073.2	094.8	-0.735	POST VACUUM
18:15:13	070.8	080.1	090.4	072.3	094.7	-0.745	VACUUM HOLD
18:16:09	072.0	083.7	091.4	063.4	094.3	-0.834	VACUUM HOLD
18:17:08	068.7	086.3	092.7	055.3	094.4	-0.878	VACUUM HOLD
18:18:09	064.3	088.3	093.7	051.6	094.8	-0.905	VACUUM HOLD
18:19:11	060.1	090.0	094.9	050.4	095.5	-0.918	VACUUM HOLD
18:20:10	056.4	090.9	095.5	057.8	096.2	-0.924	VACUUM HOLD
18:21:10	053.1	091.8	096.1	063.0	096.7	-0.929	VACUUM HOLD
18:22:11	050.3	092.3	096.5	063.9	097.1	-0.932	VACUUM HOLD
18:23:09	048.1	092.7	096.9	067.4	097.5	-0.935	VACUUM HOLD
18:24:11	046.2	093.0	097.0	070.5	097.7	-0.935	VACUUM HOLD
18:25:11	044.5	093.0	097.1	071.8	097.8	-0.937	VACUUM HOLD
18:26:11	043.0	093.1	097.2	073.3	098.0	-0.938	VACUUM HOLD
18:27:10	041.6	093.2	097.2	074.5	098.1	-0.939	VACUUM HOLD
18:28:11	040.3	093.3	097.2	075.2	098.2	-0.940	VACUUM HOLD
18:29:10	039.2	093.3	097.2	075.6	098.3	-0.941	VACUUM HOLD
18:30:11	038.1	093.4	097.1	076.1	098.4	-0.942	VACUUM HOLD
18:31:12	037.1	093.4	097.0	076.4	098.4	-0.942	VACUUM HOLD
18:32:11	036.2	093.4	097.0	076.6	098.4	-0.942	VACUUM HOLD

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18:33:12	034.3	093.5	096.9	076.8	098.4	-0.944	VACUUM HOLD	
18:34:12	034.5	093.5	096.8	077.0	098.5	-0.944	VACUUM HOLD	
18:35:12	033.8	093.4	096.6	077.2	098.4	-0.943	VACUUM HOLD	
18:36:11	033.1	093.4	096.6	077.4	098.4	-0.944	VACUUM HOLD	
18:37:11	032.5	093.2	096.4	077.5	098.4	-0.944	VACUUM HOLD	
18:38:12	031.9	093.2	096.4	077.7	098.4	-0.944	VACUUM HOLD	
18:39:13	031.3	093.1	096.4	077.7	098.4	-0.945	VACUUM HOLD	
18:41:13	030.4	092.9	096.3	077.8	098.3	-0.942	VACUUM HOLD	515
18:42:12	030.1	092.8	096.2	077.7	098.3	-0.942	VACUUM HOLD	
18:43:13	029.7	092.6	096.0	077.5	098.2	-0.945	VACUUM HOLD	
18:44:14	029.5	092.5	095.9	077.4	098.2	-0.946	VACUUM HOLD	
18:45:12	029.2	092.3	095.8	077.4	098.1	-0.946	VACUUM HOLD	
18:45:15	029.2	092.3	095.7	077.4	098.1	-0.946	POST PRESSURE	
18:46:13	029.3	092.5	094.6	077.7	098.9	-0.648	POST PRESSURE	
18:47:14	029.8	093.0	094.6	075.3	099.7	-0.351	POST PRESSURE	
18:48:13	030.2	091.3	095.2	073.1	099.2	-0.140	POST PRESSURE	
18:48:29	030.2	090.9	095.4	072.7	099.0	-0.101	VACUUM BREAK	
18:49:05	030.4	090.4	095.3	072.0	098.3	-0.050	PROCESS END	

FD VALUE:- 0030.0

10.4 UNLOADING AND SEALING OF LYOPHILIZED VIALS:

Sealing started at: 19:45. Sealing completed at: 21:05.

Step No.	Checks	SOP No.	Time From	Time To	Observations	Done By##	Ckd. By##
1	Note the reading of magnehelic gauge over unloading cRAB.	SOP/CSP/111	19:13	19:14	ΔP across HEPA 5 (mm of WC)	Ranjeet	18/10/08
2	Check the in process sealing quality of sealed vials from each sealing head (2 vials) at Start and End of sealing (during process every 30 min.) and record the details in table 10.5.	SOP/CSP/111	19:45.	21:05.	Vial No. 1. OK / ~~NOT OK~~ 2. OK / ~~NOT OK~~	Ranjeet	18/10/08

10.5 IN PROCESS SEALING QUALITY CHECK

Frequency: Start and End of filling (during process every 30 min.)

Date: 18/10/08

Checks		Time									
		19:45.	20:15	20:45							
Sealing quality	*Crimping	ok	ok	ok.		N/A					
	Loose seals	Nil	Nil	Nil.							
Ckd. By##		18/10/08	18/10/08	18/10/08							18/10/08

Checks		Time									
Sealing quality	*Crimping					N/A					
	Loose seals										
Ckd. By##											18/10/08

* To be checked for Every Head
Production

QA Signature

11.0 EXTERNAL DECONTAMINATION OF FILLED AND SEALED VIALS:

11.1 CLEANING:

Step No.	Checks	Eq. Id. No.	SOP No.	Date	Time		Done By##	Ckd. By##
					From	To		
1.	Cleaning of External Decontaminating machine	CSP/023	SOP/CSP/033	18/10/08	17:40	18:05	Ranjeet	18/10/08

11.2 LINE CLEARANCE:

- Ensure the cleanliness of Vial washing area.
- Ensure no remains of previous product are there.
- Ensure that status label is properly attached with the machine.
- Ensure proper change over and setting is done as per the pack size.

Step No.	Checks	SOP No.	Date	Previous product		Ckd. by##	Verified by ###
				Product Name	Batch No.		
1.	Line clearance of External Decontaminating machine	SOP/QAD/053	18/10/08	R & D Trial Batch	—	18/10/08	18/10/08

11.3 EXTERNAL DECONTAMINATING MACHINE OPERATION:

Date: 18/10/08

External decontamination started at: 19:53

External decontamination completed at: 21:13

Step No.	Checks	SOP No.	Time		Observations	Done By##	Ckd. By##
			From	To			
1.	Pressure of Purified Water (NLT 0.5 bar)	SOP/CSP/033	19:30	19:32	0.6 bar	Ranjeet	
2.	Compressed Air Pressure (NLT 3.0 bar)	SOP/CSP/033	19:33	19:34	3.0 bar	Ranjeet	
3.	No. of vials washed	SOP/CSP/033	19:53	21:13	Qty. ~~4840~~ 4866 vials	Ranjeet	
4	No. of vials broken	---	---	---	Qty. — vials	Ranjeet	
5.	No. of vials rejected	---	---	---	Qty. — vials	Ranjeet	
6.	No. of good vials	---	---	---	Qty. ~~4840~~ 4866 vials	Ranjeet	

##Production

20/10/08 ###IPQA

12.0 CODING OF SEALED VIALS ON ALUMINUM FLIP-OFF OVER SEALS FOR BATCH IDENTIFICATION:

12.1 CLEANING:

Step No.	Checks	Eq. Id. No.	SOP No.	Date	Time		Done By##	Ckd. By##
					From	To		
1.	Cleaning of conveyor belt	CSP/164	SOP/CSP/058	18/10/08	18:10	18:18	Ranjeet	18/10/08
2.	Cleaning of Ink-jet Printer	CSP/054	SOP/CSP/057	18/10/08	18:20	18:30	Ranjeet	18/10/08

12.2 LINE CLEARANCE:

- Ensure the cleanliness of Vial washing area.
- Ensure no remains of previous product are there.
- Ensure that status label is properly attached with the machine.
- Ensure proper instructions are feeded in the printer and previous details have been omitted.

Date: 18/10/08

Step No.	Checks	Eq. Id. No.	SOP No.	Previous product		Ckd. by##	Verified by###
				Product Name	Batch No.		
1.	Line clearance for conveyor belt.	CSP/164	SOP/QAD/053	Gemcitabine Inj	8KA205	18/10/08	18/10/08
2.	Line clearance for Ink-jet Printer.	CSP/054	SOP/QAD/053	Cytarabine Inj	8LH206	18/10/08	18/10/08

12.3 BATCH OVER PRINTING INSTRUCTIONS:

Batch No	Ckd. by##	Verified by###
8PK201	18/10/08	18/10/08

Date: 18/10/08

Over-Printing started at: 19:57 Over-Printing completed at: 21:22

##Production ###IPQA

QA Signature

Dabur PHARMA	Batch Filling Record (Part-A)		Page 44 of 46
PLANT-II, BADDI			
Product Name	**Topotecan for Injection 4 mg (base)/vial**		
Batch Number	8PK201		
Batch size	12 L	**Batch Filling Code**	IO720004
Department	Production (CSL)	**BFR No.**	BFR/CSL/TOP/001
Shelf life	24 Months (Provisional)	**Version No.**	00

12.4 INITIAL VIALS CODING DETAILS:

Date	Time	Over-Printing Details	Ckd by##	Verified by###
18/10/08	19:57	8PK201	18/10/08	18/10/08
		N/A		

12.5 INPROCESS CHECKS OF OVER PRINTING:

Frequency: Every 15 min. during operation.

Date	Time	Batch No.	Observation	Done By##	Ckd. By##
18/10/08	19:57	8PK201	OK	Ranjeet	
18/10/08	20:12	8PK201	OK	Ranjeet	
18/10/08	20:27	8PK201	OK	Ranjeet	
18/10/08	20:42	8PK201	OK	Ranjeet	
18/10/08	20:57	8PK201	OK	Ranjeet	
18/10/08	21:12	8PK201	OK	Ranjeet	
		N/A			

18/10/08

13.0 QUALITY CONTROL SAMPLING:

Date	Quantity of sample		Stage	Sampled by###	Remarks
	No. Of Vials	Solution (mL)			
15/10/08	(3+3+3)* = 9 vials	170 ml + 40 ml**	After IInd filtration	15/10/08	—
18/10/08	53+62+83*** = 198 vials	—	After Lyophilisation	18/10/08	—

##Production ###IPQA

** 40 ml (25 + 15) ml taken after end of filling:- 15/10/08

* 9 vial taken during filling 15/10/08

*** 83 (80+3) vial taken for sterility and BET validation 20/10/08

QA Signature

14.0 TRANSFER OF LYOPHILIZED AND SEALED VIALS FOR QUARANTINE:

Date	Qty. transferred for quarantine	Handed over by	Received by
20/10/08	4668 vials.	[illegible]	Subhadra
—	—	—	—

15.0 YIELD AFTER FILLING AND SEALING STAGE:

a. Effective Batch size (Page 2) 10.297 L

b. Actual batch size step 15 (Page 28) 10.297. L

c. Target Fill Volume 1.957. mL

d. Quality control Bulk sample for analysis (Step 13) 210 mL

e. Sample taken for fill volume check 46.968. mL

f. Total No. of good vials after external washing (Step 6 of 11.3 page 42) 4866 Nos.

g. Yield at filling stages after accounting for quality control samples:
% Yield with respect to Actual batch size =
[(d + e) + (f x c) / (b x 1000)] X 100 = 94.97 %

(Limit: Tentative yield should be in between 90 - 100% and standard yield to be finalized after observing the trend of 10 batches. The yield less than 90 % and more than 100% should be investigated as per SOP No. SOP/QAD/030)

Variance with explanation: —

Calculated by: [signature]

Date: 20/10/08

Ckd. by: [signature]
(Production Head)

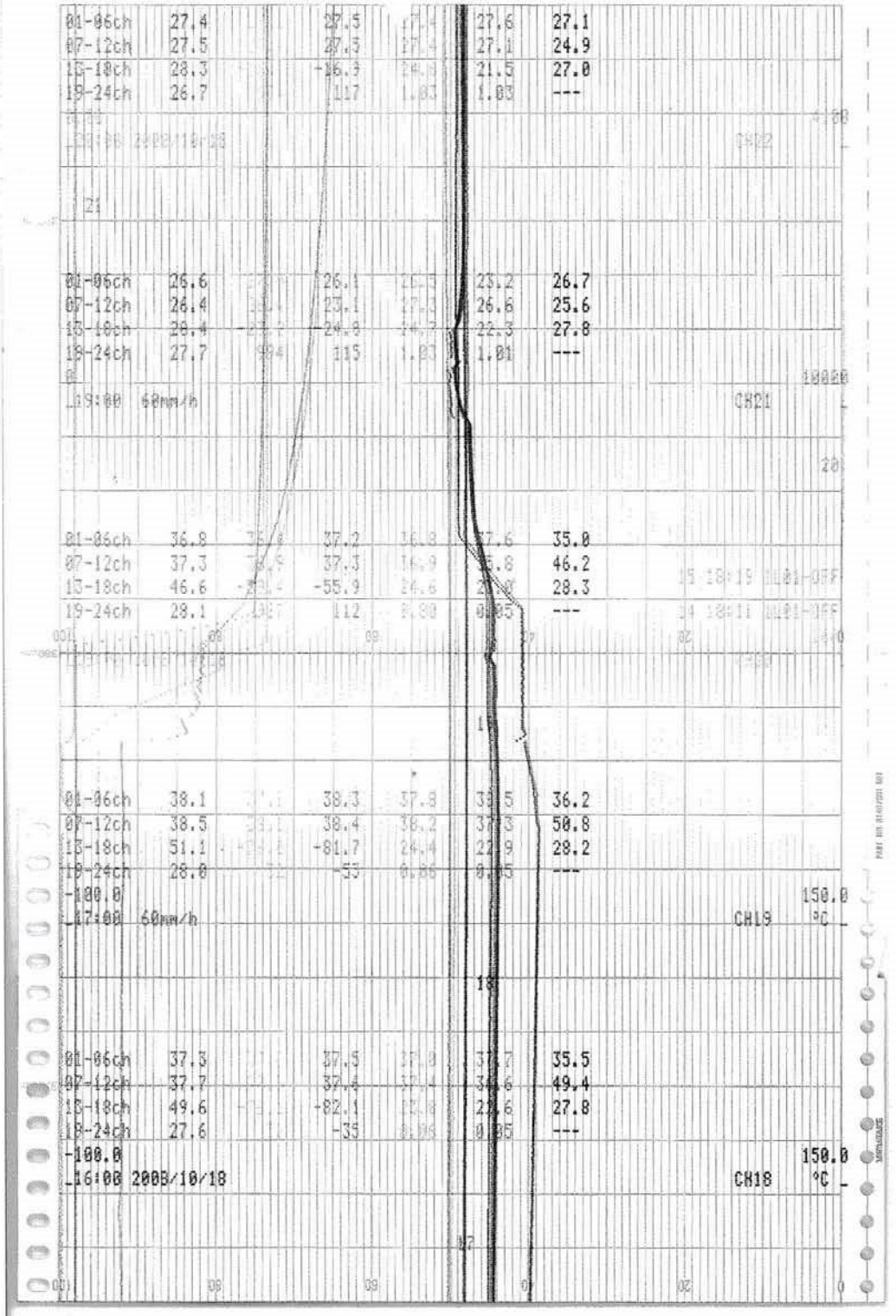
Date: 20/10/2008

QA Signature [signature]

16.0 ABBREVIATIONS:

%	Percent	NLT	Not Less Than
°C	Degree Celsius	No.	Number
A.R. No.	Analytical Reference Number	QC	Quality Control
Approx.	Approximately	q.s.	Quantity Sufficient
B.No.	Batch Number	Qty.	Quantity
NMT	Not More Than	Q.A.	Quality assurance
Ckd. by	Checked By	R.H.	Relative Humidity
CSL	Cyto Sterile Liquid	CSP	Cyto Sterile Production
Eq.Id.No.	Equipment Identification number	Mpa	Mega Pascal
Exp.	Expiry	QAD	Quality Assurance department
HDPE	High Density Polyethylene	BFR	Batch Filling Record
IPQA	In process quality assurance	g/gm	Grams
Issd.	Issued	SOP	Standard Operating Procedure
TC	Triclover	S. No.	Serial Number
L	Liters	WFI	Water For Injection
LAF	Laminar Air Flow	Std. Qty.	Standard Quantity
Max.	Maximum	Temp.	Temperature
mbar	millibar	Dept.	Department
MFG./Mfg.	Manufacturing	USP	United States Pharmacopoeia
Min./mins	Minutes	µ	Micron
mL	Milliliter	mg	Milligram
mm	Millimeter	cRAB	Closed Restricted Access Barrier
psi	Pounds per square inch	MOC	Material of Construction
CIP	Cleaning in place	SIP	Sterilization in place
IP	Indian Pharmacopoeia	*Ph.Eur.*	Pharma Europa
Kg	Kilogram	NA	Not applicable
IPA	Isopropyl alcohol	ΔP	Differential pressure
HEPA	High efficiency particulate air	--	---

QA Signature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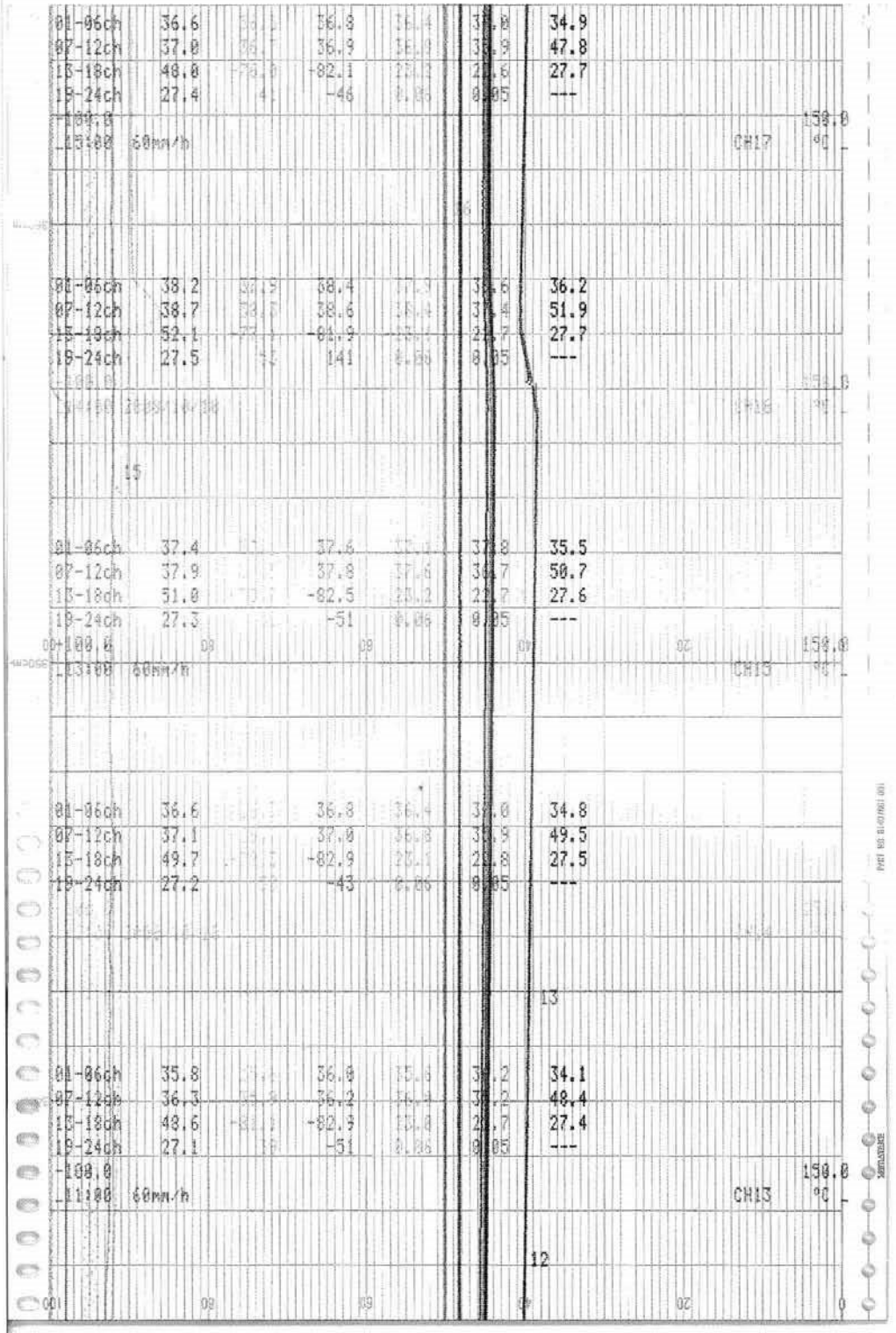
07-12ch 27.5 27.5 27.1 24.9
13-18ch 28.3 -26.9 21.5 27.0
19-24ch 26.7 117 1.03 ---
01-06ch 26.6 26.1 23.2 26.7
07-12ch 26.4 23.1 26.6 25.6
13-18ch 28.4 -24.9 22.3 27.8
19-24ch 27.7 115 1.01 ---
19:00 60mm/h
CH21
01-06ch 36.8 37.2 35.0
07-12ch 37.3 37.3 46.2
13-18ch 46.6 -55.9 28.3
19-24ch 28.1 112 ---
01-06ch 38.1 38.3 37.8 36.2
07-12ch 38.5 38.4 38.2 50.8
13-18ch 51.1 -81.7 28.2
19-24ch 28.0 ---
-100.0
150.0
17:00 60mm/h
CH19
°C
01-06ch 37.3 37.5 35.5
07-12ch 37.7 37.4 49.4
13-18ch 49.6 -82.1 27.8
19-24ch 27.6 ---
-100.0
150.0
16:00 2008/10/18
CH18
°C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07-12ch 37.0 36.9 47.8
13-18ch 48.0 -82.1 27.7
19-24ch 27.4 -46 ---
-100.0 150.0
13:00 60mm/h CH17 °C
01-06ch 38.2 38.4 36.2
07-12ch 38.7 38.6 51.9
13-18ch 52.1 -81.9 27.7
19-24ch 27.5 141 ---
15
01-06ch 37.4 37.6 35.5
07-12ch 37.9 37.8 50.7
13-18ch 51.0 -82.5 27.6
19-24ch 27.3 -51 ---
00+100.0 150.0
13:00 60mm/h CH15 °C
01-06ch 36.6 36.8 34.8
07-12ch 37.1 37.0 49.5
13-18ch 49.7 -82.9 27.5
19-24ch 27.2 -43 ---
13
01-06ch 35.8 36.0 34.1
07-12ch 36.3 36.2 48.4
13-18ch 48.6 -82.9 27.4
19-24ch 27.1 -51 ---
-100.0 150.0
11:00 60mm/h CH13 °C
12

01-06ch 35.0 34.0 35.2 14.4 33.4
07-12ch 35.4 37.1 35.3 15.2 46.8
13-18ch 47.1 -82.7 -82.4 12.4 27.3
19-24ch 27.1 34 -57 0.06 ---
-100.0 150.0
10:00 2008/10/18 CH12 °C

11

01-06ch 34.8 34.1 34.9 14.0 33.1
07-12ch 35.2 34.1 35.1 14.9 46.6
13-18ch 46.8 -81.7 -82.0 22.6 27.4
19-24ch 27.1 -58 0.00 0.05 ---
-100.0 150.0
09:00 60mm/h CH11 °C

10

01-06ch 34.4 34.6 34.1 14.7 32.8
07-12ch 34.8 34.7 14.5 15.7 46.5
13-18ch 46.7 -82.9 22.5 22.7 27.4
19-24ch 27.1 -61 0.06 0.05 ---
-100.0 150.0
08:00 2008/10/18 CH10 °C

09

01-06ch 33.8 33.1 34.0 15.6 32.3
07-12ch 34.3 33.5 34.1 14.8 44.8
13-18ch 46.7 -76.6 -81.9 22.4 27.6
19-24ch 27.3 -49 -56 0.06 ---
-100.0 150.0
07:00 60mm/h CH 9 °C

08

01-06ch 33.1 32.9 33.3 12.8 31.6
07-12ch 33.5 33.2 33.5 13.3 46.6
13-18ch 46.8 -83.8 -82.2 12.8 27.8
19-24ch 27.5 -52 0.00 0.05 ---
-100.0 150.0
06:00 2008/10/18 CH 8 °C

07

01-06ch 27.2 27.1 27.6 26.4
07-12ch 27.4 27.5 26.7 40.2
13-18ch 39.4 -83.0 22.6 27.8
19-24ch 27.4 -50 0.05 ---
-100.0 150.0
05:00 60mm/h CH 7 °C

06

01-06ch 26.1 26.1 26.2 25.6
07-12ch 26.2 26.1 25.8 31.0
13-18ch 31.0 -83.0 22.6 27.8
19-24ch 27.4 -37 0.05 ---
-100.0 150.0
04:00 2008/10/18 CH 6 °C

05

01-06ch 25.9 26.0 25.0 25.4
07-12ch 26.1 26.0 25.6 31.1
13-18ch 31.3 -82.1 22.6 27.7
19-24ch 27.4 -50 0.05 ---
-100.0 150.0
03:00 60mm/h CH 5 °C

04

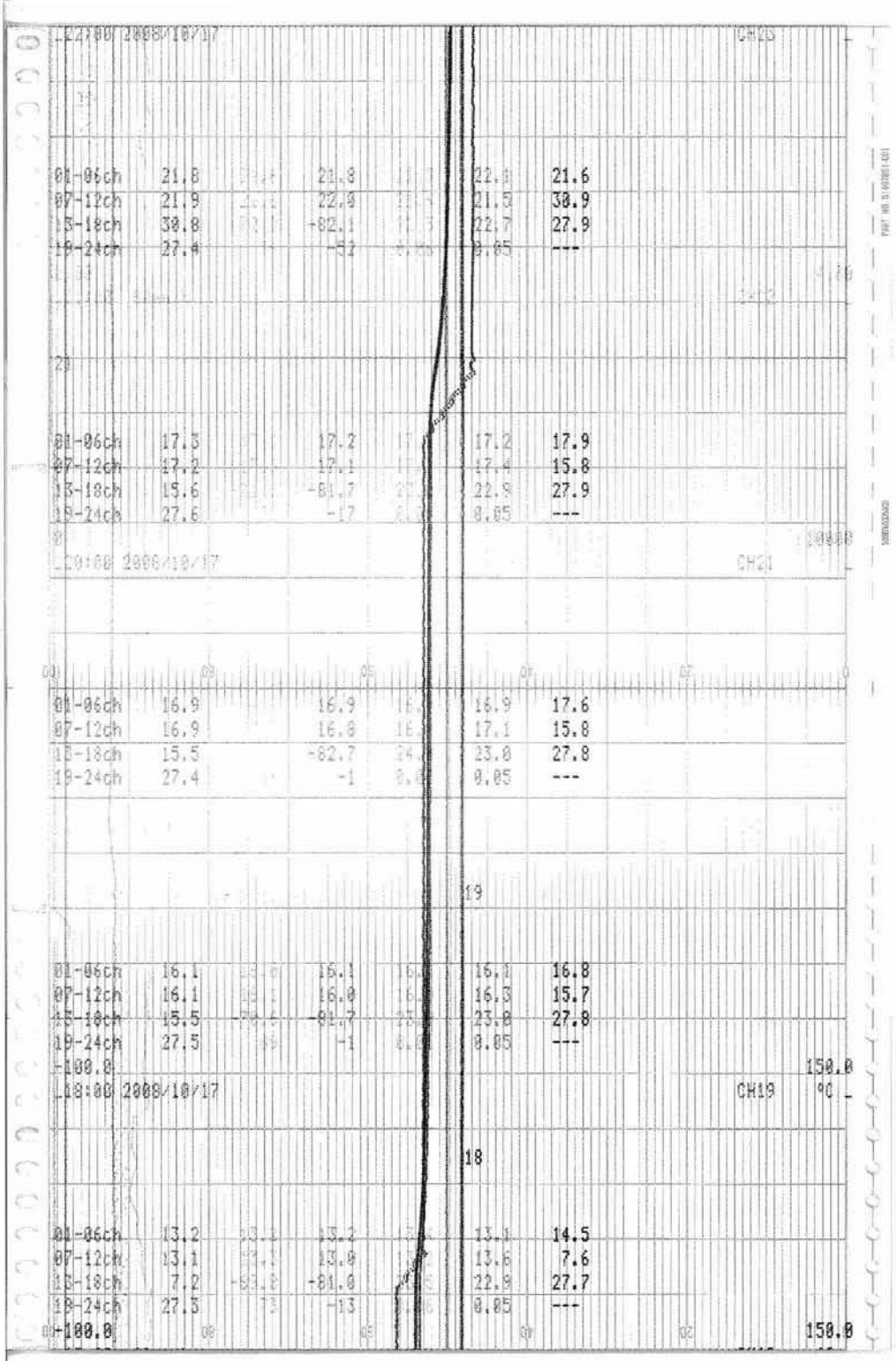
01-06ch 25.7 25.9 25.9 25.3
07-12ch 26.0 25.8 25.8 25.5 31.3
13-18ch 31.2 -80.7 -82.7 22.5 22.6 27.8
19-24ch 27.5 -54 0.05 ---
-100.0 150.0
02:00 2008/10/18 CH 4 °C

03

01-06ch 25.5 25.6 25.6 25.4 25.6 25.0
07-12ch 25.7 25.6 25.4 25.2 31.0
13-18ch 31.0 -81.3 22.6 27.7
19-24ch 27.4 -48 0.05 ---
-100.0 150.0
01:00 60mm/h CH 3 °C

02

PART NO 01407561-001


22:00 2008/10/17
CH23
01-06ch 21.8 21.8 22.0 21.6
07-12ch 21.9 22.0 21.9 30.9
13-18ch 30.8 +82.1 22.7 27.9
19-24ch 27.4 -52 0.05 ---
21:00 2008/10/17
CH22
01-06ch 17.3 17.2 17.2 17.9
07-12ch 17.2 17.1 17.4 15.8
13-18ch 15.6 -81.7 22.9 27.9
19-24ch 27.6 -17 0.05 ---
20:00 2008/10/17
CH21
01-06ch 16.9 16.9 16.9 17.6
07-12ch 16.9 16.8 17.1 15.8
13-18ch 15.5 -82.7 23.0 27.8
19-24ch 27.4 -1 0.05 ---
19:00 2008/10/17
CH19
01-06ch 16.1 16.1 16.0 16.8
07-12ch 16.1 16.0 16.3 15.7
13-18ch 15.5 -81.7 23.8 27.8
19-24ch 27.5 -1 0.05 ---
-100.0
150.0
18:00 2008/10/17
CH18
°C
01-06ch 13.2 13.2 13.1 14.5
07-12ch 13.1 13.0 13.6 7.6
13-18ch 7.2 -81.0 22.9 27.7
19-24ch 27.5 -13 0.05 ---
-100.0
150.0

17:00 60mm/h CH18 °C

01-06ch	13.0		13.0	12.8	14.2	
07-12ch	12.9		12.8	13.4	7.5	
13-18ch	7.1		-81.1	22.8	27.5	
19-24ch	27.2		-3	0.05	---	

100.0 150.0

16:00 2008/10/17 CH17 °C

01-06ch	12.5		12.5	12.4	13.8	
07-12ch	12.3		12.3	12.9	7.5	
13-18ch	7.1		-81.5	22.9	27.5	
19-24ch	27.1		-13	0.05	---	

15

00 08 08 04 02 0

01-06ch	10.0		10.0	9.8	11.8	
07-12ch	9.8		9.7	10.7	0.4	
13-18ch	0.1		-81.5	22.9	27.5	
19-24ch	27.2		34	0.05	---	

100.0 150.0

14:00 2008/10/17 CH15 °C

14

01-06ch	9.8	9.9	9.8	9.6	11.5	
07-12ch	9.6	9.9	9.5	10.5	0.3	
13-18ch	0.0	79.7	-81.7	23.0	27.5	
19-24ch	27.2	146	19	0.05	---	

100.0 150.0

13:00 60mm/h CH14 °C

13

01-06ch	9.6		9.6	9.4	11.3	
07-12ch	9.4		9.2	10.3	0.2	
13-18ch	0.0		-81.2	23.1	27.6	
19-24ch	27.2		24	0.05	---	

00 100.0 08 08 04 02 150.0

12:00 2008/10/17 CH13 °C

12

01-06ch	9.5	9.4	9.2	11.2	
07-12ch	9.3	9.1	10.1	0.3	
13-18ch	0.0	-81.2	23.1	27.6	
19-24ch	27.2	26	0.05	---	

100.0 150.0

11:00 60mm/h CH12 °C

11

01-06ch	9.3	9.3	9.1	11.0	
07-12ch	9.1	9.2	10.0	0.4	
13-18ch	0.0	-81.3	22.8	27.3	
19-24ch	27.0	36	0.05	---	

100.0 150.0

10:00 2008/10/17 CH11 °C

10

01-06ch	9.1	9.1	8.9	10.8	
07-12ch	8.9	8.8	9.8	0.4	
13-18ch	0.1	-81.0	22.5	27.0	
19-24ch	26.7	36	0.05	---	

100.0 150.0

09:00 CH10 °C

09

01-06ch	9.0	9.0	8.8	10.7	
07-12ch	8.8	8.7	9.7	0.3	
13-18ch	0.1	-81.0	22.2	26.9	
19-24ch	26.7	22	0.05	---	

100.0 150.0

08:00 2008/10/17 CH 9 °C

08

01-06ch	9.0	8.9	8.7	10.6	
07-12ch	8.8	8.6	9.6	0.2	
13-18ch	-0.2	+81.4	22.1	27.0	
19-24ch	26.8	10	0.05	---	

07

01-06ch	8.9	8.3	8.6	10.5	
07-12ch	8.6	8.5	9.5	0.3	
13-18ch	8.1	-81.2	22.1	27.1	
19-24ch	26.9	23	0.05	---	

-100.0 150.0
06:00 2008/10/17 CH 7 °C

06

01-06ch	8.7	8.6	8.5	10.4	
07-12ch	8.5	8.3	8.3	0.3	
13-18ch	8.0	-81.4	22.1	27.1	
19-24ch	26.9	12	0.05	---	

-100.0 150.0
05:00 60nm/h CH 6 °C

05

01-06ch	8.3	8.4	8.2	8.1	10.0
07-12ch	8.1	8.4	8.0	8.9	0.1
13-18ch	0.0	-80.5	22.1	27.1	
19-24ch	26.9	21	0.05	---	

-100.0 150.0
04:00 2008/10/17 CH 5 °C

04

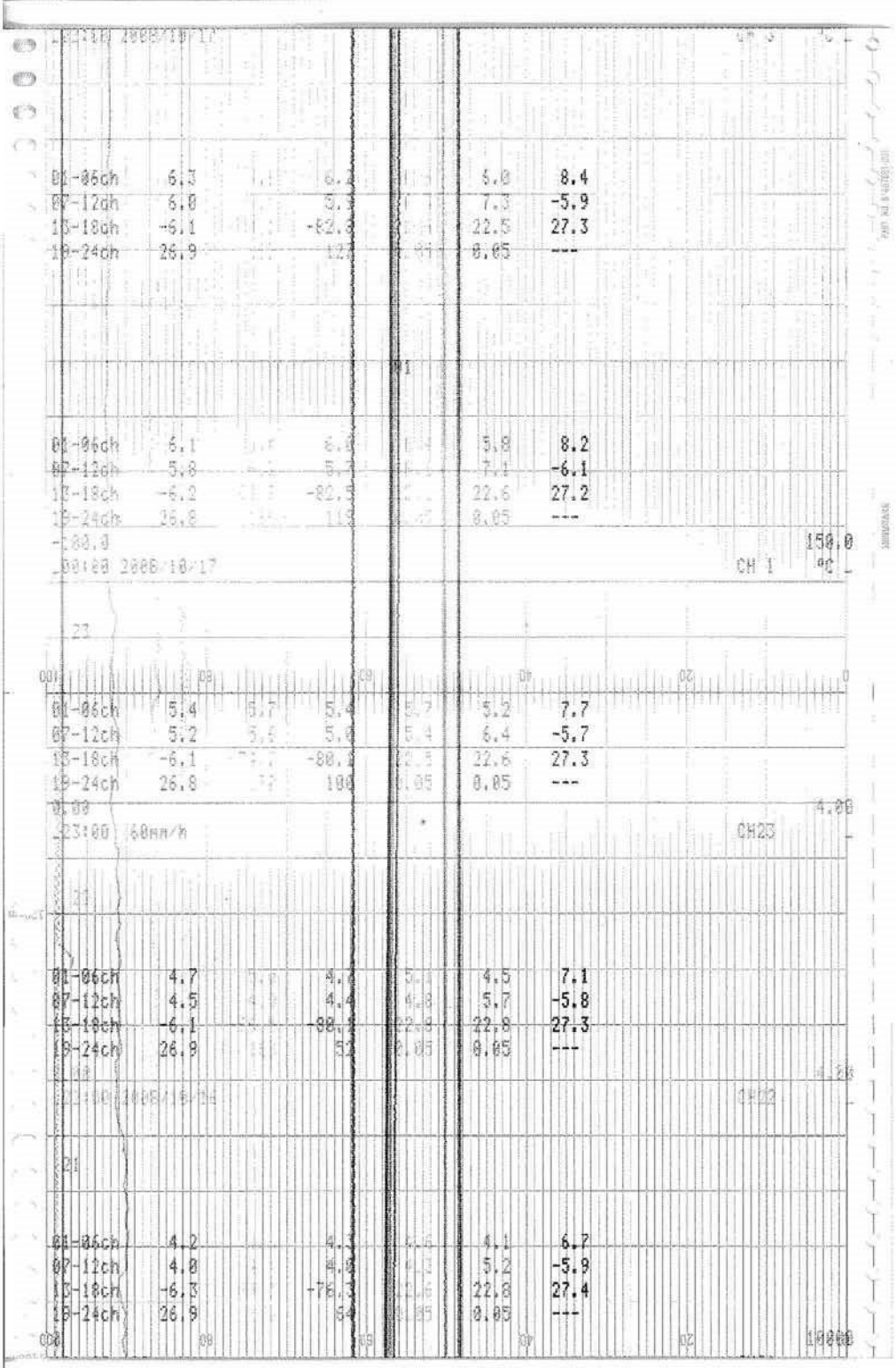
01-06ch	6.5	6.4	6.2	8.6	
07-12ch	6.2	6.1	7.5	-6.0	
13-18ch	-6.3	-80.8	22.2	27.2	
19-24ch	26.9	131	0.05	---	

-100.0 150.0
03:00 60nm/h CH 4 °C

03

01-06ch	6.4	6.3	6.1	8.5	
07-12ch	6.1	6.0	7.4	-5.7	
13-18ch	-6.1	-82.1	22.4	27.3	
19-24ch	26.9	129	0.05	---	

00 -100.0 08 16 24 32 40 48 56 150.0


01-06ch 6.3 6.2 5.0 8.4
07-12ch 6.0 5.3 7.3 -5.9
13-18ch -6.1 -82.3 22.5 27.3
19-24ch 26.9 12.3 0.05 ---
01-06ch 6.1 6.0 5.8 8.2
07-12ch 5.8 5.3 7.1 -6.1
13-18ch -6.2 -82.5 22.6 27.2
19-24ch 26.8 11.3 0.05 ---
-100.0
150.0
00:00 2008/10/17
CH 1
°C
23
01-06ch 5.4 5.4 5.2 7.7
07-12ch 5.2 5.0 6.4 -5.7
13-18ch -6.1 -80.2 22.6 27.3
19-24ch 26.8 10.0 0.05 ---
0.00
4.00
23:00 60mm/h
CH23
22
01-06ch 4.7 4.7 4.5 7.1
07-12ch 4.5 4.4 5.7 -5.8
13-18ch -6.1 -80.5 22.8 27.3
19-24ch 26.9 5.2 0.05 ---
21
CH22
20
01-06ch 4.2 4.1 4.1 6.7
07-12ch 4.0 4.0 5.2 -5.9
13-18ch -6.3 -76.3 22.8 27.4
19-24ch 26.9 5.4 0.05 ---
100.0

20:00 60mm/h

01-06ch 3.9 3.9 0.0 3.8 6.3
07-12ch 3.6 3.6 0.0 4.9 -5.9
13-18ch -6.5 +75.0 12.9 27.4
19-24ch 26.9 33 0.05 ---

19:00 NIL

19

01-06ch 3.6 3.6 0.0 3.5 6.0
07-12ch 3.3 3.3 0.0 4.6 -5.8
13-18ch -6.1 -73.0 23.0 27.3
19-24ch 26.8 65 0.05 ---
-100.0 150.0
19:00 60mm/h CH19 °C

18

00 06 09 07 02 0

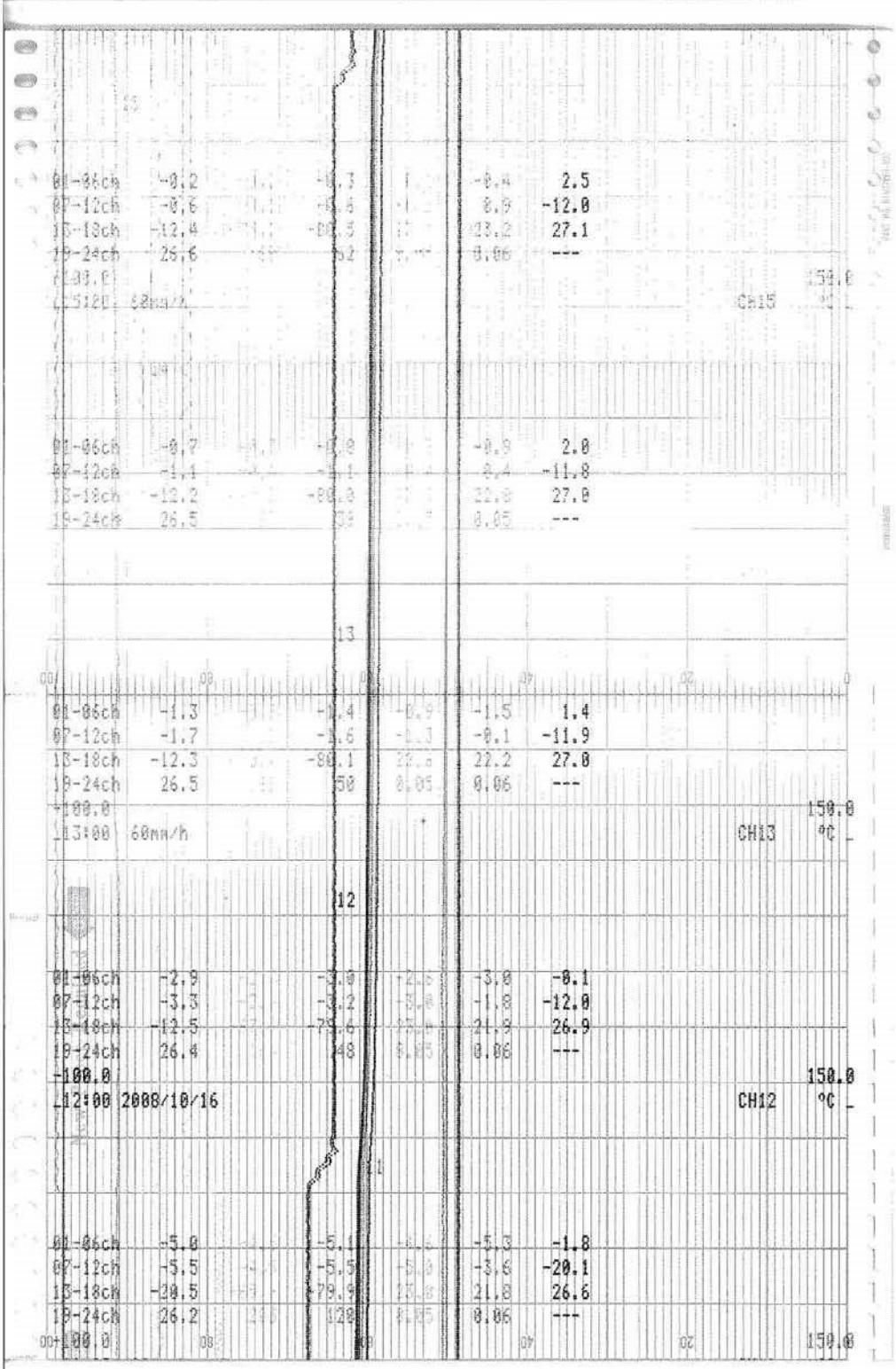
00-06ch 3.2 3.2 0.0 3.1 5.7
07-12ch 2.9 2.9 0.0 4.2 -6.0
13-18ch -6.4 -79.3 23.0 23.2 27.5
19-24ch 27.0 62 0.05 0.05 ---
-100.0 150.0
18:00 2008/10/16 CH18 °C

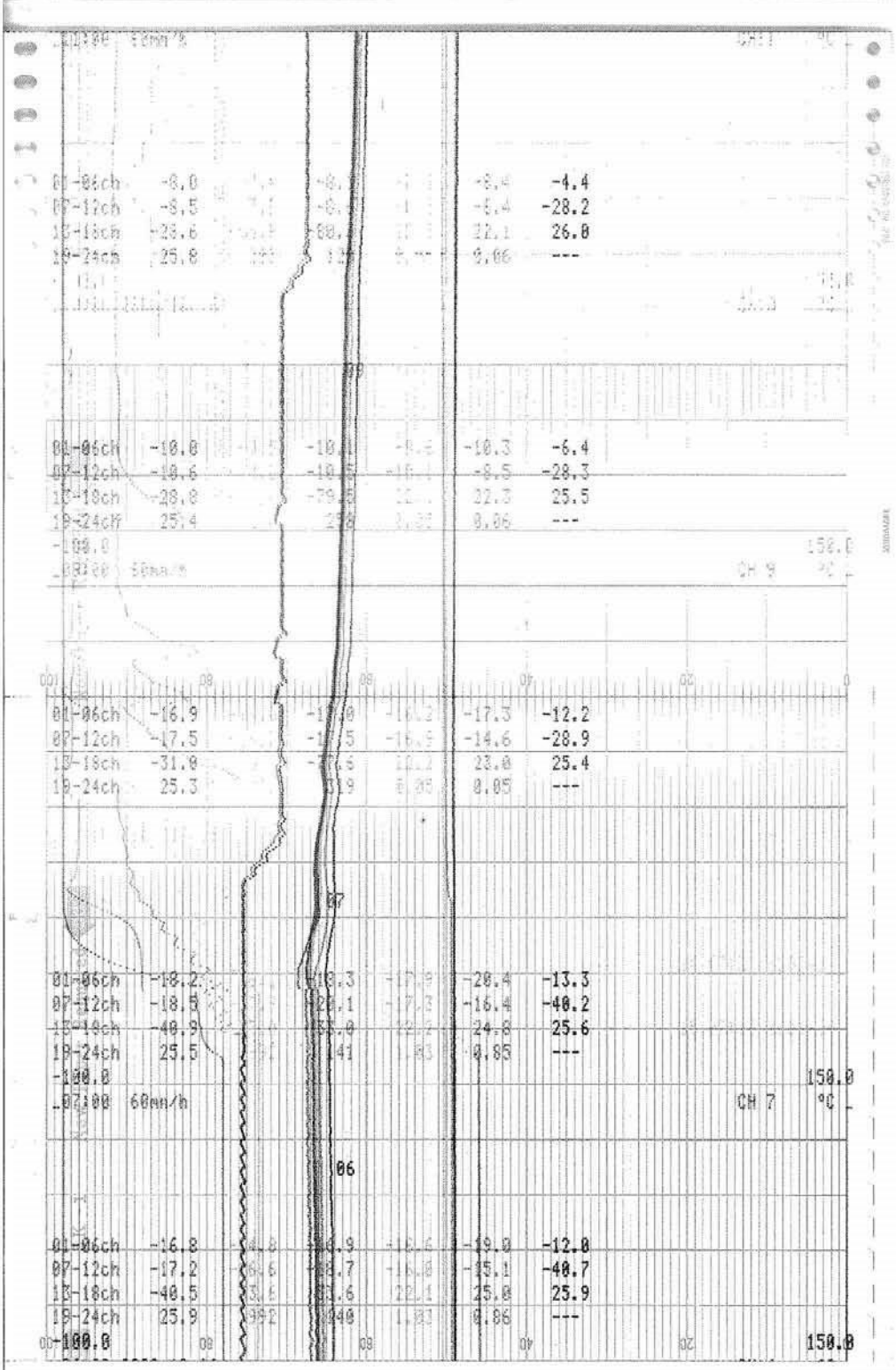
17

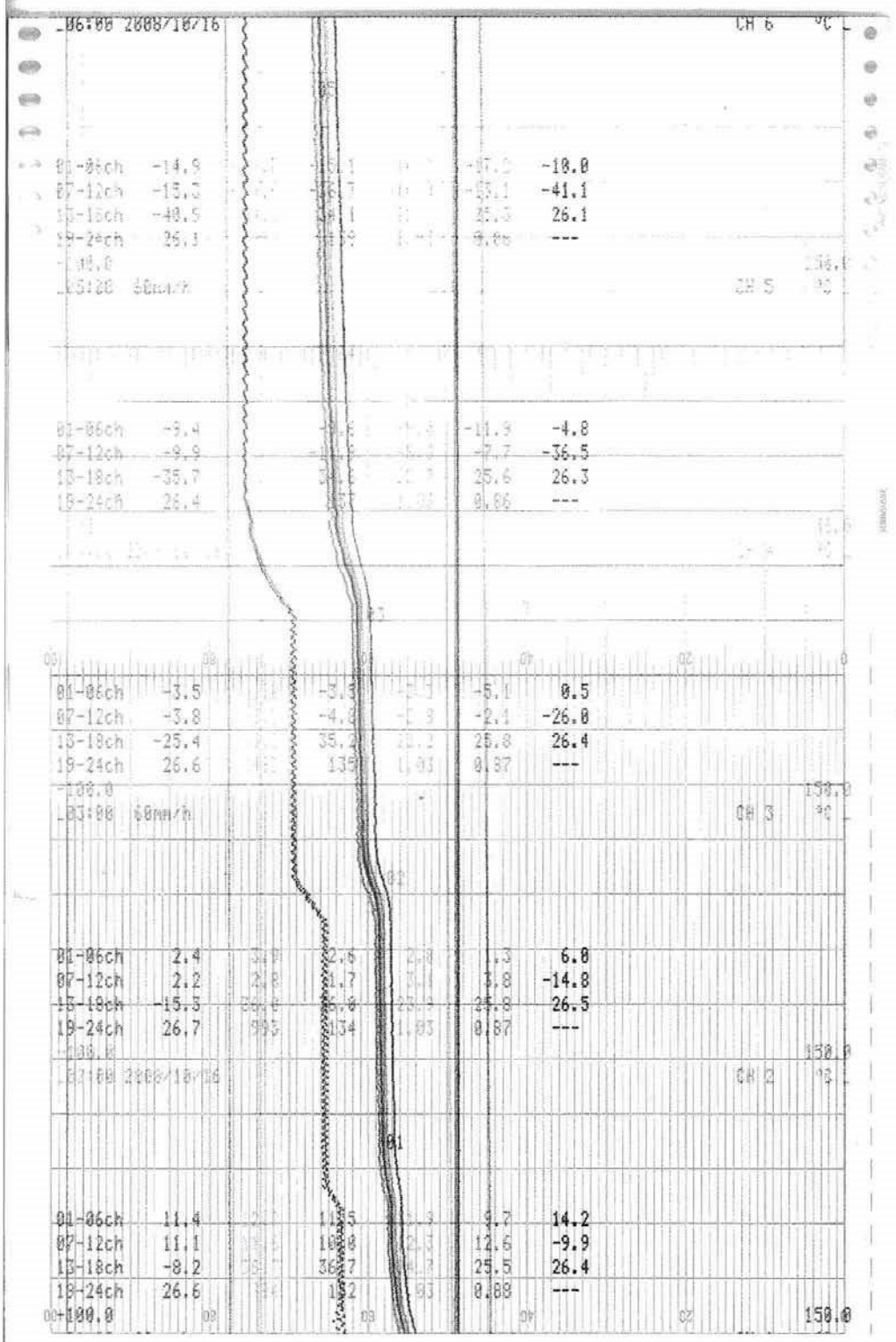
01-06ch 2.6 2.6 0.0 2.5 5.1
07-12ch 2.4 2.4 0.0 3.7 -5.8
13-18ch -6.2 -91.3 23.3 23.3 27.4
19-24ch 26.9 56 0.05 0.06 ---
-100.0 150.0
17:00 60mm/h CH17 °C

16

01-06ch 0.8 0.8 0.0 0.8 3.5
07-12ch 0.6 0.6 0.0 1.9 -6.2
13-18ch -6.8 -80.5 23.0 23.3 27.3
19-24ch 26.8 65 0.05 0.06 ---
00 04 08 09 04 02 150.0


01-06ch -0.2 -0.3 -0.4 2.5
07-12ch -0.6 -0.6 0.0 -12.0
13-18ch -12.4 -80.3 23.2 27.1
19-24ch 26.6 52 0.06 ---
100.0
15:20 60mm/h
CH15
150.0
01-06ch -0.7 -0.9 -0.9 2.0
07-12ch -1.1 -1.1 0.4 -11.8
13-18ch -12.2 -80.0 22.8 27.0
19-24ch 26.5 0.05 ---
13
01-06ch -1.3 -0.4 -0.9 -1.5 1.4
07-12ch -1.7 -1.6 -1.3 -0.1 -11.9
13-18ch -12.3 -80.1 22.2 27.0
19-24ch 26.5 50 0.05 0.06 ---
-100.0
13:00 60mm/h
CH13
150.0
°C
12
01-06ch -2.9 -3.0 -2.6 -3.0 -0.1
07-12ch -3.3 -3.2 -3.0 -1.8 -12.0
13-18ch -12.5 -79.6 21.9 26.9
19-24ch 26.4 48 0.05 0.06 ---
-100.0
12:00 2008/10/16
CH12
150.0
°C
01-06ch -5.0 -5.1 -5.3 -1.8
07-12ch -5.5 -5.5 -5.0 -3.0 -20.1
13-18ch -20.5 -79.5 21.8 26.6
19-24ch 26.2 48 0.05 0.06 ---
-100.0
150.0


01-06ch -8.0 -8.5 -4.4
07-12ch -8.5 -8.4 -28.2
13-18ch -28.6 32.1 26.0
19-24ch 25.8 0.06 ---
01-06ch -10.0 -10.3 -6.4
07-12ch -10.6 -8.5 -28.3
13-18ch -28.8 32.3 25.5
19-24ch 25.4 0.06 ---
-100.0 150.0
CH 9 °C
01-06ch -16.9 -17.3 -12.2
07-12ch -17.5 -14.6 -28.9
13-18ch -31.0 23.0 25.4
19-24ch 25.3 0.05 ---
07
01-06ch -18.2 -20.4 -13.3
07-12ch -18.5 -16.4 -40.2
13-18ch -40.9 24.8 25.6
19-24ch 25.5 0.85 ---
-100.0 150.0
07:00 60mm/h CH 7 °C
06
01-06ch -16.8 -19.0 -12.8
07-12ch -17.2 -15.1 -40.7
13-18ch -40.5 25.0 25.9
19-24ch 25.9 0.06 ---
-100.0 150.0


06:00 2008/10/16
CH 6 °C
01-06ch -14.9
07-12ch -15.3
13-18ch -40.5
19-24ch 26.1
-10.0
-41.1
26.1

01-06ch -9.4
07-12ch -9.9
13-18ch -35.7
19-24ch 26.4
-4.8
-36.5
26.3

01-06ch -3.5
07-12ch -3.8
13-18ch -25.4
19-24ch 26.6
0.5
-26.0
26.4

03:00 60mm/h
CH 3 °C
01-06ch 2.4
07-12ch 2.2
13-18ch -15.3
19-24ch 26.7
6.0
-14.8
26.5

02:00 2008/10/06
CH 2 °C
01-06ch 11.4
07-12ch 11.1
13-18ch -8.2
19-24ch 26.6
14.2
-9.9
26.4

100.0
150.0

Dabur PHARMA PLANT-II, BADDI

DISPENSED MATERIAL

Date : 14/10/08

Name of Material	:	Aluminium Flip off Seal Purple 20mm
A.R. No.	:	02PM08000062
Product Name	:	Topotecan for Inj 4mg
Batch No.	:	8PK201
Batch Size	:	12 L
Container No.	:	1 of 1
Gross weight	:	–
Tare weight	:	–
Net weight / Qty.	:	6300 Nos

Dispensed By (Warehouse) 14/10/08

Checked & Verified By (Production) 14/10/08

Form No. : SOP/QAD/033-01 Rev. 01

Dabur PHARMA PLANT-II, BADDI

DISPENSED MATERIAL

Date : 14/10/08

Name of Material	:	Glass vial Tchem 7-1
A.R. No.	:	02PM08000042
Product Name	:	Topotecan for Inj 4mg
Batch No.	:	8PK201
Batch Size	:	12 L
Container No.	:	1 of 1
Gross weight	:	–
Tare weight	:	–
Net weight / Qty.	:	6696 Nos.

Dispensed By (Warehouse) 14/10/08

Checked & Verified By (Production)

Form No. : SOP/QAD/033-01 Rev. 01

Dabur PHARMA PLANT-II, BADDI

DISPENSED MATERIAL

Date : 14/10/08

Name of Material	:	R. Plug. Flumtec 20mm
A.R. No.	:	02PM08000038
Product Name	:	Topotecan for Inj 4mg
Batch No.	:	8PK201
Batch Size	:	12 L
Container No.	:	1 of 1
Gross weight	:	–
Tare weight	:	–
Net weight / Qty.	:	7000 Nos

Dispensed By (Warehouse) 14/10/08

Checked & Verified By (Production) 14/10/08

Form No. : SOP/QAD/033-01 Rev. 01