

REDIPOR Batch Manufacturing Record

TRYPTIC SOY BROTH

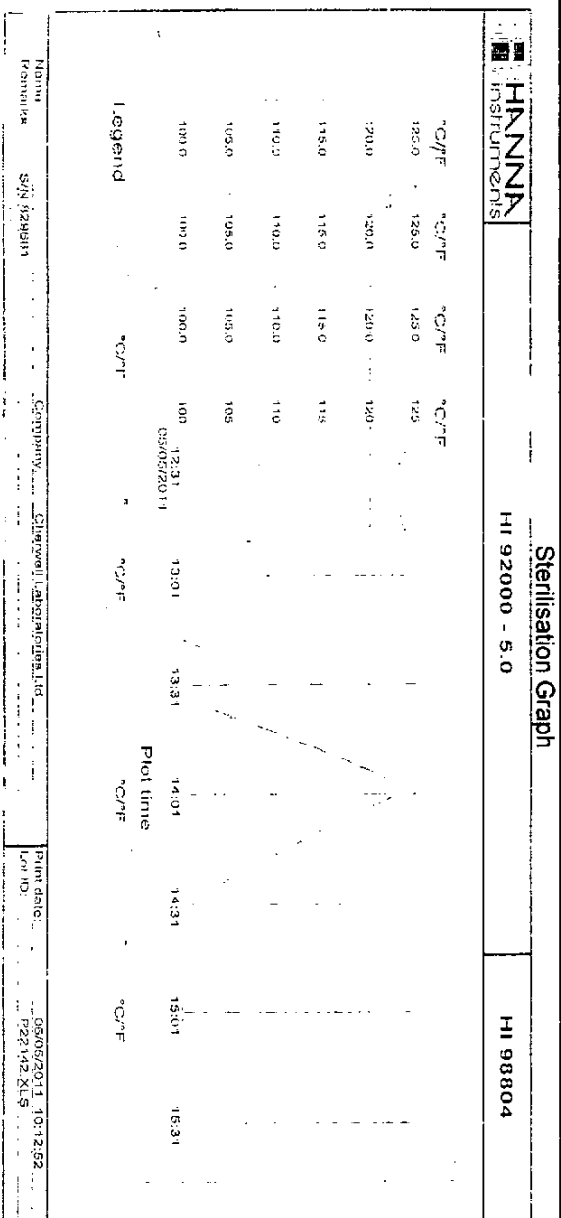
Version 3


Batch Number:	11050554B
Date of Preparation:	05/05/2011
Volume Prepd (lts)	5.5

Ingredients	Supplier & Code	Qty/Ltr	Supplier Batch No	Expiry Date	Qty Used	Add At	Operator	Checked
Tryptic Soy Broth	Difco 211823	30g	031913S	2015-09-30	165g	Start	SM	RE
Demineralised Water	Cherwell	1ltr	n/a	n/a	5.5L	Start	SM	RE

Dispensed into	
Vial	Universal Alpha
✓	Winchester Other
Din	Other
Sterilisation Parameters	
To achieve 121°C with a calculated Fo of >15 & <40	
Calculated Fo	20
Tech's Init:	RE
Autoclave Run No°	P22142

Special Instructions
pH Adjust before dispensing



Production Approval: 

Date: **09-05-11**

**QUALITY CONTROL
CERTIFICATE**
REDIPOR PREPARED MEDIA



Product Code : 223070
Description Tryptic Soy Broth
20ml in 30ml Injection Vial, CET Cap

Batch Number : I1050554B
Date of Manufacture: 05 May 2011
Expiry Date : 05 May 2012

pH (T= 7.3 ± 0.2) 7.3
Sterility Test: PASS

Positive Control organisms to show growth (Inoculum level 10-100 cfu)

<i>Organism</i>	<i>Reference</i>	<i>Result</i>
Staphylococcus aureus	ATCC 6538	Growth
Staphylococcus epidermidis	ATCC 12228	Growth
Escherichia coli	ATCC 8739	Growth
Pseudomonas aeruginosa	ATCC 9027	Growth
Bacillus subtilis	ATCC 6633	Growth
Candida albicans	ATCC 10231	Growth
Aspergillus brasiliensis	ATCC 16404	Growth

Comments:

Signed By: *[Signature]*

Authorised Signatory

Date: 9 May 2011

NOTE: Expiry Date only valid if packs stored unopened at Ambient Room Temperature not exceeding 25°C

REDIPOR Batch Manufacturing Record

TRYPTIC SOY BROTH

Version 3

Batch Number:	11050935
Date of Preparation:	09/05/2011
Volume Prepd (lts)	13.5

Ingredients	Supplier & Code	Qty/Ltr	Supplier Batch No	Expiry Date	Qty Used	Add At	Operator	Checked
Typic Soy Broth	Difco 211823	30g	0319135	2015-09-30	405g	Start	ER	MB
Demineralsed Water	Cherwell	1ltr	n/a	n/a	13.5ltr	Start	ER	MB

Sterilisation Graph

BATCH NO - 11050935

```

***Dispensing*
  70.0°C - 11:01:23
 121.3°C - 10:51:23
***Cooling*
End: 10:51:23
 121.3°C - 10:51:23
 121.4°C - 10:46:23
 121.4°C - 10:41:23
 121.0°C - 10:36:23
Start: 10:36:23
***Sterilization
 117.1°C - 10:30:54
  94.9°C - 10:20:54
  71.6°C - 10:10:54
  26.2°C - 10:00:55
***Heating
*****
Min. heat. water T: 45°C
Alt. rotating dir.: OFF
Disp. stirrer:      80rpm
Disp. T:           50°C
Steri. stirrer:    150rpm
Steri. t:          15min
Steri. T:          121°C
Op. code:          STANDARD
Name:              TSB
Number:            12
***Program Parameter

Cycle No:          343
Date:              09.05.2011
Time:              10:00:55
Lot-No:           -----
***Start Process

MEDIACLAVE (SN:10083123)
*****
    
```

Sterilisation Parameters		
Temp:	121°C	
Time:	15 minutes	
Unit:	10T-30	
Set by:	ER	
Dispense Temp °C:	50	
Tubing Req'd: GP BROTH	MB	
Dispensed into:		
90mm	Contact	Other
		✓
Special Instructions		

Production Approval: 

Date: 16-05-11

**QUALITY CONTROL
CERTIFICATE**
REDIPOR PREPARED MEDIA



Product Code : 218010
Description Tryptic Soy Broth
100ml in 100ml Sterile Infusion Bag

Batch Number : 11050935
Date of Manufacture: 09 May 2011
Expiry Date : 09 August 2011

pH (T= 7.3 ± 0.2) 7.3
Sterility Test: PASS

Positive Control organisms to show growth (Inoculum level 10-100 cfu)

<i>Organism</i>	<i>Reference</i>	<i>Result</i>
Staphylococcus aureus	ATCC 6538	Growth
Staphylococcus epidermidis	ATCC 12228	Growth
Escherichia coli	ATCC 8739	Growth
Pseudomonas aeruginosa	ATCC 9027	Growth
Bacillus subtilis	ATCC 6633	Growth
Candida albicans	ATCC 10231	Growth
Aspergillus brasiliensis	ATCC 16404	Growth

Comments:

Signed By:

A handwritten signature in black ink, appearing to read "Kauo", is written over the "Signed By:" label.

Authorised Signatory

Date:

13 May 2011

NOTE: Expiry Date only valid if packs stored unopened at Ambient Room Temperature not exceeding 25°C

REDIPOR Batch Manufacturing Record

TRYPTIC SOY BROTH

Version 3

Batch Number:	11051005
Date of Preparation:	10/05/2011
Volume Prep'd (lts)	7

Ingredients	Supplier & Code	Qty/Ltr	Supplier Batch No	Expiry Date	Qty Used	Add At	Operator	Checked
Tryptic Soy Broth	Difco 211823	30g	0319135	2015-09-30	210g	Start	MD	Q1
Demineralised Water	Cherwell	1ltr	n/a	n/a	78g	Start	MD	Q1

Sterilisation Graph

BATCH NO 11051005

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***Dispensing
    59.5°C - 08:11:40
   121.3°C - 08:01:40
***Cooling
End: 08:01:40
   121.3°C - 08:01:40
   121.3°C - 07:56:40
   121.4°C - 07:51:40
   121.0°C - 07:46:40
Start: 07:46:40
***Sterilization
   120.5°C - 07:45:58
    95.0°C - 07:35:58
    59.3°C - 07:25:58
    24.1°C - 07:15:58
***Heating

*****
Min. heat. water T: 45°C
Alt. rotating dir.: OFF
Disp. stirrer: 80rpm
Disp. T: 50°C
Steri. stirrer: 150rpm
Steri. t: 15min
Steri. T: 121°C
Op. mode: STANDARD
Name: T58
Number: 31
***Program Parameter

Cycle No: 472
Date: 10.05.2011
Time: 07:15:58
Lot-No:
***Start Process

MEDIACLAVE (SN:10060175)
*****
    
```

Sterilisation Parameters		
Temp:	121°C	
Time:	15 minutes	
Unit:	INT-3	
Set by:	Q1	
Dispense Temp °C:	50	
Tubing Reqd:	MD	
Dispensed info:		
90mm	Contact	Other
Special Instructions		

Production Approval: 

Date: 16-05-11

**QUALITY CONTROL
CERTIFICATE**
REDIPOR PREPARED MEDIA



Product Code : 210200
Description Tryptic Soy Broth
10ml in 10ml Ampoule

Batch Number : 11051005
Date of Manufacture: 10 May 2011
Expiry Date : 10 May 2012

pH (T= 7.3 ± 0.2) 7.4
Sterility Test: PASS

Positive Control organisms to show growth (Inoculum level 10-100 cfu)

Organism	Reference	Result
Staphylococcus aureus	ATCC 6538	Growth
Staphylococcus epidermidis	ATCC 12228	Growth
Escherichia coli	ATCC 8739	Growth
Pseudomonas aeruginosa	ATCC 9027	Growth
Bacillus subtilis	ATCC 6633	Growth
Candida albicans	ATCC 10231	Growth
Aspergillus brasiliensis	ATCC 16404	Growth

Comments:

Signed By: *Bauer*

Authorised Signatory

Date: 16 May 2011

NOTE: Expiry Date only valid if packs stored unopened at Ambient Room Temperature not exceeding 25°C