

SARACA LABORATORIES LIMITED (UNIT-I) CONTROLLED BY QA
BATCH PRODUCTION RECORD



Sign & Date 22/08/24

1.0 BATCH DETAILS

Product	Gabapentin	Batch Started on	<u>26/08/24</u>
Stage	GP (IPA + Methanol + Water)	Batch Completed on	<u>29/08/24</u>
Batch No.	GP/ 08 2024 02/8		

2.0 MATERIAL USAGE DETAILS:

Material input										
S. No.	Raw Material	Unit	Standard Quantity	Allowed Range	Actual Quantity	In-house B. No. / A. R. No.	Performed by	Checked by	Remarks	
1.	Purified water (Lot-I)	L	2500	2450 to 2550	2500	UP-08	PSB	U.S.	-	
2.	GP HCl	Kg	1800	1728 to 2090	1999.00	GP/SPH (K/1000) 200 0139, 0140, 0141 0142	PSB	U.S.	-	
3.	CS Lye (48% w/w) (Lot-I)	L	190	180 to 200	190	CL/200412	PSB	U.S.	-	
4.	Activated Carbon	Kg	10	8 to 12	10	PSCB/200404	PSB	U.S.	-	
5.	Purified water (Lot-II)	L	20	15 to 25	20	UP-08	PSB	U.S.	-	
6.	Purified water (Lot-III)	L	500	450 to 550	500	UP-08	PSB	U.S.	-	
7.	CS Lye (48% w/w) (Lot-II)	L	250	225 to 275	250	CL/200412	PSB	U.S.	-	
8.	Purified water (Lot-IV)	L	800	100	90 to 110	100	UP-05	PSB	U.S.	-
				100	90 to 110	100	UP-05	PSB	U.S.	-
				100	90 to 110	100	UP-05	PSB	U.S.	-
				100	90 to 110	100	UP-05	PSB	U.S.	-
				100	90 to 110	100	UP-05	PSB	U.S.	-
				100	90 to 110	100	UP-05	PSB	U.S.	-
				100	90 to 110	100	UP-05	PSB	U.S.	-
				100	90 to 110	100	UP-05	PSB	U.S.	-
9.	IPA (Lot -I)	L	2230	2200 to 2260	2230	PA/240428M	PSB	U.S.	-	
10.	Methanol	L	450	425 to 475	450	OM/240424M	PSB	U.S.	-	
11.	Purified water (Lot-V)	L	270	250 to 270	270	UP-07	PSB	U.S.	-	
12.	IPA (Lot -II)	L	500	480 to 520	500	PA/240428M	PSB	U.S.	-	

Prepared by (Asst. Manager-Production/designee)	Reviewed by (Head - Production/designee)	Approved by (Head - QA/designee)
<u>M</u> <u>15/07/2024</u> Sign & Date	<u>M</u> <u>16/07/24</u> Sign & Date	<u>U.S.</u> <u>16/08/24</u> Sign & Date

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Batch No.: GP/ 08 2024 0218

3.0 LIST OF EQUIPMENTS:

S.No.	Name of the Equipment	ID No.
1	Glass Lined reactor	GLRE-1010
2	Glass Lined reactor	GLRE-1014
3	Stainless steel Centrifuge	SSCF-1001
4	Stainless steel Centrifuge	SSCF-1002
5	SSPCS	SSPCS-1001
6	Glass Lined reactor	GLRE-1015
7	SSANFD	SSANFD-1006
8	Stainless steel Hopper	SSHP-1001
9	SSRCVD	SSRCVD-1001

4.0 RAW MATERIAL MEASURING SHEET:

Purified Water , Flow meter No. <u>FM-1010</u>				CS Lye (SSRC 1010)			
Op. No.	Initial reading (L)	Final reading (L)	Difference (L)	Op. No.	Initial volume (L)	Final volume(L)	Difference (L)
1	2500	0	2500	4	190	0	190
5	20	0	20	CS Lye (SSRC 1004)			
9	500	0	500	12	250	0	250
Purified Water (SSJRC 1005)				IPA (SSRC 1011)			
Op. No.	Initial reading (L)	Final reading (L)	Difference (L)	55	2230	0	230
17	800	700	100	Methanol (SSRC 1012)			
22	700	600	100	56	450	0	450
27	600	500	100	IPA (SSRC 1011)			
32	500	400	100	66			
37	400	300	100				
42	300	200	100				
47	200	100	100				
52	100	0	100				
57	270	0	270				

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
Batch No.: GP/ 08 2024 02/8

5.0 MANUFACTURING PROCEDURE:

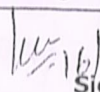
Op. No.	Description of operation	Equip. No(s).	Date	Time		Duration	Performed by	Checked by	Remarks
				From	To				
1.	Check the cleanliness of the reactor. Charge Purified Water (Lot-I) into the reactor. Cleaned/Uncleaned Vol: 2500L	GLRE-1010	26/08/24	16:00	17:40	X	P	K	-
2.	Charge GP HCl into the reactor under stirring.		26/08/24	17:40	19:00	X	P	K	-
3.	Stir for 20 to 30 minutes.		26/08/24	19:00	19:30	00:30	P	X	-
4.	Charge CS Lye (Lot-I) from the receiver SSRC-1010 to the reactor below 30°C. Check for a clear solution Temp: Vol: 190L, Clear /Not Clear	SSRC-1010 to GLRE- 1010	26/08/24	19:30	20:00	X	P	K	-
5.	Charge Activated carbon slurry (Purified Water Lot-II + Activated carbon) into the reactor.	GLRE-1010	26/08/24	20:00	20:10	X	P	K	-
6.	Stir for 20 to 30 minutes.		26/08/24	20:10	20:40	00:30	P	X	-
7.	Check the cleanliness of the reactor. Filter reaction mass through the filter setup (SSCF-1001, SSMF-1001 & SSMF-1002). Initially re-circulate the mass for 10 to 15 minutes. Note: Check the solution is clear and free from charcoal particles through view glass Solution : Clear/Unclear If found satisfactory, transfer the filtered mass to another clean reactor (GLRE 1014).	GLRE-1014	26/08/24	22:40	01:00	02:20	PSS	X	-
8.	After completion of filtration flush the filter setup with Nitrogen pressure.		27/08/24	01:00	01:15	X	PSS	X	-
9.	Charge Purified Water Lot-III into reactor.	GLRE-1010	27/08/24	01:15	01:30	X	PSS	U&	-
10.	Transfer the Water through the filter setup into GLRE 1014.	GLRE- 1010	27/08/24	01:30	01:45	X	PSS	X	-

Prepared by
(Asst. Manager-Production/designee)

15/07/2024

Sign & Date

Reviewed by
(Head - Production/designee)

16/07/24

Sign & Date

Approved by
(Head - QA/designee)

16/07/24

Sign & Date

Revision No.: 04

Effective Date: 01-08-2024

MFR Ref. No.: RD/MF/GP/II(W)/GP-004

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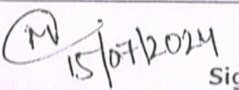
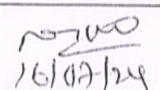
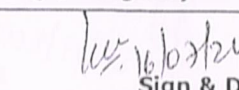
Op. No.	Description of operation	Equip. No(s).	Date	Time		Duration	Performed by	Checked by	Remarks
				From	To				
11.	After completion of filtration flush the filter setup with Nitrogen pressure.	SSLF- 1002 SSMF- 1001 SSMF- 1002	27/08/24	01:45	02:00	X	PSB	X	✓
12.	Slowly adjust the mass pH to 7.0 to 7.5 with filtered CS Lye (Lot-II) from receiver SSRC-1004 below 40°C. Note: Record the temperature every 30± 5 min pH: 7.17	GLRE- 1014	27/08/24	02:00	03:30	X	PSB	U.S.	-

Time	02:00	02:30	03:00	03:30					
Temp. °C)	27.2	30.1	35.6	39.8					PSB
Sign	PSB	PSB	PSB	PSB					27/08/24

Op. No.	Description of operation	Equip. No(s).	Date	Time		Duration	Performed by	Checked by	Remarks
				From	To				
13.	Maintain for 30 minutes at 30°C to 40°C.	GLRE- 1014	27/08/24	03:30	04:00	00:30	PSB	X	-
14.	Cool to below 5°C.		27/08/24	04:00	10:00	X	✓ B. Rao	X	

Time	04:00	05:00	06:00	07:00	08:00	09:00	10:00		
Temp. (°C)	39.8	34.2	29.5	20.4	14.2	9.4	5.0		
Sign	PSB	PSB	PSB	✓ B. Rao	✓ B. Rao	✓ B. Rao	✓ B. Rao		✓ B. Rao 27/08/24

Op. No.	Description of operation	Equip. No(s).	Date	Time		Duration	Performed by	Checked by	Remarks
				From	To				
15.	Check the cleanliness of Centrifuge. Load the Lot-I material into the centrifuge at speed knob position 1 Cleaned/Uncleaned	SSCF-1001/ 1002	27/08/24	10:00	10:30	X	✓ B. Rao	✓	-
16.	Spin dry the material for 15 to 30 min. by using centrifuge speed knob at position 3		27/08/24	10:30	11:00	00:30	✓ B. Rao	X	-
17.	Wash the material with chilled Purified water (Lot-IV) from receiver SSJRC-1005 by using speed knob at position 1 and collect the ML's into receiver SSRC-1014. Vol : 100 L		27/08/24	11:00	11:10	X	✓ B. Rao	✓	

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Op. No.	Description of operation	Equip. No(s).	Date	Time		Duration	Performed by	Checked by	Remarks
				From	To				
18.	Spin dry the material for 30 to 45 min. by using at speed knob position 3 Check the sample for chloride content (Chlorides : NMT 100 ppm) Complies / Does not comply. If not, repeat the operation no. 17 & 18. Volume : <u> </u>	SSJRC-1005 to SSCF-1001/1002 to SSRC-1014	27/08/24	11:10	11:50	00:40	✓ Ew	W	-
19.	Unload the material into a single poly lined HDPE container		27/08/24	11:50	12:50	X	✓ Ew	W	-
20.	Load the Lot-II material into the centrifuge at speed knob position 1		27/08/24	10:30	11:00	X	✓ Ew	W	-
21.	Spin dry the material for 15 to 30 min. by using centrifuge speed knob at position 3		27/08/24	11:00	11:30	00:30	✓ Ew	X	-
22.	Wash the material with chilled Purified water (Lot-IV) from receiver SSJRC-1005 by using speed knob at position 1 and collect the ML's into receiver SSRC-1014. Vol : <u>100 L</u>	SSJRC-1005 to SSCF-1001/1002 to SSRC-1014	27/08/24	11:30	11:40	X	✓ Ew	W	-
23.	Spin dry the material for 30 to 45 min. by using at speed knob position 3 Check the sample for chloride content (Chlorides : NMT 100 ppm) Complies / Does not comply. If not, repeat the operation no. 22 & 23. Volume : <u> </u>		27/08/24	11:40	12:20	00:40	✓ Ew	W	-
24.	Unload the material into single poly lined HDPE container.		27/08/24	12:20	13:20	X	✓ Ew	W	-

Prepared by (Asst. Manager - Production/designee)	Reviewed by (Head - Production/designee)	Approved by (Head - QA/designee)
<u>M</u> 15/07/2024 Sign & Date	<u>N200</u> 16/07/24 Sign & Date	<u>W</u> 16/07/24 Sign & Date

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