

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



Sign & Date 22/08/24

**1.0 BATCH DETAILS**


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

**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



	<b>SARACA LABORATORIES LIMITED (UNIT-I)</b> <b>BATCH PRODUCTION RECORD</b>
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
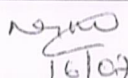
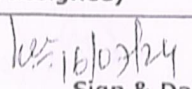
Batch No.: GP/ 08 2024 0218

**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				

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



## SARACA LABORATORIES LIMITED (UNIT-I)

## BATCH PRODUCTION RECORD

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. <b>Note:</b> 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)M  
15/07/2024

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Reviewed by  
(Head - Production/designee)M  
16/07/24

Sign &amp; Date

Approved by  
(Head - QA/designee)M  
16/07/24

Sign &amp; Date

Revision No.: 04

Effective Date: 01-08-2024

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

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