	SARACA LABORATORIES LIMITED (UNIT-I) BATCH PRODUCTION RECORD

ISSUE CONTROLLED BY QA
Sign & Date: 22/08/24

1.0 BATCH DETAILS

Product	Gabapentin	Batch Started on	26/08/24
Stage	GP (IPA + Methanol + Water)	Batch Completed on	29/08/24
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			-
2.	GP HCl	Kg	1800	1728 to 2090	1999.00	GP/SPH/2404 2no 0139, 0140, 0141 0142			-
3.	CS Lye (48% w/w) (Lot-I)	L	190	180 to 200	190	CL/2404/12			-
4.	Activated Carbon	Kg	10	8 to 12	10	PSCB/2404/04			-
5.	Purified water (Lot-II)	L	20	15 to 25	20	UP-08			-
6.	Purified water (Lot-III)	L	500	450 to 550	500	UP-08	PSB		-
7.	CS Lye (48% w/w) (Lot-II)	L	250	225 to 275	250	CL/2404/12	PSB		-
8.	Purified water (Lot-IV)	L	800	90 to 110	100	UP-05			-
				90 to 110	100	UP-05			-
				90 to 110	100	UP-05			-
				90 to 110	100	UP-05			-
				90 to 110	100	UP-05			-
				90 to 110	100	UP-05			-
				90 to 110	100	UP-05			-
				90 to 110	100	UP-05			-
9.	IPA (Lot -I)	L	2230	2200 to 2260	2230	IPA/2404/28M	PSB		-
10.	Methanol	L	450	425 to 475	450	MH/2404/24M	PSB		-
11.	Purified water (Lot-V)	L	270	250 to 270	270	UP-07	PSB		-
12.	IPA (Lot -II)	L	500	480 to 520	500	IPA/2404/28M			-

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

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. FM-1010			
Op. No.	Initial reading (L)	Final reading (L)	Difference (L)
1	2500	0	2500
5	20	0	20
9	500	0	500
Purified Water (SSJRC 1005)			
Op. No.	Initial reading (L)	Final reading (L)	Difference (L)
17	800	700	100
22	700	600	100
27	600	500	100
32	500	400	100
37	400	300	100
42	300	200	100
47	200	100	100
52	100	0	100
57	270	0	270

CS Lye (SSRC 1010)			
Op. No.	Initial volume (L)	Final volume(L)	Difference (L)
4	190	0	190
CS Lye (SSRC 1004)			
12	250	0	250
IPA (SSRC 1011)			
55	2230	0	230
Methanol (SSRC 1012)			
56	450	0	450
IPA (SSRC 1011)			
66			

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5.0 MANUFACTURING PROCEDURE:

Op. No.	Description of operation	Equip. No(s).	Date	Time From	Time To	Duration	Performed by	Checked by	Remarks
1.	Check the cleanliness of the reactor. Charge Purified Water (Lot-I) into the reactor. Cleaned/~~Uncleaned~~ Vol: 2500 L	GLRE-1010	26/08/24	16:00	17:40	X	[signature]	[signature]	-
2.	Charge GP HCl into the reactor under stirring .		26/08/24	17:40	19:00	X	[signature]	[signature]	-
3.	Stir for 20 to 30 minutes.		26/08/24	19:00	19:30	00:30	[signature]	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: 190 L, Clear / ~~Not Clear~~	SSRC-1010 to GLRE- 1010	26/08/24	19:30	20:00	X	[signature]	[signature]	-
5.	Charge Activated carbon slurry (Purified Water Lot-II + Activated carbon) into the reactor.	GLRE-1010	26/08/24	20:00	20:10	X	[signature]	[signature]	-
6.	Stir for 20 to 30 minutes.		26/08/24	20:10	20:40	00:30	[signature]	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 27/08/24	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	[signature]	-
10.	Transfer the Water through the filter setup into GLRE 1014.	GLRE- 1010	27/08/24	01:30	01:45	X	PSS	X	-

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[signature] 15/07/2024 Sign & Date	[signature] 16/07/24 Sign & Date	[signature] 16/07/24 Sign & Date