	BATCH PRODUCTION AND CONTROL RECORD		Page 1 of 32
Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Effective Date	02/10/2023

	Name	Title	Date
Prepared By		Initiator Manufacturing	02/10/2023
Reviewed By		Manufacturing HOD	02/10/2023
		Quality Assurance Review	02/10/2023
Approved By		Quality Assurance HOD	02/10/2023

REVISION SUMMARY

BPCR Number	Revision Number	Effective Date	Reason for revision
	00	02/10/2023	01.First Issue Company name change from division to Hence BPCR of changed to . (Reference CRF No's: CRF-U08-009065 & CRF-UII-000001).

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

LIST OF RAW MATERIALS AND WEIGHING DETAILS

S.No	Raw Material Name/ Item Code	Batch No. / Lot No.	Used at Step No's	UOM	Standard Quantity	Gross Qty.	Tare Qty.	Net Qty.	Done by	Checked by
1.	N,N-Dimethylamino Propiophenone Hydrochloride (C2187470/C4047460)	381-24-156711 381-24-156712 381-24-157007	4 8 2	Kg	350.0	218.35 86.90 91.97	23.69 12.04 11.49	194.66 74.86 80.48	RDM 29/12/2023	S 29/12/2023
2.	Sodium Hydroxide (C4042430)	381-24-156493	3	Kg	231.0	232.00	1.00	231.00	RDM 28/12/2023	S 28/12/2023
3.	Methanol (C4050200)	381-24-156464	9	L	175	–	–	175	RDM 29/12/2023	S 29/12/2023
4.	Toluene *(Fresh/Recovery) (C4050270/C4161705)	2338101244 2338101158 2338101159 2338101072	7, 32, 37, 62, 68, 74, 103, 108, 112	L	4641 + = 4641	–	–	2100 1378 722 441	03/01/2024	03/01/2024
			7		1400	–	–	1400	RDM 28/12/2023	S 28/12/2023
			32		350	–	–	350	30/12/2023	30/12/2023
			37		350	–	–	350	30/12/2023	30/12/2023
	Toluene *(Fresh/Recovery) (C4050270/C4161706)		62		1400	–	–	1400	01/01/2024	01/01/2024
			68		350	–	–	350	01/01/2024	01/01/2024
			74		350	–	–	350	02/01/2024	02/01/2024
			103		399	–	–	399	03/01/2024	03/01/2024
			108		42	–	–	42	03/01/2024	03/01/2024
			112*		–	–	–	–	–	–
5.	Hydrochloric acid (CP Grade) * (C4030781)	2338101004 2338101006	21, 80, 121, 133	L	290.5+12 = 302.5	–	–	290.5 12	RDM 03/01/2024	S 03/01/2024
			21		140	–	–	140	29/12/2023	29/12/2023
					140	–	–	140	29/12/2023	S 29/12/2023
			80		10.5	–	–	10.5	02/01/2024	02/01/2024
			121*		–	–	–	12	03/01/2024	03/01/2024
			133*		–	–	–	–	–	–
6.	Sodium borohydride (C4042370)	381-24-155690	15	Kg	30.8	33.80	3.00	30.80	RDM 29/12/2023	S 29/12/2023

BATCH PRODUCTION AND CONTROL RECORD

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Batch No.		Batch Size	350.0 Kg

S.No	Raw Material Name/ Item Code	Batch No. / Lot No.	Used at Step No's	UOM	Standard Quantity	Gross Qty.	Tare Qty.	Net Qty.	Done by	Checked by
7.	4-Chlorobenzotrifloride (C4030259)	HIP-24-14777839	54	Kg	308.0	324.10	16.10	308.0	31/12/2023	31/12/2023
8.	Dimethylsulfoxide (DMSO) (Fresh/Recovery) (C4030650/C4161707)	2338101155	**48 & 52**	L	1487.5	-	-	1487.5	31/12/2023	31/12/2023
			48		1400	-	-	1400	31/12/2023	31/12/2023
			52		87.5	-	-	87.5	31/12/2023	31/12/2023
9.	Sodium hydroxide (Pellets) (C4042431)	381-24-1550794	53	Kg	238.0	251.60	13.60	238.0	31/12/2023	31/12/2023
10.	Ethyl chloroformate* (C4030700)	381-24-1564288	**104, 109 & 113**	Kg	340.2 +- = 340.20	364.70	24.50	340.20	03/01/2024	03/01/2024
			104		312.2	333.9	21.7	312.2	03/01/2024	03/01/2024
			109		28.0	30.80	2.80	28.0	03/01/2024	03/01/2024
			113*		-	-	-	-	-	-
11.	Triethylamine (C4031620)	HIP-24-1526570	107	Kg	28.0	30.80	2.80	28.0	03/01/2024	03/01/2024
12.	Purified Water		**2,18, 58, 79, 86, 92, 116, 129, 146 & 156.6**	L	7392	-	-	5292	04/01/2024	04/01/2024
		PW-28-12-2023	2		231	-	-	231	28/12/2023	28/12/2023
		PW-29-12-2023	18		700	-	-	700	29/12/2023	29/12/2023
		PW-01-01-2024	58		1400	-	-	1400	01/01/2024	01/01/2024
		PW-01-01-2024	79		350	-	-	350	02/01/2024	02/01/2024
		PW-01-01-2024	86		350	-	-	350	02/01/2024	02/01/2024
		-	92		350	-	-	-	-	-
		PW-02-01-2024	116		625	-	-	625	03/01/2024	03/01/2024
		PW-02-01-2024			600	-	-	600	03/01/2024	03/01/2024
		-	129		1750	-	-	-	-	-
		PW-03-01-2024	146		1001	-	-	1001	04/01/2024	04/01/2024
		PW-04-01-2024	156.6		35	-	-	35	04/01/2024	04/01/2024

S.No	Raw Material Name/ Item Code	Batch No. / Lot No.	Used at Step No's	UOM	Standard Quantity	Gross Qty.	Tare Qty.	Net Qty.	Done by	Checked by
13.	Hexane (C4050097)	2888101436	147 & 156.6	L	476	-	-	476	04/01/2024	04/01/2024
			147		441	-	-	441	04/01/2024	04/01/2024
			156.6		35	-	-	35	04/01/2024	04/01/2024

* *Quantity may vary as it is based on the in-process check completion.*

LIST OF RAW MATERIALS FOR EQUIPMENT CLEANING

S. No.	Raw Material Name /Item Code	UOM	Standard Quantity
1	Methanol (C4050200)	L	200

LIST OF MAJOR EQUIPMENTS & SOP (OPERATION & CLEANING) DETAILS

S. No.	Equipment			SOP Details	
	Name	ID No	Capacity	Operation	Cleaning
1.	S.S.Reactor	SRB014	1000 L	UIIMF053	UIIMF078
2.	S.S.Reactor	SRB012	5000 L	UIIMF053	UIIMF078
3.	S.S.Reactor	SRB006	3000 L	UIIMF053	UIIMF078
4.	S.S.Reactor	SRB010	5000 L	UIIMF053	UIIMF078
5.	G.L. Reactor	GLB007	5000 L	UIIMF053	UIIMF079
6.	Agitated Nutch filter Dryer	AFB001	2000 L	UIIMF194	UIIMF195
7.	Weighing Machine	WMB006	150.0 Kg	UIIMF074	
8.	Weighing Machine	WMB010	150.0 Kg		
9.	Weighing Machine	WMB011	300.0 Kg		

	BATCH PRODUCTION AND CONTROL RECORD		
Product Name		Market Code	U
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Batch No.		Batch Size	350.0 Kg

MANUFACTURING INSTRUCTIONS

Date & Time of starting: 28/12/2023 @ 21-00 Hrs

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
1	**Inspect** reactor SRB014 for cleanliness. (as per SOP No.UIIMF116)	21-00	N.A.	N.A.	N.A.	–	BS 28/12/2023	28/12/2023
2	***Safety precaution:*** *Ensure nitrogen inertization procedure is followed as per the SOP UIIMF046 before starting the operation.*							
	Charge purified water 231 L into the reactor SRB014 (as per SOP No. UIIMF055)	21-10	21-35	00-25	N.A.	–	BS 28/12/2023	28/12/2023
3	*Caustic Soda Flakes is highly corrosive solid material. Use PVC full suit, suitable gloves, goggles and breathing apparatus while handling.*							
	Start stirring, charge sodium hydroxide 231.00 Kg into the reactor SRB014. (as per SOP No. UIIMF055) at 25-30°C.	21-35	22-50	01-15	28.8	–	RDM 28/12/2023	28/12/2023
4	Stir the contents of the reactor SRB014 for 30 minutes at 25-30°C.	22-50	23-20	00-30	29.2	–	RDM 28/12/2023	–
5	Transfer the sodium hydroxide solution from reactor SRB014 to addition tank ATB006 at 25-30°C.	23-20	23-55	00-35	29.5	–	RDM 28/12/2023	28/12/2023
6	**Inspect** reactor SRB006 for cleanliness. (as per SOP No.UIIMF116)	23-00	N.A.	N.A.	N.A.	–	RDM 28/12/2023	28/12/2023
7	***Safety precaution:*** *Ensure nitrogen inertization procedure is followed as per the SOP UIIMF046 before starting the operation.*							
	Toluene is Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles.							
	Charge toluene 1400 L into the reactor SRB006 from day tank/ receiving tank DTB006/RTB031/RTB034/RTB035 (as per SOP No. UIIMF055)	23-05	23-45	00-40	N.A.	–	RDM 28/12/2023	28/12/2023
8	3-Dimethylamine Propiophenone Hydrochloride (DAP HCL) *is powdered material. Use nose masks, gloves and goggles. Ensure earthing. Harmful if swallowed.*							
	Start stirring and charge N,N-Dimethylamino Propiophenone Hydrochloride 350.0 Kg into the reactor SRB006 at 25-30°C. (as per SOP No. UIIMF055)	23-45	01-20	01-35	28.1	RPM: 40	RDM 29/12/2023	29/12/2023
9	*Methanol is Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles.*							
	Charge methanol 175 L into the reactor SRB006 at 25-30°C. (as per SOP No: UIIMF055) ***Note: Slurry mass observed.***	01-20	01-36	00-16	27.7	***Slurry mass obtained / ~~Not~~***	RDM 29/12/2023	29/12/2023
10	Cool the reaction mass at 10-15°C. (as per SOP No. UIIMF029)	01-36	02-18	00-42	13.5	–	RDM 29/12/2023	29/12/2023
11	Adjust the reaction mass pH 12.0 - 13.0 with ~182 L 50%w/w aqueous sodium hydroxide into the reactor SRB006 from addition tank ATB006 at10 – 15°C.	02-18	02-55	00-37	14.1	–	RDM 29/12/2023	29/12/2023

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
12	Stir the reaction mass in the reactor SRB006 for 30 minutes at 10 – 15°C.	02-55	03-25	00-30	13.7	–	29/12/2023	29/12/2023
13	Send the sample to QCD for pH (as per SOP: UIIMF007).	03-36	N.A.	N.A.	N.A.	–	29/12/2023	29/12/2023
14	Results of pH (Limit: 12.0 -13.0)	N.A.	04-00	N.A.	N.A.	For results Refer In-process sheet	29/12/2023	29/12/2023
15	*Sodium borohydrate is powdered material, toxic and highly flammable solid .Use nose masks gloves and goggles. Ensure earthing. Harmful if swallowed. Wear breathing apparatus plus protective gloves.* ***Add sodium borohydride 30.8 Kg in the reactor SRB006 at 10-25°C. Under nitrogen atmosphere. (as per SOP No. UIIMF055) (Addition is slightly exothermic)*** ***Note: Continue blanketing of nitrogen until pH adjustment to 6.0 to 6.5 with concentrated. Hydrochloride is completed in the subsequent steps.***	04-05	04-18	00-13	14.8	–	29/12/2023	29/12/2023
16	Raise the temperature of the reaction mass to 25-30°C. (as per SOP No: UIIMF030)	04-18	04-50	00-32	25.2	–	29/12/2023	29/12/2023
17	***Maintain the reaction mass at 25–30°C till 3-(Dimethylamino) propiophenone content NMT 0.5%. It takes ~10 hours to achieve this and reaction mass remains as a suspension***	04-50	18-45	13-55	28.3	For results Refer In-process sheet	29/12/2023	29/12/2023

Note: 1. Record the time and temperature for every 30±5 minutes in table- I.
2. Sample to QCD for HPLC after 10 hours and after that every 2 hours intervals till 3-(Dimethylamino) propiophenone content NMT 0.5%.
3. Use process parameters recording sheet for recording of time and temperature and use additional in- process sheet for recording of in-process sampling details if required.

Table – I

Time (Hr. – Min.)	Temperature (°C)	Done By	Time (Hr. – Min.)	Temperature (°C)	Done By
05-20	27.2	29/12/2023	09-20	28.6	29/12/2023
05-52	28.5	29/12/2023	09-50	28.7	29/12/2023
06-20	28.6	29/12/2023	10-20	28.8	29/12/2023
06-50	28.7	29/12/2023	10-50	28.9	29/12/2023
07-20	28.9	29/12/2023	11-20	29.0	29/12/2023
07-50	28.8	29/12/2023	11-50	29.1	29/12/2023
08-20	28.6	29/12/2023	12-20	28.4	29/12/2023
08-50	28.4	29/12/2023	12-50	28.2	29/12/2023

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Product Name		Market Code	U
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Batch No.		Batch Size	350.0 Kg

Table – I

Time (Hr. – Min.)	Temperature (°C)	Done By	Time (Hr. – Min.)	Temperature (°C)	Done By
13-20	28.0	29/12/2023			
13-50	28.1	29/12/2023			
14-21	28.5	29/12/2023			
14-50	28.8	29/12/2023			
15-20	29.1	29/12/2023			
15-20	29.3	29/12/2023			
16-22	29.6	29/12/2023			
16-50	29.2	29/12/2023			
17-21	29.5	29/12/2023			
17-52	29.1	29/12/2023			
18-20	28.6	29/12/2023			
18-45	28.3	29/12/2023			
–	–	–			29/12/2023

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
18	After HPLC complies, add purified water 700 L into the reaction mass at 25–30°C.	18-50	19-30	00-40	28.8	–	29/12/2023	29/12/2023
19	Stir the reaction mass for15 minutes to get clear solution.	19-30	19-45	00-15	N.A.	Solution clear/ ~~not clear~~	29/12/2023	29/12/2023
20	Cool the reaction mass at 10°C.	19-45	21-10	01-25	10.0	–	29/12/2023	–
21	*Con. hydrochloric acid is highly corrosive material. Use PVC full suit, suitable gloves, goggles and breathing apparatus while handling.*							
	Charge Con. Hydrochloric Acid 280 L lot wise (140 L + 140 L) into the addition tank ATB016 (as per the SOP No. UIIMF055).	20-00	20-40	00-40	N.A.	–	29/12/2023	29/12/2023
		22-40	23-10	00-30		–	29/12/2023	29/12/2023
22	Adjust pH of the reaction mass to 6.0 - 6.5 with con. Hydrochloric acid ~280 L at 10 – 30°C from addition tank ATB016. ***Note: If require use more quantity of concentrated hydrochloride for pH adjustment. pH adjustment is highly exothermic with evolution of hydrogen gas and foaming.***	21-10	01-00	03-50	19.8	–	30/12/2023	30/12/2023

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
23	Send the sample to QCD for pH (As per SOP:UIIMF007)	01-15	N.A.	N.A.	N.A.	–	30/12/2023	30/12/2023
24	Results of pH (Limit:6.0-6.5)	N.A.	02-20	N.A.	N.A.	For results Refer In-process sheet	30/12/2023	30/12/2023
25	Thereafter adjust pH (12.0 -13.0) with 280 L of 50% w/w Aqueous sodium hydroxide solution into the reactor SRB006 from addition tank ATB006 (Balance qty Aqueous sodium hydroxide solution prepared at stepno.5) at 20 – 40°C.	02-30	03-10	00-40	26.5	–	30/12/2023	30/12/2023
26	Send the sample to QCD for pH (As per SOP:UIIMF007)	03-20	N.A.	N.A.	N.A.	–	30/12/2023	30/12/2023
27	Results of pH (Limit : 12.0-13.0)	N.A.	04-00	N.A.	N.A.	For results Refer In-process sheet	30/12/2023	30/12/2023
28	Stir the reaction mass for 30 minutes at 25 – 30°C.	04-10	04-40	00-30	27.2	–	30/12/2023	–
29	Stop stirring and settle the reaction mass for 30 minutes at 25 – 30°C.	04-40	05-10	00-30	27.5	–	30/12/2023	–
30	Separate the bottom Aqueous layer into receiving tank RTB011 and unload the Organic layer into receiving tank RTB012.	05-10	06-05	00-55	N.A.	*Aqueous layer Volume:* 1560 L *Organic layer Volume:* 1780 L	30/12/2023	30/12/2023
31	Transfer the Aqueous Layer from receiving tank RTB011 to the reactor SRB006.	06-05	06-40	00-35	N.A.	–	30/12/2023	30/12/2023
32	*Toluene is Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles.* Charge toluene 350 L into the reactor SRB006 from day tank/ receiving tank DTB006/RTB031/RTB034/RTB035 at 25-30°C (as per the SOP No. UIIMF055).	06-40	07-00	00-20	26.2	–	30/12/2023	30/12/2023
33	Stir the reaction mass for 30 minutes at 25 – 30°C.	07-00	07-30	00-30	27.1	–	30/12/2023	–
34	Stop stirring and settle the reaction mass for 30 minutes at 25 – 30°C.	07-30	08-00	00-30	27.4	–	30/12/2023	–
35	Separate the bottom Aqueous layer into receiving tank RTB011 and unload the Organic layer into receiving tank RTB012.	08-00	08-30	00-30	N.A.	*Aqueous layer Volume:* 1550 L	30/12/2023	30/12/2023

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Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
36	Transfer the Aqueous Layer from receiving tank RTB011 to the reactor SRB006	08-30	08-55	00-25	N.A.	-	30/12/2023	30/12/2023
37	*Toluene is Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles.* Charge toluene 350 L into the reactor SRB006 from day tank/ receiving tank DTB006/RTB031/RTB034/RTB035 at 25-30°C (as per the SOP No. UIIMF055).	08-55	09-20	00-25	27.2	–	30/12/2023	30/12/2023
38	Stir the reaction mass for 30 minutes at 25 – 30°C.	09-20	09-50	00-30	27.2	–	30/12/2023	-
39	Stop stirring and settle the reaction mass for 30 minutes at 25 – 30°C.	09-50	10-20	00-30	27.2	–	30/12/2023	-
40	Separate the bottom Aqueous layer into receiving tank RTB011.	10-20	11-00	00-40	N.A.	–	30/12/2023	30/12/2023
41	Transfer the total organic layer from receiving tank RTB012 to reactor SRB006 at 25 – 30°C.	11-00	12-00	01-00	27.5	*Total organic layer Volume:* 2480 L	30/12/2023	30/12/2023
42	Apply vacuum (NLT 570 mmHg) to reactor SRB006 and distil toluene below 60°C into receiving tank RTB008 and transfer intermittently to RTB032 till no more toluene distils by observing through view glass. *Note:N,N-Dimethyl-3-Phenyl-3-Hydroxy-Propylamine is obtained as a thick residue.*	12-00	22-45	10-45	59.6	*Toluene distillate volume:* 2000L *B.No:* 2338101279	30/12/2023	30/12/2023

Note: Record the time, temperature and vacuum for every 30±5minutes in table–II. Use process parameters recording sheet for recording of time, temperature and vacuum if required.

Table – II

Time (Hr.– Min.)	Temperature (°C)	Vacuum (mmHg)	Done By	Time (Hr.– Min.)	Temperature (°C)	Vacuum (mmHg)	Done By
13-00	48.2	600	30/12/2023	17-30	51.4	600	30/12/2023
13-30	48.6	600	30/12/2023	18-00	51.8	600	30/12/2023
14-00	49.0	600	30/12/2023	18-30	52.2	600	30/12/2023
14-30	49.2	600	30/12/2023	19-00	53.6	675	30/12/2023
15-00	49.5	600	30/12/2023	19-30	54.2	675	30/12/2023
15-30	49.8	600	30/12/2023	20-00	54.8	675	30/12/2023
16-00	50.1	600	30/12/2023	20-30	55.2	675	30/12/2023
16-30	50.6	600	30/12/2023	21-00	56.4	675	30/12/2023
17-00	50.9	600	30/12/2023	21-31	56.9	675	30/12/2023

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Batch No.		Batch Size	350.0 Kg

Table – II

Time (Hr.– Min.)	Temperature (°C)	Vacuum (mmHg)	Done By	Time (Hr.– Min.)	Temperature (°C)	Vacuum (mmHg)	Done By
22:00	57.3	675	30/12/2023				
22:30	58.2	675	30/12/2023				
22:45	59.6	675	30/12/2023				
			30/12/2023				30/12/2023

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
43	Send the sample to QCD for Moisture content of residue	23:00	N.A.	N.A.	N.A.	–	30/12/2023	30/12/23
44	Results of Moisture content (Limit: NMT:1.0% w/w) Note: *If it is more than 1.0%w/w Proceed from step no. 45, otherwise continue the step no. 48.*	N.A.	00:40	N.A.	N.A.	For results Refer In-process sheet	31/12/2023	31/12/23

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Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
45	Continue the toluene distillation below 60°C (NLT 570 mmHg) to reactor SRB006 into receiving tank RTB008 and transfer intermittently to RTB032 till no more toluene distils by observing through view glass. *Note: N,N-Dimethyl-3-Phenyl-3-Hydroxy-Propylamine is obtained as a thick residue.*	–	–	–	–	*Toluene distillate volume:* – *L* *B.No:* –	–	–

Note: Record the time, temperature and vacuum for every 30±5minutes in table–III. Use process parameters recording sheet for recording of time, temperature and vacuum if required.

Table – III

Time (Hr.– Min.)	Temperature (°C)	Vacuum (mmHg)	Done By	Time (Hr.– Min.)	Temperature (°C)	Vacuum (mmHg)	Done By
			31/12/2023				31/12/2023

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
46	Send the sample to QCD for Moisture content of residue	–	N.A.	N.A.	N.A.	–	–	–
47	Results of Moisture content (Limit: NMT:1.0% w/w)	N.A.	–	N.A.	N.A.	For results Refer In-process sheet	–	–
48	Charge Dimethylsulfoxide (DMSO) 1400 L from storage tank STB010 into the reactor SRB006 at 25-30°C. (as per the SOP No. UIIMF055)	00-50	01-40	00-50	28.4	–	31/12/2023	31/12/2023
49	Start stirring, until clear solution is observed ***Note: (It take ~15 minutes to get clear solution reaction mass is a clear colorless solution).***	01-40	01-55	00-15	N.A.	*Clear solution Obtained/ Not*	31/12/2023	31/12/2023
50	**Inspect** reactor SRB012 for cleanliness. (as per SOP No. UIIMF116)	01-45	N.A.	N.A.	N.A.	–	31/12/2023	31/12/2023
51	***Safety precaution:*** *Ensure nitrogen inertization procedure is followed as per the SOP UIIMF046 before starting the operation.*							
	Transfer the reaction mass from reactor SRB006 to reactor SRB012.	01-55	02-35	00-40	N.A.	–	31/12/2023	31/12/2023
52	Wash the reactor SRB006 with (Dimethyl Sulfoxide) DMSO 87.5 L and transfer the washings to the reactor SRB012.	02-35	02-50	00-15	N.A.	–	31/12/2023	31/12/2023
53	*Sodium hydroxide pellets Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles*							
	Start stirring, add slowly sodium hydroxide pellets 238.0 Kg to the reactor SRB012. (as per the SOP No. UIIMF055) at 25-30°C under nitrogen atmosphere.	02-50	03-25	00-35	28.2	–	31/12/2023	31/12/2023
54	*4-chlorobenzotrifloride Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles*							
	Add slowly 4-chlorobenzotrifloride 308.0 Kg to the reactor SRB012. (as per the SOP No. UIIMF055) above the reaction mass temperature at 25-30°C.	03-25	03-55	00-30	28.6	–	31/12/2023	31/12/2023
55	***Raise the temperature of the reaction mass at 92-95°C. Note: colour of reaction mass changes to light brown colour.***	03-55	06-30	02-35	92.8	–	31/12/2023	31/12/2023

	BATCH PRODUCTION AND CONTROL RECORD		
Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
56	Stir the reaction mass at 92-95°Ctill N,N-Dimethyl-3-Phenyl-3-Hydroxy-Propylamine content NMT 3.0% ***it takes~30 hours to achieve this.*** ***Note: After completion of reaction colour of the reaction mass is brown colour.***	06-30	15-00	32-30	94.5	For results Refer In-process sheet	Leena 01/01/2024	01/01/2024

Note: 1.Record the time and temperature for every 01±5minutes in table –IV. Use process parameters recording sheet for recording of time, temperature and use additional in-process sampling sheet for additional in-process sampling if required.
2. Send sample to QCD for HPLC analysis after 30 hour maintenance and after that every 2hour intervals till N,N-*Dimethyl-3 Phenyl-3-Hydroxy-Propylamine content NMT3.0%*
3. While perform in-process sampling follow the current version of SOP No. UIIMF007.

Table – IV

Time (Hr. – Min.)	Temperature (°C)	Done By	Time (Hr. – Min.)	Temperature (°C)	Done By
07-30	93.4	S 31/12/2023	01-32	94.5	01/01/2024
08-32	93.8	S 31/12/2023	02-30	94.2	01/01/2024
09-30	94.1	S 31/12/2023	03-30	94.1	01/01/2024
10-31	94.4 ~~99~~ 31/12/2023	S 31/12/2023	04-31	94.3	01/01/2024
11-30	94.7	S 31/12/2023	05-30	94.4	01/01/2024
12-31	94.0	S 31/12/2023	06-30	94.7	DLR 01/01/2024
13-30	94.5	S 31/12/2023	07-31	94.6	DLR 01/01/2024
14-30	94.6	DLR 31/12/2023	08-30	94.6	DLR 01/01/2024
15-31	94.5	DLR 31/12/2023	09-31	94.6	DLR 01/01/2024
16-30	93.9	DLR 31/12/2023	10-30	94.5	DLR 01/01/2024
17-30	94.1	DLR 31/12/2023	11-31	94.5	DLR 01/01/2024
18-29	94.5	DLR 31/12/2023	12-30	94.5	DLR 01/01/2024
19-30	94.2	DLR 31/12/2023	13-31	94.5	DLR 01/01/2024
20-31	93.6	DLR 31/12/2023	14-30	94.6	Leena 01/01/2024
21-30	93.8	DLR 31/12/2023	15-00	94.5	Leena 01/01/2024
22-30	94.0	31/12/2023	–	–	–
23-30	94.1	31/12/2023	–	–	–
00-30	94.3	01/01/2024	–	–	–

	BATCH PRODUCTION AND CONTROL RECORD		
Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Table – IV

Time (Hr. – Min.)	Temperature (°C)	Done By	Time (Hr. – Min.)	Temperature (°C)	Done By
		Leena 01/01/2024			Leena 01/01/2024

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
57	After HPLC complies, cool the reaction mass of reactor SRB012 temperature to 80°C. (as per the SOP No. UIIMF029)	15-10	16-00	00-50	80.0	-	Leena 01/01/2024	01/01/2024
58	Charge purified water 1400 L into the reactor SRB012 at 80-60°C. (as per the SOP No. UIIMF055).	16-00	17-00	01-00	67.2	-	Leena 01/01/2024	01/01/2024
59	**Inspect** reactor SRB010 for cleanliness. (as per SOP No. UIIMF116)	16-45	N.A.	N.A.	N.A.	-	Neeraj 01/01/2024	01/01/2024
60	***Safety precaution:*** *Ensure nitrogen inertization procedure is followed as per the SOP UIIMF046 before starting the operation.*							
	Transfer the total mass from reactor SRB012 to reactor SRB010.	17-00	17-30	00-30	N.A.	-	Leena 01/01/2024	01/01/2024
61	Stir the reaction mass for 15 minutes at 80-60°C.	17-30	17-45	00-15	66.5	-	Neeraj 01/01/2024	-
62	Charge toluene 1400 L into the reactor SRB010 from day tank DTB006 for fresh toluene charging and recovery toluene charging from receiving tank RTB031/RTB033/RTB034/RTB035 through receiving tank RTB028 (1.0 KL) lot wise at 60–65°C. (as per the SOP No. UIIMF055).	17-45	18-30	00-45	61.6	-	Neeraj 01/01/2024	01/01/2024
63	Stir the reaction mass for 30 minutes at 60-65°C.	18-30	19-00	00-30	62.3	-	Neeraj 01/01/2024	-
64	Stop stirring and settle the reaction mass into reactor SRB010 for 30 minutes at 60–65°C.	19-00	19-30	00-30	63.1	-	Neeraj 01/01/2024	-
65	Separate the bottom aqueous layer into the receiving tank RTB026 at 60-65°C.	19-30	20-35	01-05	63.0	*Aqueous layer Volume:* 3260 L	Neeraj 01/01/2024	01/01/2024
66	Unload the organic layer into receiving tank RTB027 at 60-65°C.	20-35	21-10	00-35	62.8	*Organic layer Volume:* 1990 L	Neeraj 01/01/2024	01/01/2024
67	Transfer the aqueous layer from receiving tank RTB026 to the reactor SRB010.	21-10	21-52	00-42	N.A.	-	Neeraj 01/01/2024	01/01/2024

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
Toluene is Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles.								
68	Charge toluene 350 L into the reactor SRB010 from day tank DTB006 for fresh toluene charging and recovery toluene charging from receiving tank RTB031/RTB033/RTB034/RTB035 through receiving tank RTB028 (1.0 KL) at 60–65°C. (as per SOP No.UIIMF055)	21-52	22-20	00-28	61.7	–	01/01/2024	VL 01/01/2024
69	Stir the contents of the reactor SRB010 for 30 minutes at 60 – 65°C.	22-20	22-50	00-30	62.6	–	01/01/2024	–
70	Stop stirring and settle the contents of the reaction mass into reactor SRB010 for 30 minutes at 60-65°C.	22-50	23-20	00-30	62.9	–	01/01/2024	–
71	Separate the bottom aqueous layer into the receiving tank RTB026 at 60-65°C.	23-20	00-30	01-10	62.7	*Aqueous layer Volume:* 32.50 L	02/01/2024	VL 02/01/2024
72	Unload the organic layer into the receiving tank RTB027 at 60-65°C.	00-30	00-50	00-20	62.4	–	02/01/2024	VL 02/01/2024
73	Transfer the aqueous layer from receiving tank RTB026 to the reactor SRB010.	00-50	01-30	00-40	N.A.	–	02/01/2024	VL 02/01/2024
74	*Toluene is Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles.* Charge toluene 350 L into the reactor SRB010 from day tank DTB006 for fresh toluene charging and recovery toluene charging from receiving tank RTB031/RTB033/RTB034/RTB035 through receiving tank RTB028 (1.0 KL) at 60–65°C. (as per SOP No.UIIMF055)	01-30	02-00	00-30	61.1	–	02/01/2024	VL 02/01/2024
75	Stir the contents of the reactor SRB010 for 30 minutes at 60–65°C.	02-00	02-30	00-30	61.9	–	02/01/2024	–
76	Stop stirring and settle the contents of the reactor SRB010 for 30 minutes at 60–65°C.	02-30	03-00	00-30	62.4	–	02/01/2024	–
77	Separate the bottom aqueous layer into the receiving tank RTB026 ***(collect the aqueous layer for Dimethylsulfoxide Recovery)*** at 60 – 65°C.	03-00	04-05	01-05	62.8	*DMSO* ***aqueous layer*** *Volume:* 32.40 L	02/01/2024	VL 02/01/2024
78	Transfer the total organic layer from receiving tank RTB027 to the reactor SRB010.	04-05	05-00	00-55	N.A.	–	02/01/2024	VL 02/01/2024

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min)			Temp. (°C)	Remarks/In-process Results	Done By	Checked By
		From	To	Duration				
79	Start stirring and charge purified water 350 L into the reaction mass of the reactor SRB010 at 60-65°C. (as per the SOP No. UIIMF055).	05-00	05-35	00-35	61.9	–	02/01/2024	02/01/2024
80	Adjust the pH of the reaction mass with Con. Hydrochloric Acid (10.5 L) pH: 6.5-7.0 at 60 – 65°C.	05-35	06-20	00-45	62.4	–	02/01/2024	02/01/2024
81	Send the sample to QCD for pH (as per SOP No: UIIMF007).	06-35	N.A.	N.A.	N.A.	–	02/01/2024	02/01/2024
82	Result of pH. *[Limit : pH : 6.5 – 7.0]*	N.A.	07-25	N.A.	N.A.	For results Refer In-process sheet	02/01/2024	02/01/2024
83	Stir the contents of the reactor SRB010 for 30 minutes at 60–65°C.	07-35	08-05	00-30	62.6	–	02/01/2024	–
84	Stop stirring and settle the contents of the reactor SRB010 for 30 minutes at 60 – 65°C.	08-05	08-35	00-30	63.3	–	02/01/2024	–
85	Separate the bottom aqueous layer into receiving tank RTB026 at 60–65°C.	08-35	09-00	00-25	63.4	*Aqueous layer quantity:* 370 L	02/01/2024	02/01/2024
86	Total organic layer wash with purified water 350 L into reactor SRB010 at 60-65°C.	09-00	09-25	00-25	61.5	–	02/01/2024	02/01/2024
87	Stir the content of the reactor SRB010 for 30 minutes at 60-65°C.	09-25	09-55	00-30	62.3	–	02/01/2024	–
88	Stop stirring and settle the contents of the reactor SRB010 for 30 minutes at 60 – 65°C.	09-55	10-25	00-30	63.1	–	02/01/2024	–
89	Separate the bottom aqueous layer into receiving tank RTB026 at 60 – 65°C.	10-25	10-55	00-30	63.4	*Aqueous layer quantity:* 350 L	02/01/2024	02/01/2024
90	Send organic layer sample to QCD for N,N-Dimethylamino-3-Phenyl-3-hydroxypropylamine content NMT1.0% ***Note: Aqueous layer traces shall not be carried out into organic layer by taking care.***	11-10	N.A.	N.A.	N.A.	–	02/01/2024	02/01/2024
91	Results of N,N-Dimethylamino-3-Phenyl-3-hydroxypropylamine content NMT1.0% *Note: If results is N,N-Dimethylamino-3-Phenyl-3-hydroxy-propylamine content more than 1.0%, proceeds from step.92 otherwise proceed from step no.98.*	N.A.	14-02	N.A.	N.A.	For results Refer In-process sheet	02/01/2024	02/01/2024
92	Total organic layer wash with purified water 350 L into reactor SRB010 at 60-65°C.	–	–	–	–	–	–	–
93	Stir the contents of the reactor SRB010 for 30 minutes at 60-65°C.	–	–	–		–	–	–

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
94	Stop stirring and settle the contents of the reactor SRB010 for 30 minutes at 60 – 65°C.	–	–	–	–	–	–	–
95	Separate the bottom aqueous layer into receiving tank RTB026 at 60 – 65°C.	–	–	–	–	*Aqueous layer quantity: — L*	–	–
96	Send organic layer sample to QCD for HPLC N,N-Dimethylamino-3-Phenyl-3-hydroxypropylamine content NMT1.0% ***Note: Aqueous layer traces shall not be carried out into organic layer by taking care.***	–	N.A.	N.A.	N.A.	–	–	–
97	Results of HPLC N,N-Dimethylamino-3-Phenyl-3-hydroxypropylamine content NMT1.0%.	N.A.	–	N.A.	N.A.	For results Refer In-process sheet	–	–
98	**Inspect** reactor GLB007 for cleanliness (as per SOP No. UIIMF116)	18-10	N.A.	N.A.	N.A.	–	Loing 02/01/2024	02/01/2024
99	***Safety precaution:*** *Ensure nitrogen inertization procedure is followed as per the SOP UIIMF046 before starting the operation.*							
	Total organic layer transfer from reactor SRB010 to reactor GLB007.	18-20	18-50	00-30	N.A.	–	Loing 02/01/2024	02/01/2024
100	Heat the reaction mass to 100-112°C.	18-50	20-00	01-10	106.1	–	Loing 02/01/2024	02/01/2024
101	***Maintain the reaction mass at reflux temperature (100-112°C) separate water from the Azeotropic distillation till water collection stops***	20-00	21-33	01-33	108.7	For results Refer In-process sheet	Loing 02/01/2024	02/01/2024

Note: 1.Record the time and temperature for every 30±5minutes in table –V. Use process parameters recording sheet for recording of time, temperature and use additional in-process sampling sheet for additional in-process sampling if required.

2. After water collection stopped, Send sample to QCD for water content limit NMT0.10% w/w.
3. *If water content Less than 0.10%w/w proceed form step no. 102 otherwise continue Azeotropic distillation at atmospheric pressure and remove water send sample to QCD for water content Limit: NMT 0.10%w/w.*
4. *While perform in-process sampling follow the current version of SOP No. UIIMF007.*

Table – V

Time (Hr. – Min.)	Temperature (°C)	Done By	Time (Hr. – Min.)	Temperature (°C)	Done By
20-30	107.8	Loing 02/01/2024			
21-00	108.2	Loing 02/01/2024			
21-33	108.7	Loing 02/01/2024			
–	–	–			
–	–	–			
–	–	–			
–	–	–			
–	–	–			Loing 02/01/2024

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
102	Cool the reaction mass to 75 – 80°C. (as per SOP No. UIIMF029) *Note: Under Nitrogen atmosphere.*	21-45	00-30	02-45	78.2	–	03/01/2024	VL 03/01/2024
103	*Toluene is Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles.*							
	Charge 399 L Toluene into the addition tank ATB013 from day tank DTB006 for fresh toluene charging and recovery toluene charging from receiving tank RTB031/RTB033/RTB034/RTB035. (as per SOP No.UIIMF055)	00-00	00-15	00-15	N.A.	–	03/01/2024	VL 03/01/2024
		01-15	01-30	00-15		–	03/01/2024	VL 03/01/2024
Note: while charging wear breathing air suit, gloves, goggles and nose mask.								
104	Charge Ethyl chloroformate 312.2 Kg into the addition tank ATB013. (as per SOP No.UIIMF055)	00-15	00-25	00-10	N.A.	–	03/01/2024	VL 03/01/2024
		01-30	01-40	00-10		–	03/01/2024	VL 03/01/2024
105	***Add ethyl chloroformate + toluene solution from addition tank ATB013 to reactor GLB007 at 75–80°C in 2hrs±10 minutes under nitrogen atmosphere. Note: This addition is exothermic and maintain the reaction mass temperature at 75 – 80°C by controlling the addition rate.***	00-30	02-40	02-10	78.2	–	03/01/2024	VL 03/01/2024

Note: 1.Record the time and temperature for every 15±5minutes in table –VI. Use process parameters recording sheet for recording of time, temperature and use additional in-process sampling sheet for additional in-process sampling if required.

Table – VI

Time (Hr. – Min.)	Temperature (°C)	Done By	Time (Hr. – Min.)	Temperature (°C)	Done By
00-45	77.6	03/01/2024	02-15	77.9	03/01/2024
01-00	77.6	03/01/2024	02-30	78.0	03/01/2024
01-15	77.7	03/01/2024	02-40	78.2	03/01/2024
01-30	77.8	03/01/2024	–	–	–
01-45	77.8	03/01/2024	–	–	–
02-00	77.9	03/01/2024	–	–	–

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
106	Stir the reaction mass of GLB007 for 1 hour ± 10 minutes at 75 – 80°C.	02-40	03-50	01-10	78.3	–	03/01/2024	VL 03/01/2024
107	Charge Triethylamine 28.0 Kg into the reactor GLB007 at 75-80°C in 5-10 minutes. (as per SOP No. UIIMF055).	03-50	04-00	00-10	78.4	–	03/01/2024	VL 03/01/2024

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
	Toluene is Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles.							
108	Charge 42 L Toluene into the addition tank ATB013 from day tank DTB006 for fresh toluene charging and recovery toluene charging from receiving tank RTB031/RTB033/ RTB034/RTB035. (as per SOP No.UIIMF055)	03-30	03-40	00-10	N.A.	–	03/01/2024	03/01/2024
	Note: while charging wear breathing air suit, gloves, goggles and nose mask.							
109	Charge Ethyl chloroformate 28.0 Kg into the addition tank ATB013. (as per SOP No.UIIMF055)	03-40	03-55	00-15	N.A.	–	03/01/2024	03/01/2024
110	Add ethyl chloroformate + toluene solution from addition tank ATB013 to reactor GLB007 by maintain the temperature at 75–80°C in 5-10 minutes under nitrogen atmosphere.	04-00	04-10	00-10	78.2	–	03/01/2024	03/01/2024
111	Maintain the reaction mass of GLB007 at 75-80°C and send sample to QCD for HPLC till *N-Methylfluoxetine content is less than 2.0%.* (as per SOP No: UIIMF007). ***Note: It takes ~1 hour to achieve.***	04-10	08-25	04-15	77.1	For results Refer In-process sheet	03/01/2024	03/01/2024

Note: 1.Record the time and temperature for every 15±5minutes in table –VII. Use process parameters recording sheet for recording of time, temperature and use additional in-process sampling sheet for additional in-process sampling if required.

2. Send sample to QCD after1 hour maintain for N-Methylfluoxetine content should be NMT 2.0%. If reaction is not meeting with the specification proceed from step no.112. Otherwise proceed from step no.117.

3. While performing in-process sampling follow the current version of SOP No. UIIMF007.

***** Unreacted N-Methylfluoxetine =Batch size X unreacted % N-Methyl Fluoxetine content by HPLC % area normalization.***

Quantity of Ethylchloroformate to be added= Unreacted N-Methylfluoxetine X66.9X 3 / 75

$$= \left(\frac{\text{–} \times 66.9}{\text{–}\ 75} \right) X3 = \text{–}\ L$$

Quantity of Toluene for Ethylchloro formate Mixture = 1.95 X Quantity of Ethyl chloroformate

= 1.95 X _____ = – L

Table –VII

Time (Hr. – Min.)	Temperature (°C)	Done By	Time (Hr. – Min.)	Temperature (°C)	Done By
04-25	78.2	03/01/2024	04-55	78.3	03/01/2024
04-40	78.2	03/01/2024	05-10	78.3	03/01/2024

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Table –VII

Time (Hr. – Min.)	Temperature (°C)	Done By	Time (Hr. – Min.)	Temperature (°C)	Done By
05-25	78.3	03/01/2024	08.10	77.2	03/01/2024
05-40	78.3	03/01/2024	08.25	77.1	03/01/2024
05-55	78.4	03/01/2024			
06-10	78.6	03/01/2024			
06.25	78.7	03/01/2024			
06.40	78.5	03/01/2024			
06.55	78.3	03/01/2024			
07-10	78.1	03/01/2024			
07.25	77.8	03/01/2024			
07-40	77.6	03/01/2024			
07-55	77.4	03/01/2024			03/01/2024

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
	Toluene is Highly flammable, may be if swallowed, skin, respiratory and eye irritant, toxic if inhaled. Ensure closed handling, grounding and bonding, inertion with nitrogen. Use gloves, nose masks and goggles.							
112	Charge ____ L Toluene into the addition tank from day tank DTB006 for fresh toluene charging and recovery toluene charging from receiving tank RTB031/RTB033/ RTB034/RTB035. (as per SOP No.UIIMF055)				N.A.			
	Note: while charging wear breathing air suit, gloves, goggles and nose mask.							
113	Charge Ethyl chloroformate ____Kg into the addition tank (as per SOP No.UIIMF055)				N.A.			
114	Add ethyl chloroformate + toluene solution from addition tank ATB013 to reactor GLB007 by maintain the temperature at 75–80°C in 5-10 minutes under nitrogen atmosphere.							
115	Maintain the reaction mass of GLB007 at 75-80°C and send sample to QCD for HPLC till *N-Methylfluoxetine content is less than 2.0%.* (as per SOP No: UIIMF007). ***Note: It takes ~1 hour to achieve.***					For results Refer In-process sheet	03/01/2024	

Note: 1.Record the time and temperature for every 15±5minutes in table –VIII. Use process parameters recording sheet for recording of time, temperature and use additional in-process sampling sheet for additional in-process sampling if required.
2. Send sample to QCD after1 hour N-Methylfluoxetine content is less than 2.0%.
3. While performing in-process sampling follow the current version of SOP No. UIIMF007

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Table –VIII

Time (Hr. – Min.)	Temperature (°C)	Done By	Time (Hr. – Min.)	Temperature (°C)	Done By
		03/01/2024			03/01/2024

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
116	Charge purified water 1225 L into the receiver RTB038 in single lot / RTB007 lot wise (625 L + 600 L) (as per SOP No.UIIMF055) (apply hot water circulation to the jacket and heat 75-80°C).	07.30	08.20	00.50	76.2	–	03/01/2024	03/01/2024
		09.05	09.35	00.30	76.8	–	03/01/2024	03/01/2024
117	Charge preheated purified water from receiver RTB038/RTB007 (as per SOP No.UIIMF055) to reactor GLB007 at 75 – 80°C. ***Note: If temperature is low layer separation is not clear.***	08.35	09.00	00.25	77.3	–	03/01/2024	03/01/2024
		09.40	10.00	00.20	77.6	–	03/01/2024	03/01/2024
118	Stir the reaction mass for 10-15 minutes at 75-80°C in the reactor GLB007.	10.00	10.15	00.15	77.2	–	03/01/2024	03/01/2024
119	Send the sample to QCD for pH (as per SOP No. UIIMF007)	10.30	N.A.	N.A.	N.A.	–	03/01/2024	03/01/2024
120	Result of pH (Limit: pH 1.5 ±0.5) *Note: If pH is not within the limit proceed from step no.121, otherwise proceed for step no.124.*	N.A.	11.15	N.A.	N.A.	For results Refer In-process sheet	03/01/2024	03/01/2024
121	Adjust the pH (1.5 ± 0.5) with conc. Hydrochloric acid.	11.20	11.45	00.25	N.A.	*HCL Qty:* 12 L	03/01/2024	03/01/2024
122	Send the sample to QCD for aqueous layer pH (as per SOP No. UIIMF007).	12.00	N.A.	N.A.	N.A.	–	03/01/2024	03/01/2024
123	Result of pH (Limit: pH 1.5 ±0.5)	N.A.	12.32	N.A.	N.A.	For results Refer In-process sheet	03/01/2024	03/01/2024
124	Stir the reaction mass for 30 minutes at 75-80°°C.	12.40	13.10	00.30	76.8	–	03/01/2024	–
125	Settle the reaction mass for 30 minutes at 75-80°C of the reactor GLB007.	13.10	13.40	00.30	76.6	–	03/01/2024	–

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
126	Separate the bottom aqueous layer into FRP tank/containers.	13-40	14-43	01-03	N.A.	–	03/01/2024	03/01/2024
127	Send Organic layer sample to QCD for HPLC for N-Methylfluoxetine content (as per SOP No. UIIMF007).	14-55	N.A.	N.A.	N.A.	–	03/01/2024	03/01/2024
128	Result of HPLC N-Methylfluoxetine content NMT0.15% ***Note: (If N-Methylfluoxetine content is not within the limit proceed from step no. 129, otherwise proceed step no, 142.***	N.A.	16-50	N.A.	N.A.	For results Refer In-process sheet	03/01/2024	03/01/2024
129	Charge 1750 L purified water into the reactor GLB007 at 75-80°C (as per the SOP No. UIIMF055).							
130	Stir the reaction mass in the reactor GLB007 for 30 minutes.				N.A.			
131	Send the sample to QCD for pH (as per SOP No. UIIMF007)		N.A.	N.A.	N.A.			
132	Result of pH (Limit: pH 1.5 ±0.5) ***Note: If pH is not within the limit proceed from step no133, otherwise proceed for step no.137***	N.A.		N.A.	N.A.	For results Refer In-process sheet		
133	Adjust the pH (1.5 ± 0.5) with conc. Hydrochloric acid				N.A.	*HCL Qty: L*		
134	Stir the reaction mass in the reactor GLB007 for 10 minutes at 75-80°C.							
135	Send the sample to QCD for aqueous layer of pH (as per SOP No.		N.A.	N.A.	N.A.			
136	Result of pH (Limit: pH 1.5 ±0.5)	N.A.		N.A.	N.A.	For results Refer In-process sheet		
137	Stir the reaction mass for 30 minutes				N.A.			
138	Settle the reaction mass for 30 minutes at 75-80°C of the reactor GLB007.							
139	Separate the bottom aqueous layer into FRP tank/containers.				N.A.			
140	Send the sample to QCD for HPLC of Organic layer (as per SOP No. UIIMF007).		N.A.	N.A.	N.A.			
141	Result of HPLC *(Limit of N-Methylfluoxetine content. NMT 0.15%)*	N.A.		N.A.	N.A.	For results Refer In-process sheet	03/01/2024	
142	**Discard the aqueous layer**	16-55	17-35	00-40	N.A.	–	03/01/2024	03/01/2024

	BATCH PRODUCTION AND CONTROL RECORD		
Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
143	Heat and Apply vacuum (NLT 570 mmHg) to reactor GLB007 and distil toluene up to 100°C into receiving tank RTB030 and intermittently transfer in to RTB033 till no more solvent distils by observing through view glass. ***Note: Collect the distillate for toluene recovery***	17-35	07-30	13-55	94.2	*Toluene Distilled volume* 2500 L	04/01/2024	04/01/2024

Note: 1.Record the time and temperature for every 30±5minutes in table –IX. Use process parameters recording sheet for recording of time, temperature and use additional in-process sampling sheet for additional in-process sampling if required.
2. Continuous Distillation under vacuum NLT 570 mmHg.

Table –IX

Time (Hr. – Min.)	Temperature (°C)	Vacuum (mmHg)	Done By	Time (Hr. – Min.)	Temperature (°C)	Vacuum (mmHg)	Done By
18-15	64.2	600	03/01/2024	05-15	89.7	675	04/01/2024
18-44	61.5	600	03/01/2024	05-45	91.4	675	04/01/2024
19-15	59.8	600	03/01/2024	06-17	92.1	675	04/01/2024
19-45	58.3	600	03/01/2024	06-45	92.8	675	04/01/2024
20-16	58.1	600	03/01/2024	07-15	93.5	675	04/01/2024
20-45	57.9	600	03/01/2024	07-30	94.2	675	04/01/2024
21-15	58.3	600	03/01/2024	-	-	-	-
21-47	58.7	600	03/01/2024	-	-	-	-
22-15	61.5	600	03/01/2024	-	-	-	-
22-45	64.2	675	03/01/2024	-	-	-	-
23-15	67.8	675	03/01/2024	-	-	-	-
23-46	69.4	675	03/01/2024	-	-	-	-
00-15	71.1	675	04/01/2024	-	-	-	-
00-45	72.6	675	04/01/2024	-	-	-	-
01-14	74.3	675	04/01/2024	-	-	-	-
01-45	76.7	675	04/01/2024	-	-	-	-
02-14	78.9	675	04/01/2024	-	-	-	-
02-45	80.0	675	04/01/2024	-	-	-	-
03-15	81.6	675	04/01/2024	-	-	-	-
03-46	84.2	675	04/01/2024	-	-	-	-
04-15	86.8	675	04/01/2024	-	-	-	-
04-45	88.3	675	04/01/2024	-	-	-	-

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
144	Continue the distillation and maintain the reactor temperature at 90- 100°C under vacuum (NLT 620 mmHg) to the reactor GLB007 for 30-40 minutes. ***Note: results an oily mass.***	07-30	08-10	00-40	99.2	*Vacuum:* 690 *Total Toluene Distilled volume* 2510 *L*	04/01/2024	04/01/2024
145	Cool the reaction mass to 60 – 65°C.(as per SOP No. UIIMF029)	08-10	09-15	01-05	64.3	–	04/01/2024	–
146	Charge purified water 1001 L into the reactor GLB007 at 65–40°C. (as per SOP No.UIIMF055)	09-15	10-00	00-45	48.6	–	04/01/2024	04/01/2024
	Note: while charging wear gloves, goggles and nose mask.							
147	Charge hexane 441 L into the reactor GLB007 at 40 – 50°C (as per the SOP No. UIIMF055) ***Note: Use AODD pump for solvent transfer from containers to reactor***	10-00	10-30	00-30	43.9	–	04/01/2024	04/01/2024
148	Stir for 30 minutes at 40-45°C.	10-30	11-00	00-30	41.1	–	04/01/2024	–
149	Cool the reaction mass to 20 – 25°C in 1 hour 30 minutes. (as per SOP No. UIIMF029) Note: ***Product starts crystallizing out***	11-00	12-30	01-30	24.1	***Product starts crystallizing out / Not***	04/01/2024	–
150	Stir the content for 1 hour at 20-25°C.	12-30	13-30	01-00	20.6	–	04/01/2024	–
151	Further Cool the slurry mass to 2 – 5°C in 1hour 30 minutes. (as per SOP No. UIIMF029)	13-30	15-00	01-30	4.8	–	04/01/2024	04/01/2024
152	Stir the slurry mass of the reactor GLB007 for 1 hour 30 minutes at 2-5°C.	15-00	16-30	01-30	3.2	–	04/01/2024	–
153	**Inspect** Agitated Nutsche Filter Dryer AFB001 for cleanliness. (as per SOP UIIMF116).	15-45	N.A.	N.A.	N.A.	–	04/01/2024	04/01/2024
154	Visually check the agitator rotation is in forward direction after switch on the Agitated Nutsche Filter Dryer AFB001 and material discharge valve should be closed. (as per SOP UIIMF194).	15-55	16-05	00-10	N.A.	✓ Ok / Not Ok	04/01/2024	04/01/2024
155	Ensure bag is fitted appropriately, Sufficient supply of nitrogen & vacuum supply valves are in condition.	16-05	16-15	00-10	N.A.	–	04/01/2024	04/01/2024
156	156.1. Keep the agitator at top level.	16-15	16-20	00-05	N.A.	–	04/01/2024	04/01/2024

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
	156.2. Feed the material into Agitated Nutsche Filter Dryer AFB001 from Reactor GLB007 and collect the mother liquor (ML's) into receiving tank RTB014/ RTB016.	16-30	18-00	01-30	N.A.	–	04/01/2024	04/01/24
	156.3. Apply nitrogen pressure ~2.0 Kg/cm2 and collect the mother liquor (ML's) into receiving tank RTB014/RTB016.	18-00	19-50	01-50	N.A.	–	04/01/2024	04/01/24
	156.4. Rotate the agitator in forward direction for pressing the material for 30 min under nitrogen pressure and collect the mother liquor (ML's) into receiving tank RTB014/ RTB016.	19-50	20-20	00-30	N.A.	–	04/01/2024	04/01/24
	156.5. Keep the agitator in forward direction for ~15 min (Take agitator blade up and down 2 to 3 time).	20-20	20-35	00-15	N.A.	–	04/01/2024	04/01/24
	156.6. Wash the reactor GLB007 with a mixture of Purified water 35 L and Hexane 35 L (1:1) under stirring (as per the SOP No. UIIMF055) and cool the reactor at 5–10°C (as per the SOP No. UIIMF029).	19-00	19-40	00-40	7.6	–	04/01/2024	04/01/24
	156.7. Wash the cake with mixture of Purified water 35 L and Hexane 35 L (1:1) from Reactor GLB007 and run the Agitated Nutsche Filter Dryer AFB001 forward direction and collect the mother liquor (ML's) into receiving tank RTB014/ RTB016. ***Note: Before washing, Ml's expulsion valve should be closed.***	20-35	20-50	00-15	N.A.	–	04/01/2024	04/01/24
	156.8. Press the material under nitrogen pressure and collect the mother liquor (ML's) into receiving tank RTB014/ RTB016.	20-50	23-25	02-35	N.A.	*Total Recovered hexane volume* 340L	04/01/2024	04/01/2024
	156.9. Keep the agitator in forward direction for ~15 min (Take agitator blade up and down 2 to 3 time).	23-25	23-40	00-15	–	–	04/01/2024	04/01/2024

BATCH PRODUCTION AND CONTROL RECORD

Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

Step No.	Operations	Time (Hr–Min) From	To	Duration	Temp. (°C)	Remarks/In-process Results	Done By	Checked By
	156.10. Replace the nitrogen by applying vacuum to AFB001.	23-40	23-50	00-10	N.A.	-	Loing 04/01/2024	04/01/2024
	156.11. Rotate the agitator in reverse direction and dry the material under vacuum NLT 550 mmHg. (Agitator at Lower level) and maintain vacuum for 2 h±15 min.	23-50	01-50	02-00	N.A.	Vacuum: 710 mmHg	Loing 05/01/2024	05/01/2024
	156.12. Start hot water circulation to Agitated Nutsche Filter Dryer AFB001 and raise the temperature to 40 – 45°C.	01-50	03-25	01-35	40.2	-	Loing 05/01/2024	05/01/2024
	156.13. Dry the material at 40 – 45°C under vacuum NLT 550 mmHg for 28 hours. *Note: During drying agitator position should be at cutting position. (Reverse direction).*	03-25	07-25	28-00	N.A.	-	DLe 06/01/2024	06/01/2024

Note: Record the time, temperature and vacuum for every 1 hour±5 minutes in table–X.

Table – X

Time (Hr- Min)	Temperature (°C)	Vacuum (mmHg)	Done By	Time (Hr- Min)	Temperature (°C)	Vacuum (mmHg)	Done By
DAS	Attached	-	-				
			DLe 06/01/2024				DLe 06/01/2024

Step No.	Operations	Time (Hr–Min)			Temp. (°C)	Remarks/In-process Results	Done By	Checked By
		From	To	Duration				
	156.14.Cool the material to below 40°C by applying RT water circulation and release the vacuum by applying nitrogen. At Lower level (forward direction).	07-25	08-50	01-25	38.7	–	DLP 06/01/2024	06/01/2024
	156.15.Keep the agitator in reverse direction and unload the dried material into pre-weighed HDPE containers containing double LDPE Bags from Agitated Nutsche Filter Dryer AFB001.	08-50	12-00	03-10	N.A.	–	DLP 06/01/2024	06/01/2024
	156.16.Weigh the material and record the weights in Table-XI.	12-00	12-20	00-20	N.A.	–	DLP 06/01/2024	06/01/2024
157	After completion of drying, pack the material, paste "Quarantine" labels on HDPE containers and send requisition to QCD for complete analysis.	N.A.	–	N.A.	N.A.	N.A.	N.A.	N.A.

Table – XI

Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighing balance ID No.	Weighed by	Checked by
1.	3.02	31.22	28.20	WMB010/WMB011	DLP 06/01/2024	06/01/2024
2.	3.00	35.56	32.56			
3.	3.04	32.40	29.36			
4.	3.02	34.54	31.52			
5.	3.06	32.52	29.46			
6.	3.00	31.54	28.54			
7.	3.02	28.46	25.44			
8.	3.00	35.52	32.52			
9.	3.02	33.04	30.02			
10.	3.02	33.06	30.04			
11.	3.04	32.92	29.88			
12.	3.02	35.16	32.14			
13.	3.02	33.44	30.42			
14.	3.00	35.02	32.02			
15.	–	–	–			
16.	–	–	–			
Total Weight			422.12			

YIELD DETAILS

			Calculated By	Checked By
Theoretical yield	:	624.59 Kg		
Yield range	:	389.81 Kg (62.41%) to 476.37 Kg (76.27%)		
Obtained Yield	:	422.12 Kg		
Yield %	:	$\frac{100 \times 422.12}{624.59} = 67.58$ %	DLt 06/01/2024	06/01/2024

STORAGE CONDITIONS

Store in a well closed container, at controlled room temperature (Store at 25°C, excursion permitted between 15°C and 30 °C).

	BATCH PRODUCTION AND CONTROL RECORD		
Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.	2338101279	Batch Size	350.0 Kg

EQUIPMENT CLEANING DETAILS

Step No.	Equipment		Previous Batch No.	Time (Hr–Min)			Done By	Checked By
	Name	ID No.		From	To	Duration		
1	S.S. Reactor	SRB014	2338101278	18-30	20-45	02-15	28/12/2023	28/12/2023
5	S.S. Reactor	SRB014	2338101279	01-10	03-30	02-20	29/12/2023	29/12/2023
6	S.S. Reactor	SRB006	–	–	–	–	–	–
50	S.S. Reactor	SRB012	–	–	–	–	–	–
52	S.S. Reactor	SRB006	2338101279	03-00	05-15	02-15	31/12/2023	31/12/2023
59	S.S. Reactor	SRB010	2338101278	14-25	16-30	02-05	01/01/2024	01/01/2024
60	S.S. Reactor	SRB012	2338101279	18-30	21-10	02-40	01/01/2024	01/01/2024
98	G.L. Reactor	GLB007	–	–	–	–	–	–
99	S.S. Reactor	SRB010	2338101279	19-30	21-50	02-20	02/01/2024	02/01/2024
153	Agitated Nutsche Filter Dryer	AFB001	–	–	–	–	–	–
156.7	G.L. Reactor	GLB007	2338101279	22-10	00-50	02-40	05/01/2024	05/01/2024
156.15	Agitated Nutsche Filter Dryer	AFB001	2338101279	13-30	16-20	02-50	06/01/2024	06/01/2024

	BATCH PRODUCTION AND CONTROL RECORD		
Product Name		Market Code	U
Stage		MPCR No.	
BPCR Number		Revision Number	00
Batch No.		Batch Size	350.0 Kg

DESCRIPTION OF DEVIATIONS OBSERVED DURING BATCH PROCESSING

Date	Description of deviation	Justification	Signature

Date of Completion : 06/01/2024
Time of Completion : 17-20

06/01/2024
Signature of the Approved Manufacturing Chemist :

Signature of the Approved Quality control Chemist :

Signature of the QA Person :