## PRE FEASIBILITY REPORT FOR ENVIRONMENT CLEARANCES

## 1) EXECUTIVE SUMMARY :

M/s. Bizotic Life Science Pvt. Ltd. is to be involved in manufacturing of Bulk drugs & intermediate of 2 Ton of Pregablin per month within premises located at Plot No: 152/4/1, New Kharechiya, Dist. Morbi, State: Gujarat.

As the unit is going to add new products in synthetic organic chemical activity and project location is not within GIDC/notified industrial area, therefore it requires prior EC.). Bizotic will got EC from MoEF and valid CC&A for proposed products.

There shall be no forest, wild life sanctuary, eco sensitive area present within 10 km area from the project site.

The water required for domestic & industrial purpose will be sourced from municipal and tube wells located nearby project premises. Domestic effluent shall be disposed in to existing Septic tank / Soak pit system.

Industrial effluent after primary, secondary and tertiary treatment and conforming to the prescribed standards shall be reused for green belt development within premise.

one common ETP is to be provided for M/s. Bizotic Life Science Pvt. Ltd & treat their combined effluent, as their quality of effluent have similar in nature & characteristics.

Hazardous waste generated from the process and other industrial activity will be stored in a separate hazardous storage area and then it will be disposed at nearest TSDF site for secured land filling or at hazardous waste incinerator facility.

The municipal solid wastes generated during operation phase will be collected in separate bin and disposed to nearest Nagar Palika or Gram Panchyat site.

Proper safety will be provided during storage, handling and use of hazardous substance.

Portable Fire Extinguishers shall be provided at key location.

Rain Water Harvesting System proposed within project premises to avoid wastage of rain fall.

The net plot area is 6475 Sq. mtr . The site is divided into 5 pockets varying from 200 Sq.mtr to 2300 Sq. mtr. depending upon site layout.

Total area of project site is 6475 Sq.mtr. Among These Total built up area is 2298 Sq. mtr.

Common Plot is 530 Sq.mtr. Internal Road Area is 2024 Sq. mtr. Open Parking Area is 206 S.q mtr & Open Land & Margin Area is 1418 Sq. mtr.

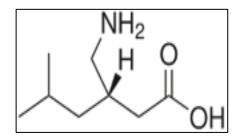
## 2. INTRODUCTION OF PROJECT / BACKGROUND INFORMATION

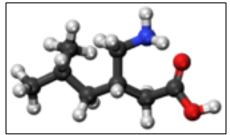
#### 2.1 IDENTIFICATION OF PROJECT AND PROJECT PROPONENT

M/s. Bizotic Life Science Pvt. Ltd Proposes to produce the Drugs. Of 2 Ton of Pregablin per month within premises located at Plot No: 152/4/1, New Kharechiya, Dist. Morbi, State: Gujarat.

**Pregabalin** is a *gamma*-Aminobutyricacidanaloganticonvulsant and analgesicused for neuropathic pain and as an add on therapy for partial seizures with or without secondary generalization in adults.

Molecular Structure of Pregabalin is as follows:





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The process of manufacture involves following steps:

Step 1: Preparation of (3R)-3-(carbamoylmethyl)-5-methyl hexanoic

acidphenyl ethyl amine salt

- Step 2: Preparation of (3R)-3-(carbamoylmethyl)-5-methyl hexanoic acid
- Step 3: Preparation of (3S)-3- (Aminomethyl)-5-methylhexanoic acid (Tech.

Pregabalin)

- Step 4: pH adjustment
- Step 5: Purification of technical grade pregabalin

Step 1A: Preparation of unwanted isomer from MLR

Step 1B: Conversion of unwanted isomer into Racemic compound

#### PROJECT PROPONENT

M/s. Bizotic Lifescience Pvt. Ltd. is a private limited company. Mr. Bharat Kunvaraji is a director of Company. The promoters are highly qualified and have global experience. Mr. Umesh Pokal is a manager of the company.

#### 2.2 NATURE OF THE PROJECT

The process for manufacturing of the bulk drugs has been developed by in-house R & D. The primary purpose of the manufacturing of products is to manufacture some life saving bulk drugs. Wastewater generated from process & utility will be treated in effluent treatment plant and after necessary treatment it will be utilized for gardening purpose within premises. There shall be no process emission from project.

#### 2.3 NEED FOR THE PROJECT

Due to market demand, Bizotic Life Science proposes to produce this drug for manufacturing of some important and some life saving drugs which are important for the human health.

#### 2.3 DEMAND / SUPPLY GAP

Not Avaliable

#### 2.4 IMPORT VS INDIGENOUS PRODUCTION

#### 2.6 EXPORT POSSIBILITY

Yes

#### 2.7 DOMESTIC/EXPORT MARKETS

Yes

## 2.8 EMPLOYMENT GENERATION (DIRECT & INDIRECT) DUE TO THE PROJECT

Due to addition of new products, employment will be increased. The unit will hire local people from the nearby villages. Due to addition of new products, employment

generation will be more than 6 people (4 men + 2 women). There is already 15 employees (9 men + 6 women) working at existing plant. Therefore Total employment from this project will be 21 people (13 men + 8 women).

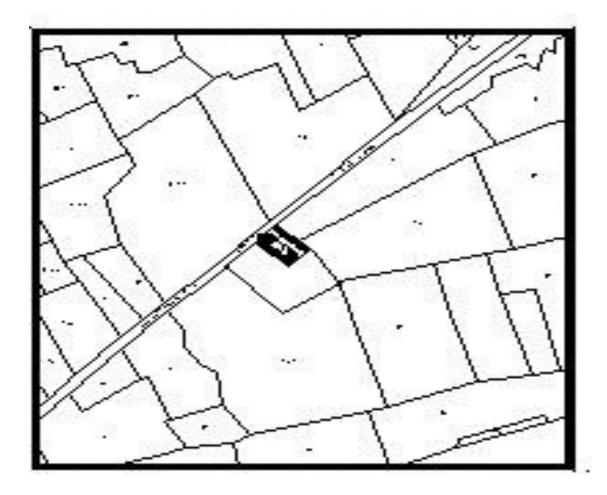
## 3. PROJECT DESCRIPTION:

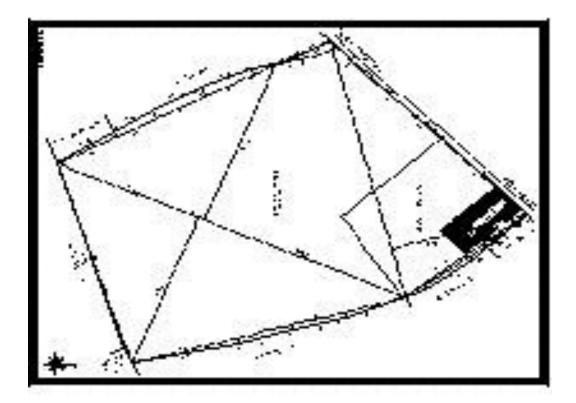
#### 3.1 TYPE OF PROJECT

The concept of proposed project is to manufacture 2 Ton of Pregabalin per month at proposed existing production facility.

#### 3.2 LOCATION

The latitude and longitude of the project site are between 22°81'46.72 "N and 70°82'93.15"E respectively.





#### **3.3 DETAILS OF ALTERNATE SITES**

There is No alternate site is considered for Bizotic Project.

#### 3.4 SIZE / MAGNITUDE OF OPERATION

Not Applicable

#### 3.5 PROJECT DESCRIPTION WITH PROCESS DETAILS

Project description with process, chemical reaction and mass balance is attached in Annexure - 1.

#### 3.6 RAW MATERIAL WITH REQUIRED QUANTITY, SOURCE, MARKETING AREA OF FINAL PRODUCTS, MODE OF TRANSPORT OF RAW MATERIAL AND FINISHED PRODUCT

For Product and Raw material with required quantity, please refer Annexure - 2.

#### 3.7 RESOURCE OPTIMIZATION / RECYCLING AND REUSE

Industrial effluent generated from the various processes will be treated in effluent treatment plant. Effluent after primary, secondary and tertiary treatment and conforming to the prescribed standards shall be utilized for gardening within premises. Rain water harvesting will be adopted.

#### 3.8 AVAILABILITY OF WATER, ITS SOURCE, ENERGY / POWER REQUIREMENT AND SOURCE

#### Water Availability & Its Source

Source of Water: Bore well & Tube Well

#### Water Consumption

SL. NO.	USERS	FRESH WATER FEED (m3/ day)	RECYCL E FEED (m3/ day)	TOTAL FEED (m3/ day)
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A	Domestic	1	0	1
В	Industrial			
1	Process	1.6	0	1.6
2	Washing	2	0	2
3	Boiler Feed	0.5	0	0.5
4	Cooling Makeup	0.5	0	0.5
5	Gardening	0.5	2	2.5
6 Others (R.O. & Softening Rejects)		0.5		0.5
	· · · · · · · · · · · · · · · · · · ·			
	TOTAL	6.6	2	8.6

#### Energy / Power Requirement & Its Source

#### Proposed Energy details:

Source: Paschim Gujarat Vij Company Ltd. (PGVCL)

Connected Load: 500 KVA

## 3.9 QUANTITY OF WASTES TO BE GENERATED (LIQUID AND SOLID) AND SCHEME FOR THEIR MANAGEMENT / DISPOSAL

(A)Quantity of Liquid Waste to be Generated & Its Management / Disposal:

SL. NO.	USERS	EVAPORATIO N LOSSES (m3/day)	GROUND/SUMP PIT LOSSES (m3/day)	EFFLUENT GENERATIO N TO ETP (m3/day)
А	Domestic	0.03	0.2	0.77
В	Industrial			
1	Process	0.2		0
2	Washing	0.06		1.94
3	Boiler Feed	0.05		0.45
4	Cooling Makeup	0.475		0.025
5	Gardening		2.5	
6	Others (R.O. & Softening Rejects)			
		0.815	2.7	3
	TOTAL		6.7	

#### WASTEWATER GENERATION

#### DESCRIPTION OF EFFLUENT TREATMENT PLANT

The wastewater generated from process as well as from the utility will be given primary, secondary and tertiary treatment. The treated wastewater will be utilized for gardening purpose within premises. Thus, to evaluate ETP capacity, it is necessary to determine quantity of effluent generating and to be generated from plant and which is as under...

SL. NO.	USERS	RECYCLE @40 % EFFLUENT GENREATIO N BACK TO PLANT (m3/ day)	DISPOSA L to CETP (m3/day)
А	Domestic		
В	Industrial		
1	Process	n	
2	Washing	*	
3	Boiler Feed		
4	Cooling Makeup	1.27	1.91
5	Gardening	*	
6	Others (R.O. & Softening Rejects)	-	
	TOTAL	3.18	3

## (B)Quantity of Solid Waste to be Generated & Its Management / Disposal:

Hazardous/solid waste generated from the process, effluent treatment plant and other industrial activity will be stored in a separate hazardous waste storage area .

## 3.10 SCHEMATIC REPRESENTATIONS OF THE FEASIBILITY DRAWING WHICH GIVE INFORMATION OF EIA PURPOSE

## 4. SITE ANALYSIS

#### 4.1 CONNECTIVITY

The project site is well connected with all infrastructures like National Highway, Railway, Airport, telephone, internet, fax, post, etc. Nearest town, city, district headquarters is Bhavnagar located 12.35 km in N direction from the project site.

National Highway No. 6 is located 25 Km.

Nearest railway station is Morbi Railway Station located 22.5 km from the project site.

Nearest airport is Rajkot located 63.4 km from the project site.

#### 4.2 LAND FORM, LAND USE AND LAND OWNERSHIP

The land is non agriculture. The land is totally flat. The ownership of the land is unit itself. The proposed project will not cause any permanent or temporary change to land use.

Sr. No.		Title	Area(Sq. mtr)
1		Total Built Up Area	2297.25
	I	Shed with Office & Toilet Block	2177.25
	II	Labour Quarters	60.00
	111	Labour Facility	60.00
2		Common Plot	529.55
3		Internal Road Area	2023.68
4		Open Parking Area	206.04
5		Open Land & Margin Area	1418.48
		Total	6475.00

#### LAND AREA BIFURCATION

#### 3. TOPOGRAPHY

For Topography map, please refer Annexure - 3.

#### 4.4 EXISTING LAND USE PATTERN, SHORTEST DISTANCE FROM THE PERIPHERY OF THE PROJECT TO PERIPHERY OF THE FOREST, NATIONAL PARK, WILD LIFE SANCTUARY, ECO SENSITIVE AREA, WATER BODIES (DISTANCE FROM THE HFL OF THE RIVER),

The land is non agriculture. The project site does not fall in the CRZ area it does not located in notified industrial area. There shall be no forest, wild life sanctuary, eco sensitive area provided within 10 km from the project site.

The details of water bodies and nearest park are mentioned below:

- > No Water bodies are located near to project site.
- > Nazar baug Park is25 km from the project site.

For Land Use, Please refer Annexure - 4.

#### 4.5 EXISTING INFRASTRUCTURE

New products will be manufactured within existing production facility and infrastructure available. The project site is well connected with all infrastructures like National Highway, Railway, Airport, telephone, internet, fax, post, etc.

Nearest town, city, district headquarters is Rajkot located 12.35 km in N direction from the project site. National Highway No. 6 is located 25 Km.

Nearest railway station is Morbi located at 22.5 km located from the project site.

Nearest airport is Rajkot located 63.4 km from the project site.

#### 4.6 SOIL CLASSIFICATION

Agricultural land, Detail soil analysis Pending

#### 4.7 CLIMATIC DATA FROM SECONDARY SOURCES

-NA-

#### 4.8 SOCIAL INFRASTRUCTURE AVAILABLE

- Nearby Village

#### 2. PLANING BRIEF

#### **5.1 PLANNING CONCEPT**

Bizotic Life Science PVT LTD. Is to be involved in the manufacturing of Bulk Drugs and intermediate manufacturing. All the basic facilities like tap water, sanitation & drinking water, lunch space & First aid box will be provided within premises.

The project site is well connected with the road, railway, air & port. Finished products and raw materials will be transported through road. There is no requirement for the development of other road or railway.

#### **5.2 POPULATION PROJECTION**

Total Employees to be required will be 30 approximately including 6-7 labours.

#### 2.3. LAND USE PLANNING

Sr. No.		Title	Area(Sq. mtr)
1		Total Built Up Area	2297.25
	I	Shed with Office & Toilet Block	2177.25
	II	Labour Quarters	60.00
	Ш	Labour Facility	60.00
2		Common Plot	529.55
3		Internal Road Area	2023.68
4		Open Parking Area	206.04
5		Open Land & Margin Area	1418.48
		Total	6475.00

The breakup of the land area is mentioned in the below table:

#### 2.4. ASSESSMENT OF INFRASTRUCTURE DEMAND (PHYSICAL & SOCIAL)

The project site is well connected with all the infrastructure facilities.

Local people will be hired for Project and they will be trained within unit. Thus, no social infrastructure will require.

#### **5.5 AMENITIES / FACILITIES**

All the basic facilities like tap water, sanitation & drinking water, lunch space is provided within premises. First aid box, free medicines & doctor service (on call basis) is provided. Adequate PPE's is provided to all workers.

## 6. PROPOSED INFRASTRUCTURE

1.	Industrial Area	6475
2.	ResidentialArea	Not Applicable
3.	GreenBelt	Not Applicable
4.	Social Infrastructure	Not Applicable
5.	Connectivity	Nearest RailwayStation–Morbi 22.5 km
		Nearest Airport– Rajkot 63.4 km
		Nearest Highway –NationalHighwayNo.6 25 km.
6.	Drinking Water Management	Source of water for domestic purpose will be from borewell & tubewell.

7.	Sewerage System	Provisions done in plant
8.	Industrial Waste Management	Process Residue– Collection ,Storage, Transportation, Disposal atHazardous WasteIncinerator for incinerationa tCHWIF
		ETP sludge ,Spentcarbon ,HyflowPowder– Collection ,Storage ,Transportation ,Disposal at TSDF site for secured landfill
		Discardedcontainers– Collection,Storage,DecontaminationandDiscarded toregisteredre-cyclersapproved byGPCB/CPCB
		Used oil – Collection ,Storage ,Transportation, Disposal by selling oRegistered Re-refiners approved by GPCB/CPCB.
9.	SolidWaste Management	MSW disposed to nearest NagarPalika or Gram Panchyatsite.
10.	PowerRequirement&Suppl y /Source	Source:Paschim Gujarat Vij CompanyLtd. ConnectedLoad: 500 KVA

## 7. REHABILITATION AND RESETTLEMENT (R & R) PLAN

No Rehabilitation & Resettlement (R & R) plan is involved in the production .

### 8. PROJECT SCHEDULE & COST ESTIMATES

## 8.1 LIKELY DATE OF START OF CONSTRUCTION AND LIKELY DATE OF COMPLETION

Date of Start of Construction: 01/01/2016Date of Completion of Project: 30/06/2016

#### 2. PROJECT COST ESTIMATION : 500 lakhs

## 9. ANALYSIS OF PROPOSAL

# 9.1 FINANCIAL AND SOCIAL BENEFITS WITH SPECIAL EMPHASIS ON THE BENEFIT TO THE LOCAL PEOPLE INCLUDING TRIBAL POPULATION, IF ANY, IN THE AREA

No tribal population exists within 10 km radius of project area. Due to proposed project it is expected that employment will increase for people who reside nearby project area. Due to increase in raw material and product transportation activity, indirect employment will generate. As local people will get job, their living status will increase. Due to rain water harvesting system, water table level in project area will increase which is beneficial to surrounding farmers.

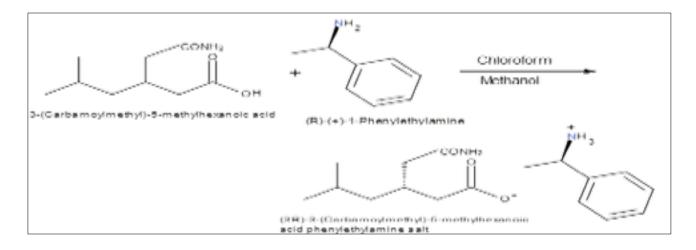
### ANNEXURE 1

The process of manufacture involves the following steps:

- Step 1: Preparation of (3R)-3-(carbamoylmethyl )-5-methyl hexanoic acidphenyl ethyl amine salt
- Step 2: Preparation of (3R)-3-(carbamoylmethyl)-5-methyl hexanoic acid
- Step 3: Preparation of (3S)-3- (Aminomethyl)-5-methylhexanoic acid (Tech. Pregabalin)
- Step 4: pH adjustment
- Step 5: Purification of technical grade pregabalin
- Step 1A: Preparation of unwanted isomer from MLR
- Step 1B: Conversion of unwanted isomer into Racemic compound

## **PROCESS DESCRIPTION**

## STAGE 1:

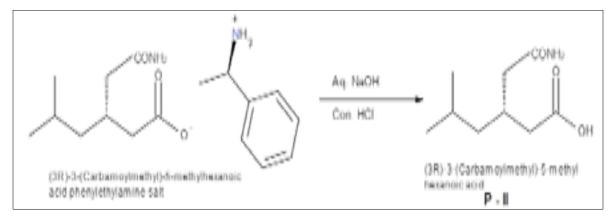


#### Procedure :

- 1. Charge Chloroform into reactor.
- 2. Charge Methanolinto reactor.
- 3. Charge (±)-3-(carbamoymethyl)-5-methyl hexanoic acid into reactor.
- 4. Raise the temperature of the reaction mass to  $50 55^{\circ}$ C.
- 5. Add R-(+)-1-phenyl ethyl mine to the above slurry slowly at  $50 55^{\circ}$ C.
- 6. Maintain for 15 min at 50  $55^{\circ}$ C.
- 7. Again add R-(+)-1-phenyl ethyl mine to reaction mass at 50 55°C.
- 8. Check the mass, it should be clear.
- 9. Maintain mass for 30 min at 50 55°C.
- 10. Stop heating and charge (3R)-(-)-3-(carbamoylmethyl)-5-methyl-hexanoic acid as a seeding for crystallization under stirring.

- 11. Cool the mass slowly to 30-35°C.
- 12. Maintain under stirring for 30 min at 30 -35  $^{\circ}$ C.
- 13. Centrifuge the material and wash with chloroform.
- 14. The wet cake is ready for next stage.

### STAGE 2:

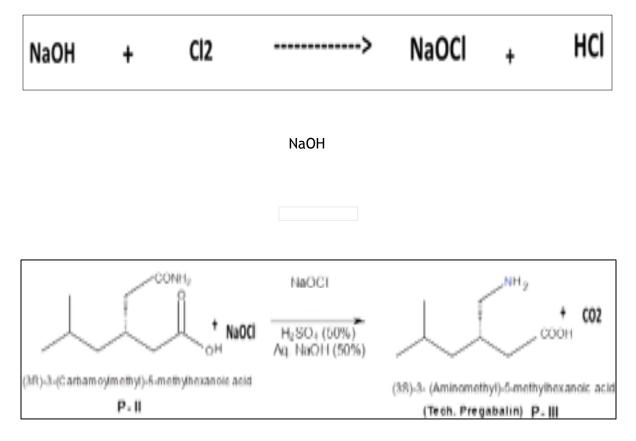


#### Procedure:

- 1. Charge water (lot-1) into reactor.
- 2. Charge (3R)-3-(Carbamoylmethyl)-5-methylhexanoic acidphenylethylamine salt into reactor.
- 3. Cool the reaction mass up to 10 to  $15^{\circ}$ C.
- 4. Adjust the mass pH to 10-11 using sodium hydroxide solution. (Dissolve sodium hydroxide in water(Lot-2))
- 5. Maintain the mass for 30 min under stirring.
- 6. Solution should be clear.
- 7. Charge chloroform (lot-1) into the reactor.
- 8. Maintain reaction for 30 min under stirring.
- 9. Settle the mass for 30 min.
- 10. Separate the lower chloroform layer.
- 11. Again charge chloroform (lot-2) into the reactor.
- 12. Maintain reaction mass for 30 min under stirring.
- 13. Settle the mass for 30 min.

- 14. Separate the lower chloroform layer.
- 15. Slowly adjust the pH to 2-3 using con. HCl.
- 16. Maintain the mass at 10-15°C for 1 hr.
- 17. Centrifuge the material.
- 18. Wash the material with water (lot-3).
- 19. The wet cake is ready for next stage.

### STAGE 3:



#### Procedure:

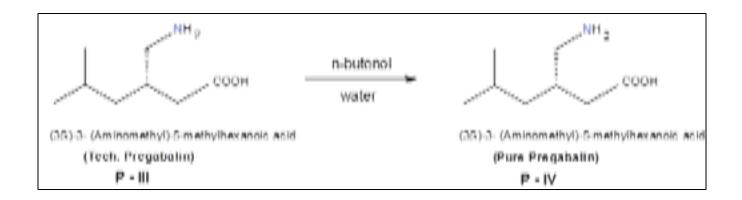
- 1. Charge water lot-1 into the reactor.
- 2. Charge NaOH lot-1 into the reactor.
- 3. Cool the mass to 0 to  $5^{\circ}$ C.
- 4. Add chlorine gas in to the reactor slowly at 0 to  $10^{\circ}$ C (gas purging).
- 5. After addition of gas, transfer the sodium hypochlorite solution in to the Buffer Tank.

- 6. Then in the same reactor, charge water lot-2 into the reactor.
- 7. Charge NaOH lot-2 in reactor.
- 8. Cool the mass to 0-5 °C.
- 9. Charge (3R)-3-(Carbamoylmethyl)-5-methylhexanoic acid into reactor from Stage 2.
- 10. Maintain the mass for 30 min.
- 11. Add sodium hypochlorite solution slowly at 0 to 15 °C (exothermic reaction)
- 12. After addition maintain mass for 2 hr at 15 to  $20^{\circ}$ C.
- 13. Slowly raise the temperature to 50 -55  $^{\circ}$ C.
- 14. Maintain the reaction mass at 50 -55  $^{\circ}$ C for 30-45 min.
- 15. Cool the mass to  $30 35^{\circ}$ C.
- 16. Filter the mass through hi flow bed (sparkler filter).

#### STAGE 4:

- 7. Now, put the mass into a Mixing Vessel to adjust the mass pH 3.5 by adding 50  $\%~H_2SO_4$  solution at 30-35°C.
- 8. Adjust the mass pH 7-7.5 using 50 % NaOH solution at 25-30°C.
- 9. Maintain the mass at 20-25°C for 1 hr.
- 10. Centrifuge the material.

#### STAGE 5:



#### Procedure:

- 1. Charge n-butenol into reactor.
- 2. Charge tech- pregabalin into reactor.
- 3. Charge water into reactor.
- 4. Heat the mass to 80 to 85  $^{\circ}$ C.
- 5. Maintain for 30 min at  $80 85^{\circ}$ C.
- 6. Cool the mass slowly to  $8 12^{\circ}C$
- 7. Maintain mass at 8-12°C for 1 hr.
- 8. Filter the material.
- 9. Dry the material at  $45 50^{\circ}$ C.

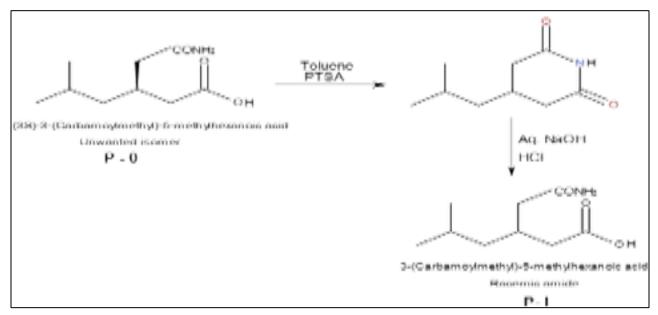
#### STAGE 1A:

MLR Conc. H2SO4 (FROM STAGE I) Conc. H2SO4 NaOH Soln UNWANTED ISOMER (P-1	0)
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#### Procedure:

- 1. Charge MLR in to the reactor.
- 2. Charge sodium Hydroxide solution in to the reactor.
- 3. Maintain the mass for 1 hr under stirring.
- 4. Settle the mass for 30 mins.
- 5. Separate the lower chloroform layer.
- 6. Slowly adjust pH 2-3 using Con. Hydrochloric acid.
- 7. Maintain the mass at 10 to  $15^{\circ}$ C for 1 hr.
- 8. Centrifuge the material.
- 9. The wet cake is ready for next stage.

## STAGE 1B:



#### Procedure:

- 1. Charge toluene into the reactor.
- 2. Charge unwanted isomer into reactor.
- 3. Charge PTSA into reactor.
- 4. Heat the mass to reflux temperature (110-115°C) for 10 hrs.
- 5. Cool the mass to  $60-65^{\circ}$ C.
- 6. Slowly charge sodium hydroxide solution (dissolved sodium hydroxide in water lot-1).
- 7. Maintain the reaction at 60-65°C for 2-3 hrs.
- 8. Cool the mass to  $20-30^{\circ}$ C.
- 9. Separate the layers.
- 10. Take aq. Layer in to the reactor.
- 11. Adjust the pH to 2-2.5 using Con. HCl.
- 12. Cool the mass to 10-15 °C.
- 13. Maintain mass for 1 hr at 10-15°C.
- 14. Filter the material through a centrifuge.
- 15. Wash the material with water (Lot-2) at  $10-15^{\circ}$ C.
- 16. Dry the material at  $50-60^{\circ}$ C till m/c less than 1.0%.
- 17. The material is ready to be recycled to Stage 1.

## ANNEXURE 2

SL. NO.	PRODUCTS	QUANTITY (Kg/Month)	QUANTITY (Ton/Month)				
1	Pregabalin	2000	2				
,	A) FOR PREGABALIN						
SL. NO.	RAW MATERIALS	QUANTITY (Kg/Month)	QUANTITY (Ton/Month)				
1	3-(Carbamoylmethyl)-5- methylhexanoic acid i.e. P-I (C9H17O3N)	1453.31	1.45				
2	(R)-(+)-1-Phenyl ethyl amine i.e. PEA (C8H11N)	707.04	0.71				
3	Chloroform (CHCl3)	27947.13	27.95				
4	Methanol (CH3OH)	351.24	0.35				
5	Water (H20)	38856.60	38.86				
6	Sodium Hydroxide (NaOH)	4286.87	4.29				
7	Conc. Hydrochloric Acid (HCl)	3763.53	3.76				
8	Sulphuric Acid (H2SO4)	3500.00	3.50				
9	Chlorine (Cl2)	446.54	0.45				
10	n-butenol (C4H7OH)	5717.65	5.72				
11	Toulene (C6H5CH3)	4685.38	4.69				
12	p-Toulene sulphonic acid (PTSA) (CH3C6H4SO3H)	90.80	0.09				
	TOTAL	91806.10	91.81				