

1.0 EXECUTIVE SUMMARY

M/s. Paradise Healthcare is located at Plot no. 201/5, GIDC Estate Panoli, Bharuch, Gujarat. M/s Paradise Healthcare has taken over M/s. Swastik Industries.(GIDC transfer letter is attached as an additional attachment.) The unit is having CCA: AWH-84997 for manufacturing of Inorganic products and has proposed EC application for manufacturing of bulk drugs & intermediates.

The unit will engage in manufacturing of bulk drugs & intermediates and production capacity will be 20 MT/Month. As per EIA notification 2006, the proposed project is falling under category 5(f).

The details of products are given below table.

TABLE 1: LIST OF PRODUCTS WITH THEIR PRODUCTION CAPACITY

Sr. No.	List of Products	CAS No.	Existing Capacity CCA AWH 84997 MT/M	Proposed Production MT/M	Total Production MT/M
1.	Copper Sulphate, Potassium Sulphate, Sodium Nitrate, Ferrous Sulphate		500	- 500	0
I	ANTIEMETIC		0	1	1
1	Aprepitant and/or its intermediatesAND/OR	170729-80-3			
	<u>Chemical name :</u> (2R)-(1R)-3,5-bis(trifluoromethylphenyl)ethoxy)-(3S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazole)methyl-morpholine.	170729-80-3			
	Intermediate :				
a	(2R,3S)-2-[(1R)-1-[3,5-Bis(trifluoromethyl)phenyl]ethoxy]-3-(4-fluorophenyl)morpholine	171338-27-5			
b	(2R)-4-Benzyl-2-[(1R)-1-[3,5-bis(trifluoromethyl)phenyl]ethoxy]morpholin-3-one	287930-75-0			
c	(R)-1-[3,5-Bis(trifluoromethyl)phenyl]ethanol	127852-28-2			
d	2-(2-Chloro-1-iminoethyl)hydrazinecarboxylic acid methyl ester	155742-64-6			

e	[2R-[2aR*),3a]-2-[1-[3,5-Bis(trifluoromethyl)phenyl]ethoxy]-3-(4-fluorophenyl)morpholine	170729-79-0			
f	N-[4-[2-(2-Amino-4,7-dihydro-4-oxo-H-pyrrolo[2,3-d]pyrimidin-5-yl)ethyl]benzoyl]-L-glutamic acid 1,5-diethyl ester	146943-43-3			
g	(2R,3S)-2-[(1R)-1-[3,5-Bis(trifluoromethyl)phenyl]ethoxy]-3-(4-fluorophenyl)morpholine 4-methylbenzenesulfonate	200000-59-5			
h	(R)-2-Methyl-CBS-oxazaborolidine	112022-83-0			
2	fosaprepitant and/or its intermediatesAND/OR	172673-20-0			
	<u>Chemical Name</u> : [3-[(2R,3S)-2-[(1R)-1-[3,5-Bis(trifluoromethyl)phenyl]ethoxy]-3-(4-fluorophenyl)-4-morpholinyl)methyl]-2,5-dihydro-5-oxo-1H-1,2,4-triazol-1-yl]phosphonic acid, Fosaprepitant	172673-20-0			
3	fosaprepitantdimeglumine and/or its intermediatesAND/OR	265121-04-8			
	<u>Chemical Name</u> : D-Glucitol, 1-deoxy-1-(methylamino)-, (3-(((2R,3S)-2-((1R)-1-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(4-fluorophenyl)-4-morpholinyl)methyl)-2,5-dihydro-5-	265121-04-8			

	oxo-1H-1,2,4-triazol-1-yl)phosphonate.				
II	ANTI HYPERTENSION		0	2	2
1	AzilsartanMedoxomil and/or its intermediatesAND/OR	863031-21-4			
	<u>Chemical Name :</u> 1-[[2'-(2,5-Dihydro-5-oxo-1,2,4-oxadiazol-3-yl)[1,1'-biphenyl]-4-yl]methyl]-2-ethoxy-1H-benzimidazole-7-carboxylic acid (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl ester	863031-21-4			
	Intermediate :				
A	Methyl 1-[(2'-cyanobiphenyl-4-yl)methyl]-2-ethoxy-1H-benzimidazole-7-carboxylate	139481-44-0			
B	1-[[2'-(2,5-Dihydro-5-oxo-1,2,4-oxadiazol-3-yl)[1,1'-biphenyl]-4-yl]methyl]-2-ethoxy-1H-benzimidazole-7-carboxylic acid ethyl ester	1403474-70-3			
C	Methyl 2-ethoxybenzimidazole-7-carboxylate	150058-27-8			
D	4-(Hydroxymethyl)-5-methyl-1,3-dioxol-2-one	91526-18-0			
2	TELMISARTAN	863031-21-4			
3	Perindopril Erbumine and/or its intermediatesAND/OR	107133-36-8			

	Chemical Name : 1-[2-(1-Ethoxycarbonylbutylamino)propanoyl]-2,3,3a,4,5,6,7,7a-octahydroindole-2-carboxylic acid 2-methyl-2-propanamine (1:1)	107133-36-8			
4	Perindopril Arginine and/or its intermediatesAND/OR	612548-45-5			
	Chemical Name : (2S)-2-Amino-5-carbamimidamidopentanoic acid - (2S,3aS,7aS)-1-[(2S)-2-{[(2S)-1-ethoxy-1-oxo-2-pentanylamino]propanoyl}octahydro-1H-indole-2-carboxylic acid				
III	ANTI COAGULANT		0	1	1
1	Dabigatran EtexilateMesylate and/or its intermediatesAND/OR	872728-81-9			
	Chemical Name : Ethyl N-[(2-{[(4-{N-[(hexyloxy)carbonyl]carbamimidoyl}phenyl)amino]methyl}-1-methyl-1H-benzimidazol-5-yl)carbonyl]-N-2-pyridinyl-β-alaninate methane sulfonate.	872728-81-9			
	Intermediate :				
A	Ethyl - [[3-amino-4-(methylamino)benzoyl]-[pyridin-2-yl-beta-amino]propanoate	212332-56-0			
B	2-[(4-cyanophenyl)amino]acetic acid	42288-26-6			

C	3-[[[2-[[[4-Cyanophenyl]amino]methyl]-1-methyl-1H-benzimidazol-5-yl]carbonyl]pyridin-2-ylamino]propionic acid ethyl ester	211915-84-3			
D	N-[[2-[[[4-(Aminoiminomethyl)phenyl]amino]methyl]-1-methyl-1H-benzimidazol-5-yl]carbonyl]-N-2-pyridinyl-beta-alanine ethyl ester	429658-95-7			
E	Ethyl 3-(((2-(((4-(((hexyloxy) carbonyl) amino) iminomethyl) phenyl) amino)\methyl)-1-methyl-1H-benzimidazol-5-yl)\carbonyl)(pyridin-2-yl)amino) propanoate	219115-06-9			
2	Rivaroxaban and/or its intermediatesAND/OR	366789-02-8			
	<u>Chemical Name :</u> 5-Chlor-N-({ (5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophencarboxamid	366789-02-8			
	Intermediates :				
A	(S)-2-Oxiranylmethyl-Isoindole-1,3-Dione				
IV	ANTIRETROVIRAL -		0	0.5	0.5
1	Darunavir and/or its intermediatesAND/OR	206361-99-1			

	<u>Chemical Name:</u> (3R,3aS,6aR)-Hexahydrofuro[2,3-b]furan-3-yl [(2S,3R)-4-[(4-aminophenyl)sulfonyl](isobutyl)amino}-3-hydroxy-1-phenyl-2-butanyl]carbamate	206361-99-1			
	Intermediate :				
A	[3r,3as, 6ar]-hydroxyhexahydrofluoro [2,3-b] furnylsuccinimidly carbonate	253265-97-3			
B	Tert butyl [(1s,2r)-1-benzyl-2-hydroxy-3-[isobutyl[(4-nitrophenyl) sulfonyl} propyl} carbamate	191226-98-9			
V	ANTI EPILEPTIC/ ANTI CONVULSANT		0	2	2
1	Lacosamide and/or its intermediatesAND/OR	175481-38-6			
	<u>Chemical Name :</u> (R)-2-acetamido-N-benzyl-3-methoxypropionamide	175481-38-6			
2	Riluzole and/or its intermediatesAND/OR	1744-22-5			
	Chemical Name : 2-Amino-6-(trifluoromethoxy)benzothiazole	1744-22-5			
VI	ANTI DIABETICS		0	2	2
1	Linagliptin and/or its intermediatesAND/OR	668270-12-0			
	Chemical name : (R)-8-(3-amino-piperidin-1-yl)-7-but-2-ynyl-3-methyl-1-(4-methyl-quinazolin-2-ylmethyl)-3,7-dihydro-purine-2,6-dione	668270-12-0			

VII	ANALGESIC		0	3	3
1	Lornoxicam and/or its intermediates and/OR	70374-39-9			
	<u>Chemical Name</u> : 6-chloro-4-hydroxy-2-methyl-n-(2-pyridyl)-2h-thieno[2,3-e]-1,2-thiazine-3- carboxamide-1,1-dioxide.	70374-39-9			
	Intermediate:				
A	6-chloro-4- hydroxy-2-methyl-3-methoxycarbonyl-2h-thieno[2,3e]-1,2-thiazine-1,1-dioxide	70415-50-8			
B	3- amino-2-thiophene carboxylic acid methyl ester	22288-78-4			
C	Methyl-5-chloro-3-chlorosulfonyl-2-thiophene carboxylate	126910-68-7			
D	5-chloro-3-sulfonlamino methyl acetate-Thiophene 2-carboxylic acid methyl ester	906522-87-0			
E	6-chloro-4-hydroxy-3-methoxycarbonyl-2H-thieno[2,3-e]-1,2-thiazine-1,1-dioxide	70374-51-5			
F	5-chloro-3-(methylamino)sulfamoyl-2-carboxylic acid methyl ester	70374-37-7			
G	5-Chloro-3-[N-(methoxycarbonylmethyl)-N-methylsulfamoyl]-thiophene-2-carboxylic acid methyl ester	70374-38-8			
VIII	ALZHEMERS - 2 MT		0	2	2

1	Memantine and/or its intermediatesAND/OR	41100-52-1			
	<u>Chemical Name</u> : 3,5-Dimethyl-1-aminoadamantane Hydrochloride	41100-52-1			
	Intermediates				
A	1,3 Dimethyl Adamentane	702-79-4			
B	1-Bromo-3,5-Dimethyl Adamentane	941-37-7			
C	AcetamidoMemantine	19982-08-2			
D	Memantine Free Base	19982-08-2			
IX	OVERACTIVE BLADDER SYNDROME		0	0.5	0.5
1	Mirabegron and/or its intermediatesAND/OR	223673-61-8			
	<u>Chemical Name</u> : 2-Amino-N-[4-[2-[(2R)-2-hydroxy-2-phenylethyl]amino]ethyl]phenyl]-4-thiazoleacetamide	223673-61-8			
2	Trospium Chloride /or its intermediatesAND/OR	10405-02-4			
	<u>Chemical Name</u> : 8-alpha-benziloyloxy-6,10-ethano-5-azoniaspiro(4.5)decanechloride;Benzilic acid, ester with 3a-hydroxyspiro[1aH,5aH-nortropane-8,1'-pyrrolidinium] chloride (8CI),				
X	ANTAGONIST		0	0.5	0.5
1	Palonosetron Hydrochloride and/or its intermediatesAND/OR	135729-62-3			
	<u>Chemical Name</u> :				

	(3aS)-2-(3S)-1-Azabicyclo[2.2.2]oct-3-yl-2,3,3a,4,5,6-hexahydro-1H-benz[de]isoquinolin-1-one monohydrochloride, Palonosetron hydrochloride.	135729-62-3			
	Intermediate :				
A	5,6,7,8-Tetrahydronaphthalene-1-carboxylic acid	4242-18-6			
B	(S)-(-)-1,2,3,4-Tetrahydro-naphthoic acid	85977-52-2			
C	(R)-1,2,3,4-Tetrahydro-naphthoic acid	23357-47-3			
D	(S)-3-Aminoquinuclidine dihydrochloride	119904-90-4			
E	(R)-3-Aminoquinuclidine dihydrochloride	123535-14-1			
2	Ticagrelor and/or its intermediatesAND/OR	274693-27-5			
	<u>Chemical Name</u> : (1S,2S,3R,5S)-3-[7-[[[(1R,2S)-2-(3,4-difluorophenyl)cyclopropyl]amino]-5-propylsulfanyltriazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)cyclopentane-1,2-diol	274693-27-5			
XI	PROSTATIC HYPERTROPHY		0	0.5	0.5
1	Silodosin and/or its intermediatesAND/OR	160970-54-7			

	Chemical Name : 1-(3-Hydroxypropyl)-5-[(2R)-2-[[2-(2,2,2-trifluoroethoxy)phenoxy]ethyl]amino]propyl]-2,3-dihydro-1H-indole-7-carboxamide	160970-54-7			
	Intermediates :				
A	1-[3-(Benzoyloxy)propyl]-2,3-dihydro-5-[(2R)-2-[[2-(2,2,2-trifluoroethoxy)phenoxy]ethyl]amino]propyl]-1H-indole-7-carbonitrile	885340-11-4			
B	1H-Indole-7-carbonitrile, 2,3-dihydro-1-(3-hydroxypropyl)-5-[(2R)-2-[[2-(2,2,2-trifluoroethoxy)phenoxy]ethyl]amino]propyl]	885340-13-6			
C	2-(2-(2,2,2-trifluoroethoxy)-phenoxy)-ethyl methanesulfonate	160969-03-9			
XII	ANTI FUNGAL		0	0.5	0.5
1	Tavaborole and/or its intermediatesAND/OR	174671-46-9			
	Chemical Name : 5-Fluoro-1,3-dihydro-2,1-benzoxaborol-1-ol; AN 2690; 5-Fluoro-1,3-dihydro-1-hydroxy-2,1-benzoxaborole	174671-46-9			
XIII	ONCOLOGY		0	0.2	0.2
1	Oxaliplatin and/or its intermediatesAND/OR	63121-00-6			
	Chemical Name :				

	Oxalato(trans-(-)-1,2-cyclohexanediamine)platinum(II).				
2	Cisplatin and/or its intermediatesAND/OR	15663-27-1			
	Chemical Name : cis-Diaminedichloroplatinum(II)				
XIV	ACNE		0	0.3	0.3
1	ADAPALANE	106685-40-9			
XV	ANTIPNEUMOCYSTIC		0	0.3	0.3
1	ATOVAQUONE	95233-18-4			
XVI	PRESERVATIVE - INTERMEDIATE		0	3	3
1	IodopropynylButylcarbamate	55406-53-6			
XVII	ANTI-PSYCHOTIC DRUG		0	0.7	0.7
1	Quetiapin Fumarate	111917-72-2			

COST OF PROJECT

The expected cost of project is Rs. 2.5 Crore. The plot had been purchased by M/s. Paradise Healthcare.

LAND

The total plot area of the unit is 1307sq.m. The green belt area will be 300 sq.m.

FUEL CONSUMPTION

After expansion, the proposed unit will use 2100 Kg/Day of Agro waste / Briquette or 900 m³/Day of Natural gas as fuel. Unit will also use diesel 40 Ltr/Hr for D.G.Set.

WATER CONSUMPTION

The unit is using 5.5 KL/day water as per existing CCA. 4 KL/day water is used for the industrial purpose and 1.5 KL/day is used for domestic purpose.

After expansion, the unit will use 28.5 KL/day water for proposed project. 26 KL/day water will be used for the industrial purpose and 2.5 KL/day will be used for domestic purpose.

WASTE WATER GENERATION

After expansion, the total waste water generation will be 9.5 KL/day. The industrial waste water generation will be 8KL/day and domestic waste water generation will be 1.5 KL/day. Unit will send its High COD effluent into MEE plant (4 KL/Day) and Low COD effluent into M/s. PETL-CETP after treatment (4 KL/Day).

GASEOUS EMISSION

There is flue gas emission from one stack attached to boiler (0.3 Ton/Hr.). There is no process emission from existing project.

After Expansion, there will be flue gas emission from one stack attached to boiler (1.2 Ton/Hr) and one stack of D.G. Set (125 KVA). There will be process emission from vents attached to the reactors.

HAZARDOUS WASTE MANAGEMENT

The hazardous waste generation from existing unit is Used oil (0.01 MT/year), Empty barrel/container/ liners contaminated with hazardous chemicals/waste (10 MT/Year).

After expansion, the hazardous waste generation from proposed project will be Used oil (1.01 MT/year), ETP waste (60 MT/year), spent carbon (24MT/year), distillation residue (10 MT/year), Empty barrel/container/ liners contaminated with hazardous

chemicals/waste (20 MT/Month) and Date expired/ off-specification product (5MT/Month).