RISPERIDONE - risperidone tablet, film coated
Zydus Lifesciences Limited

RISPERIDONE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Risperidone Tablets USP, 0.25 mg

NDC 65841-665-14

60 tablets

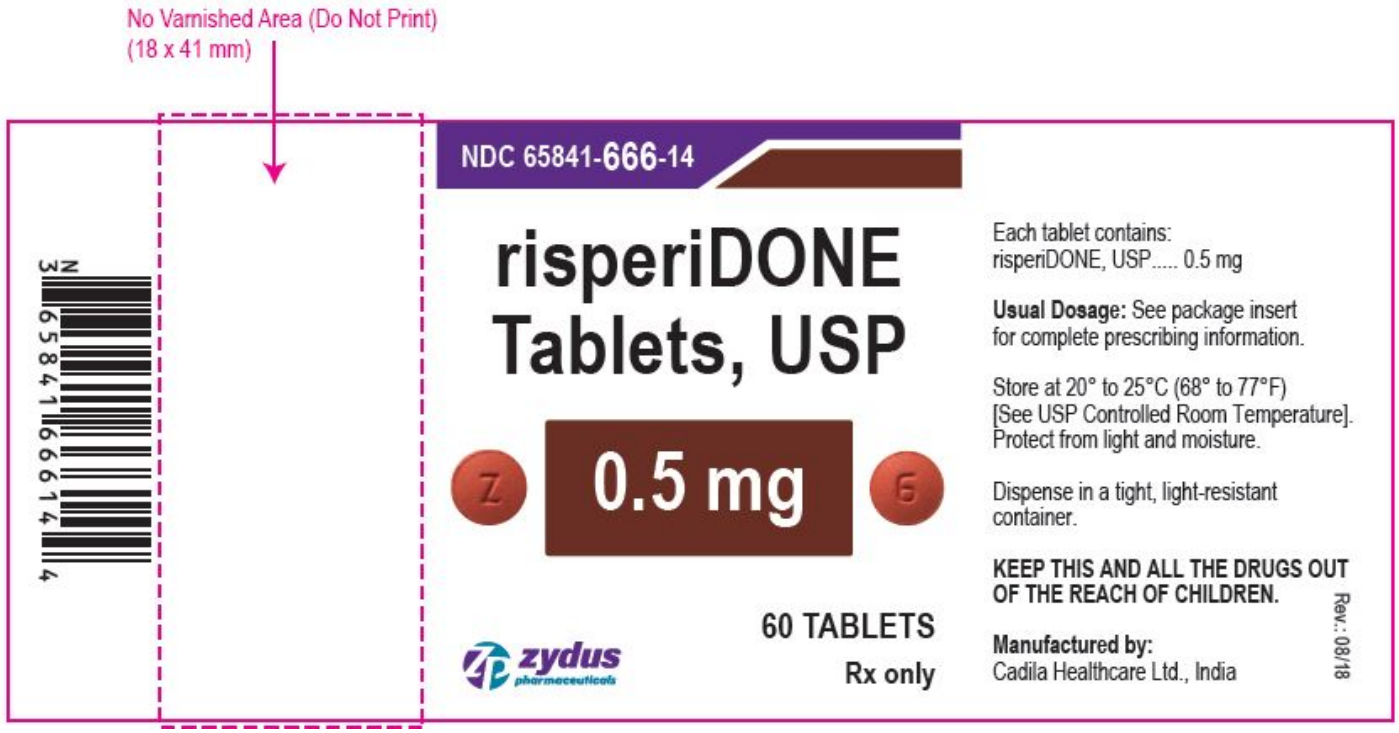
Rx only

Risperidone Tablets USP, 0.5 mg

NDC 65841-666-14

60 tablets

Rx only

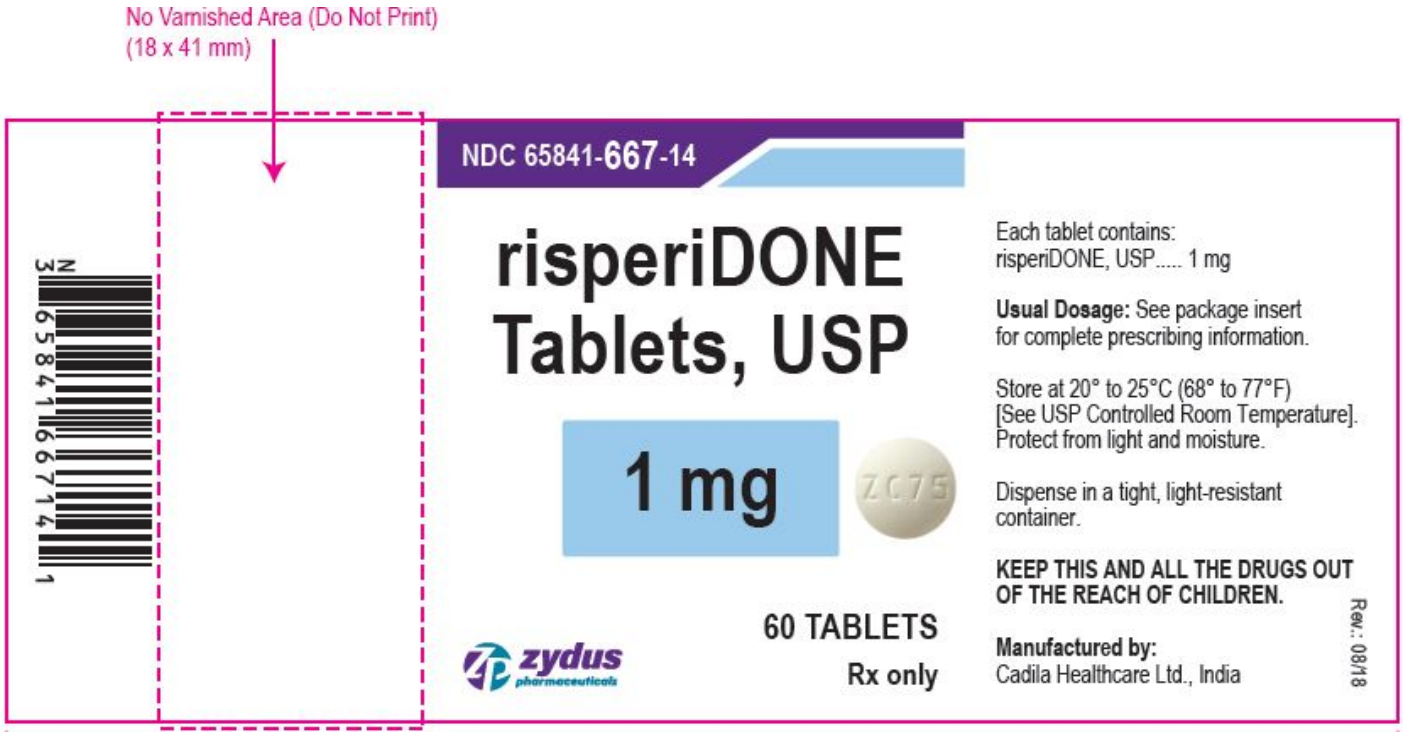


Risperidone Tablets USP, 1 mg

NDC 65841-667-14

60 Tablets

Rx only

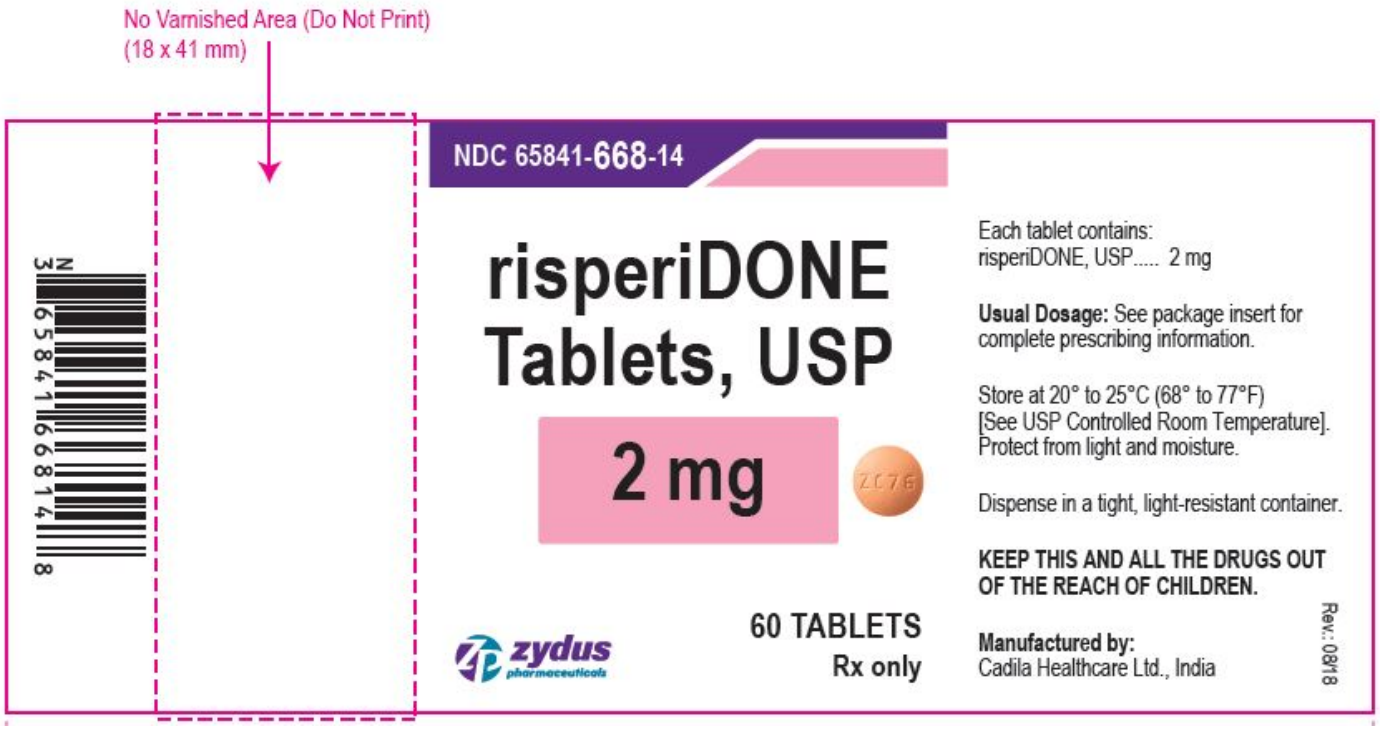


Risperidone Tablets USP, 2 mg

NDC 65841-668-14

60 Tablets

Rx only



Risperidone Tablets USP, 3 mg

NDC 65841-669-14

60 Tablets

Rx only

Risperidone Tablets USP, 4 mg

NDC 65841-670-14

60 Tablets

Rx only

RISPERIDONE

risperidone tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-665
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	0.25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	YELLOW (DARK YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	5mm
Flavor		**Imprint Code**	Z;4
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-665-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-665-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-665-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-665-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-665-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-665-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-666
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	RED (RED BROWN)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	5mm
Flavor		**Imprint Code**	Z;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-666-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-666-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

3	NDC:65841-666-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-666-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-666-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-666-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-667
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	1 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	ZC;75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-667-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-667-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-667-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-667-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-667-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-667-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-668
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	2 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	ORANGE (ORANGE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	ZC;76
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-668-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-668-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-668-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-668-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-668-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-668-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-669
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	3 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	YELLOW (YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	ZC;77
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-669-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-669-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-669-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-669-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-669-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-669-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/12/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-670
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	4 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	GREEN (GREEN)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	11mm
Flavor		**Imprint Code**	ZC;78
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-670-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-670-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-670-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-670-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-670-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-670-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-665, 65841-666, 65841-667, 65841-668, 65841-669, 65841-670), MANUFACTURE(65841-665, 65841-666, 65841-667, 65841-668, 65841-669, 65841-670)