



# **Brief note on Inactive Ingredients approved by USFDA**

**FOR DIFFERENT DOSAGE FORMS WITH SPECIFIED ROUTE OF ADMINISTRATION**

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## DISCLAIMER

- 1. The data should not be copied or transmitted to others in any means.**
- 2. All the data is compiled from USFDA open source and for correctness to be checked with online information.**
- 3. The Council is not responsible for any mistakes in the data provided.**

## **1.0 Introduction**

Inactive ingredient is a component of a drug product other than the active ingredient. An inactive ingredient plays a key role in the design of a formulation. Establishing a formulation of desired dosage form with reaching required bioavailability/bioequivalence is a cumbersome process involving time, money. Food and Drug Administration of United States of America has approved 3017 inactive ingredients for 11100 permutation/combination products specifying clearly for a particular dosage form with a specified route of administration (419). Establishing the required quantities of the inactive ingredient for a particular dosage form with a specified route of administration is one another critical step involved in the design of a formulation. USFDA has provided information to some extent with relating to maximum potency of the inactive ingredient for a specific dosage form with specific route of administration. USFDA indicates that for new drug development purposes, once an inactive ingredient has appeared in an approved drug product for a particular route of administration, the inactive ingredient is not considered new and may require a less extensive review the next time it is included in a new drug product. Pharmexcil is emphasizing through this data that Indian pharmaceutical industry is provided with crucial information that is required especially for formulation development.

Pharmexcil believes that key information plays a vital role in saving time and money especially in research. Pharmexcil is putting all effort in providing the information to its members that is feasible so as to encourage and mold new industries for research bent of mind as well as develop new products/generics in order to increase exports. It is necessary to understand that several countries are amending the existing legislations not only for quality of active ingredient but also for quality of inactive ingredient to achieve safety, efficacy and reliability. Moreover, several regulated markets insist on including the inactive active ingredients used on labels.

## **2.0 Inactive Ingredient Field Descriptions**

The different fields provided for the list of USFDA approved inactive ingredients with specified route of administration along with specific dosage form is as follows:

**Inactive Ingredient**

An inactive ingredient is any component of a drug product other than the active ingredient. Only inactive ingredients in the final dosage forms of drug products are included in this database.

**Route**

A route of administration is a way of administering a drug to a site in a patient. A comprehensive list of specific routes of administration appears in the Data Standards Manual.

**Dosage Form**

A dosage form is a form in which a drug is produced and dispensed. A comprehensive list of specific routes of administration appears in the Data Standards Manual.

**CAS Number**

The acronym "CAS" stands for "Chemical Abstracts Service," a division of the American Chemical Society that provides comprehensive electronic chemical information services. CAS assigns unique CAS Registry Numbers to chemical substances. Many inactive ingredients have CAS Registry Numbers, which are useful in searching other databases for chemical information. The CAS Registry Number itself has no chemical significance.

**Maximum Potency**

The "maximum potency" field specifies the maximum amount of inactive ingredient for each route/dosage form containing that ingredient.

When there is no calculable potency measurement for the inactive ingredient, the "maximum potency" field will be blank.

**UNII**

The acronym "UNII" stands for "Unique Ingredient Identifier"

The UNII is a part of the joint USP/FDA Substance Registration System (SRS), which has been designed to support health information technology initiatives by providing

unique identifiers for substances in drugs, biologics, foods, and devices based on molecular structure and/or descriptive information. The SRS is used to generate permanent, unique, unambiguous identifiers for substances in regulated products, such as ingredients in drug products.

### 3.0 Top Ten Inactive Ingredients

Among the inactive ingredients, table 1 indicates the top 10 inactive ingredients approved for use in a specific dosage form with a specified route of administration.

<b>Table 1: List of Top 10 Inactive Ingredients (out of 3017) Approved by USFDA for specific dosage forms with specified route of administration-Pharmexcil Analysis</b>		
<b>S. No</b>	<b>Inactive Ingredient</b>	<b>Number of different dosage forms + route (out of 419) in which inactive ingredient is used</b>
1	Sodium hydroxide	198
2	Sodium chloride	162
3	Hydrochloric acid	156
4	Citric acid	120
5	Edetate disodium	98
6	Methyl paraben	97
7	Polysorbate 80	97
8	Sodium citrate	96
9	Propylene glycol	89
10	Benzyl alcohol	87

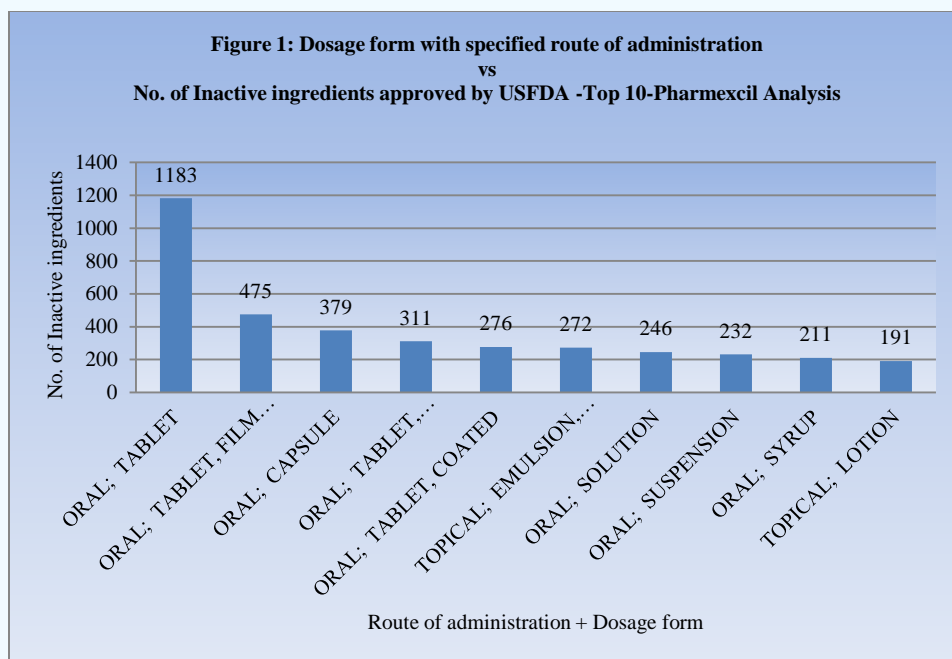
In addition to the name of the inactive ingredients and specific dosage form with specified route of administration, the maximum potency is indicated. It is observed that a total of 419 specific

combinations of route of administration; dosage form for which inactive ingredients were approved.

#### **4.0 Top Ten Dosage Forms With Specific Route Of Administration And Number Of Inactive Ingredients**

When a study is made in terms of the number of different types of inactive ingredients that are available for a specific route of administration with a specified dosage form, table 2 and figure 1 indicates that a maximum of 1183 types of inactive ingredients are used for oral; tablet drug product form.

<b>S. No</b>	<b>Route; Dosage form</b>	<b>No. of Types of Inactive Ingredients</b>
1	Oral; Tablet	1183
2	Oral; Tablet, film coated	475
3	Oral; Capsule	379
4	Oral; Tablet, Sustained action	311
5	Oral; Tablet, coated	276
6	Topical; Emulsion, cream	272
7	Oral; Solution	246
8	Oral; Suspension	232
9	Oral; Syrup	211
10	Topical; Lotion	191



It is observed that about 11 percent of the total inactive ingredients used for the USFDA approved drug products are used for commonly used oral route of administration in the form of tablet dosage form. It is necessary to understand that an inactive ingredient may be a diluent, glidant, disintegrating agent, dispersing agent, colourant, flavor, preservative, vehicle, stabilizing agent etc.

Intellectual property can be established with innovation bent of mind. Patent Facilitation Center at Pharmexcil is trying to help the pharmaceutical industry with knowledge resources that are feasible so that novelty can be achieved.

As a whole, it has been observed that 81 different dosage forms and 47 different routes of administrations are available for USFDA approved products. USFDA has approved inactive ingredients for a specific route of administration in combination with specific dosage form. It has been observed that a total of 419 specific combinations of route of administration with dosage form are available.

When a comparison is made with respect to products approved by USFDA (Orange book), it has been observed that 26710 products are approved to market in USA. It has been observed that a

total of 245 specified dosage forms with specific route of administration are available among these approved products.

<b>S. No</b>	<b>Name of Inactive ingredient approved by USFDA</b>	<b>Route + Dosage form in combination used</b>
1	SODIUM HYDROXIDE	198
2	SODIUM CHLORIDE	162
3	HYDROCHLORIC ACID	156
4	CITRIC ACID	120
5	EDETATE DISODIUM	98
6	METHYLPARABEN	97
7	POLYSORBATE 80	97
8	SODIUM CITRATE	96
9	PROPYLENE GLYCOL	89
10	BENZYL ALCOHOL	87
11	GLYCERIN	85
12	PROPYLPARABEN	83
13	MANNITOL	79
14	MAGNESIUM STEARATE	64
15	SUCROSE	64
16	SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	63
17	ALCOHOL	61
18	HYPROMELLOSES	58
19	SILICON DIOXIDE, COLLOIDAL	58
20	CELLULOSE, MICROCRYSTALLINE	56
21	LACTOSE	56
22	NITROGEN	56
23	ACETIC ACID	53
24	LACTOSE MONOHYDRATE	52
25	TALC	52
26	SODIUM ACETATE	51
27	CARBOXYMETHYLCELLULOSE SODIUM	49
28	SODIUM BISULFITE	49
29	ALCOHOL, DEHYDRATED	48
30	EDETATE CALCIUM DISODIUM	48
31	GELATIN	48



32	SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS	47
33	TITANIUM DIOXIDE	46
34	SODIUM METABISULFITE	45
35	CROSPVIDONE	43
36	SODIUM LAURYL SULFATE	43
37	FD&C RED NO. 40	41
38	SODIUM BENZOATE	41
39	SORBITOL	41
40	POLYETHYLENE GLYCOL 400	40
41	D&C YELLOW NO. 10	39
42	SODIUM BICARBONATE	38
43	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS	38
44	CITRIC ACID MONOHYDRATE	36
45	HYDROXYPROPYL CELLULOSE	36
46	HYPROMELLOSE 2910 (15000 MPA.S)	36
47	SACCHARIN SODIUM DIHYDRATE	36
48	FD&C BLUE NO. 1	35
49	FD&C YELLOW NO. 6	35
50	PHOSPHORIC ACID	34
51	SORBITOL SOLUTION	34
52	STEARIC ACID	34
53	DEXTROSE	33
54	POLYSORBATE 20	33
55	SODIUM CARBONATE	33
56	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	33
57	STARCH, CORN	33
58	SODIUM PHOSPHATE	32
59	XANTHAN GUM	32
60	ANHYDROUS LACTOSE	31
61	BENZALKONIUM CHLORIDE	31
62	LACTIC ACID	31
63	SILICON DIOXIDE	31
64	STARCH	31
65	BUTYLATED HYDROXYTOLUENE	30
66	POLYETHYLENE GLYCOL 3350	30
67	ASCORBIC ACID	29
68	CROSCARMELLOSE SODIUM	29
69	MINERAL OIL	29

70	POVIDONE K30	29
71	SODIUM STARCH GLYCOLATE	29
72	STARCH, PREGELATINIZED	29
73	TROMETHAMINE	29
74	GLYCINE	28
75	METHYLCELLULOSE	28
76	SIMETHICONE	28
77	SULFURIC ACID	28
78	POVIDONE K29/32	27
79	ISOPROPYL ALCOHOL	26
80	BUTYLATED HYDROXYANISOLE	25
81	FERRIC OXIDE RED	25
82	FERRIC OXIDE YELLOW	25
83	POTASSIUM PHOSPHATE, MONOBASIC	25
84	LACTOSE, HYDROUS	24
85	PHENOL	24
86	POLYETHYLENE GLYCOL 4000	24
87	ANHYDROUS TRISODIUM CITRATE	23
88	BENZOIC ACID	23
89	FD&C RED NO. 3	23
90	HYDROXYETHYL CELLULOSE	23
91	ETHYLCELLULOSES	22
92	FD&C YELLOW NO. 5	22
93	GLYCERYL STEARATE	22
94	POLOXAMER 188	22
95	POLYETHYLENE GLYCOL 6000	22
96	SODIUM PHOSPHATE, MONOBASIC	22
97	CHLOROBUTANOL	21
98	FERRIC OXIDE	21
99	POLYETHYLENE GLYCOL 8000	21
100	POLYVINYL ALCOHOL	21
101	ASPARTAME	20
102	CARNAUBA WAX	20
103	D&C YELLOW NO. 10--ALUMINUM LAKE	20
104	SODIUM PHOSPHATE, DIBASIC	20
105	SORBIC ACID	20
106	ACACIA	19
107	CALCIUM CHLORIDE	19

108	CARBOMER 934P	19
109	LIGHT MINERAL OIL	19
110	MEGLUMINE	19
111	CELLULOSE	18
112	CETYL ALCOHOL	18
113	FD&C BLUE NO. 2	18
114	FD&C RED NO. 40--ALUMINUM LAKE	18
115	FERROSOFERRIC OXIDE	18
116	SORBITAN MONOOLEATE	18
117	TRIETHYL CITRATE	18
118	BUTYLPARABEN	17
119	CREATININE	17
120	D&C RED NO. 33	17
121	FD&C BLUE NO. 1--ALUMINUM LAKE	17
122	FD&C YELLOW NO. 6--ALUMINUM LAKE	17
123	LECITHIN	17
124	PEPPERMINT OIL	17
125	POLYOXYL 40 STEARATE	17
126	POTASSIUM CHLORIDE	17
127	POVIDONE K90	17
128	SODIUM SULFITE	17
129	SUGAR CONFECTIONERS	17
130	TRISODIUM CITRATE DIHYDRATE	17
131	CALCIUM CARBONATE	16
132	CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS	16
133	CASTOR OIL	16
134	FD&C BLUE NO. 2--ALUMINUM LAKE	16
135	HYDROCHLORIC ACID, DILUTED	16
136	MENTHOL	16
137	OLEIC ACID	16
138	SIMETHICONE EMULSION	16
139	SODIUM PHOSPHATE, DIBASIC, DIHYDRATE	16
140	SODIUM STEARYL FUMARATE	16
141	TARTARIC ACID	16
142	THIMEROSAL	16
143	VANILLIN	16
144	CARBON DIOXIDE	15
145	FD&C GREEN NO. 3	15

146	MAGNESIUM ALUMINUM SILICATE HYDRATE	15
147	POLYSORBATE 60	15
148	POTASSIUM SORBATE	15
149	WHITE WAX	15
150	BORIC ACID	14
----	<b>Grand Total (Ingredients)</b>	<b>3017</b>

**Table 4: List indicating the number of inactive ingredients used in USFDA approved products for a specific route of administration and dosage form-Top 200-Pharmexcil Analysis-Part List**

S. No	Route; Dosage form	No. of Types of Inactive Ingredients
1	ORAL; TABLET	1183
2	ORAL; TABLET, FILM COATED	475
3	ORAL; CAPSULE	379
4	ORAL; TABLET, SUSTAINED ACTION	311
5	ORAL; TABLET, COATED	276
6	TOPICAL; EMULSION, CREAM	272
7	ORAL; SOLUTION	246
8	ORAL; SUSPENSION	232
9	ORAL; SYRUP	211
10	TOPICAL; LOTION	191
11	ORAL; CAPSULE, SUSTAINED ACTION	190
12	ORAL; TABLET, EXTENDED RELEASE	174
13	ORAL; TABLET, DELAYED ACTION, ENTERIC COATED	157
14	INTRAVENOUS; INJECTION	151
15	ORAL; POWDER, FOR SUSPENSION	141
16	TOPICAL; SOLUTION	137
17	ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED, CHEWABLE	128
18	TOPICAL; OINTMENT	128
19	IV(INFUSION); INJECTION	118
20	INTRAMUSCULAR; INJECTION	110
21	ORAL; CAPSULE, SOFT GELATIN	104
22	ORAL-28; TABLET	103
23	ORAL; CONCENTRATE	91
24	TOPICAL; GEL	91
25	OPHTHALMIC; SOLUTION	88
26	TRANSDERMAL; FILM, CONTROLLED RELEASE	87
27	ORAL; CAPSULE, ENTERIC COATED PELLETS	85

28	ORAL; TABLET, SUSTAINED ACTION, COATED	82
29	ORAL; CAPSULE, HARD GELATIN	81
30	ORAL; SOLUTION, ELIXIR	79
31	ORAL; TABLET, CONTROLLED RELEASE	79
32	IM - IV; INJECTION	76
33	ORAL; TABLET (IMMED./COMP. RELEASE), FILM COATED	76
34	VAGINAL; EMULSION, CREAM	76
35	ORAL; TABLET, SUSTAINED ACTION, FILM COATED	75
36	ORAL-21; TABLET	73
37	OPHTHALMIC; SOLUTION, DROPS	71
38	SUBLINGUAL; TABLET	71
39	ORAL; CAPSULE, EXTENDED RELEASE	66
40	ORAL; TABLET, ORALLY DISINTEGRATING	62
41	TOPICAL; SHAMPOO	61
42	ORAL; POWDER, FOR SOLUTION	55
43	SUBCUTANEOUS; INJECTION	55
44	INTRAVENOUS; SOLUTION, INJECTION	54
45	IV(INFUSION); SOLUTION, INJECTION	52
46	OPHTHALMIC; SUSPENSION	47
47	ORAL; TABLET, DELAYED ACTION	47
48	TOPICAL; CREAM, AUGMENTED	47
49	NASAL; SPRAY, METERED	45
50	ORAL; POWDER, FOR ORAL SUSPENSION	45
51	TOPICAL; SPONGE	45
52	TOPICAL; EMULSION, AEROSOL FOAM	43
53	RECTAL; SUPPOSITORY	42
54	INTRA-ARTICULAR; INJECTION	41
55	ORAL; GRANULE, FOR SUSPENSION	41
56	TOPICAL; EMULSION	40
57	INTRAVENOUS; INJECTABLE	39
58	INTRAVENOUS; POWDER, FOR INJECTION SOLUTION	39
59	IV(INFUSION); POWDER, FOR INJECTION SOLUTION	37
60	ORAL; CAPSULE, SOFT GELATIN LIQUID-FILLED	37
61	ORAL; DROPS	37
62	BUCCAL; GUM, CHEWING	36
63	IM - IV - SC; INJECTION	36
64	IM - SC; INJECTION	36
65	ORAL; SUSPENSION, SUSTAINED ACTION	36
66	ORAL; TABLET, REPEAT ACTION	36
67	ORAL; POWDER	34

68	ORAL; SUSPENSION, LIQUID	34
69	TOPICAL; SUSPENSION	34
70	OPHTHALMIC; SUSPENSION, DROPS	33
71	NERVE BLOCK; INJECTION	32
72	AURICULAR (OTIC); SOLUTION	31
73	INTRAVENOUS; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED	31
74	TOPICAL; SHAMPOO, SUSPENSION	31
75	AN,INFILTRATION; INJECTION	30
76	DENTAL; PASTE	30
77	INTRALESIONAL; INJECTION	30
78	IV(INFUSION); POWDER, FOR INJECTION SOLUTION, LYOPHILIZED	30
79	INHALATION; SOLUTION	28
80	ORAL; GRANULE	28
81	RECTAL; SOLUTION	28
82	VAGINAL; TABLET	28
83	ORAL; CAPSULE, COATED, SOFT GELATIN	27
84	TOPICAL; AEROSOL	27
85	TOPICAL; CREAM, EMULSION, SUSTAINED RELEASE	26
86	VAGINAL; SUPPOSITORY	26
87	INTRAMUSCULAR; INJECTABLE	25
88	INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION	25
89	INTRAMUSCULAR; SOLUTION, INJECTION	25
90	NASAL; SOLUTION	25
91	SOFT TISSUE; INJECTION	25
92	IM - IV; POWDER, FOR INJECTION SOLUTION	24
93	ORAL; CAPSULE, DELAYED ACTION	24
94	ORAL; POWDER, FOR RECONSTITUTION	24
95	SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED	24
96	AURICULAR (OTIC); SUSPENSION	23
97	BUCCAL; TABLET	23
98	OPHTHALMIC; OINTMENT	23
99	ORAL; TABLET, ENTERIC COATED PARTICLES	23
100	INTRASYNOVIAL; INJECTION	22
101	SUBCUTANEOUS; SOLUTION, INJECTION	22
102	DENTAL; SOLUTION	21
103	INHALATION; AEROSOL, METERED	21
104	INTRAVENOUS; SOLUTION	21
105	SUBCUTANEOUS; SUSPENSION, INJECTION	21
106	IM - IV; INJECTABLE	20
107	NASAL; SPRAY	20

108	ORAL; GRANULE, FOR ORAL SUSPENSION	20
109	ORAL; TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE	20
110	ORAL-28; TABLET, COATED	20
111	SUBCUTANEOUS; INJECTABLE	20
112	AURICULAR (OTIC); SOLUTION, DROPS	19
113	BUCCAL/SUBLINGUAL; TABLET	19
114	EPIDURAL; INJECTION	19
115	INTRABURSAL; INJECTION	19
116	INTRADERMAL; INJECTION	19
117	INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED	19
118	INTRA-ARTERIAL; INJECTION	18
119	INTRAVASCULAR; INJECTION	18
120	ORAL; LIQUID	18
121	TOPICAL; PATCH	18
122	BUCCAL; FILM, SOLUBLE	17
123	INTRACARDIAC; INJECTION	17
124	INTRAMUSCULAR; INJECTION, SUSTAINED ACTION	17
125	ORAL; SOLUTION, SYRUP	17
126	ORAL; SUSPENSION, DROPS	17
127	ORAL-21; TABLET, COATED	17
128	ORAL; CAPSULE, COATED PELLETS	16
129	ORAL; CAPSULE, SUSTAINED ACTION, HARD GELATIN	16
130	RECTAL; SUSPENSION	16
131	TOPICAL; AEROSOL, METERED	16
132	IM - IV; SOLUTION, INJECTION	15
133	IV - SC; INJECTION	15
134	ORAL; TABLET (IMMED./COMP. RELEASE), COATED	15
135	ORAL; TABLET, DELAYED RELEASE	15
136	ORAL-20; TABLET	15
137	TOPICAL; SWAB	15
138	CAUDAL BLOCK; INJECTION	14
139	OPHTHALMIC; POWDER, FOR SOLUTION	14
140	ORAL; POWDER, FOR ORAL SOLUTION	14
141	ORAL; TABLET, MULTILAYER, EXTENDED RELEASE	14
142	ORAL; TABLET, SUSTAINED RELEASE, FILM COATED	14
143	TOPICAL; EMULSION, LOTION	14
144	TOPICAL; FILM, CONTROLLED RELEASE	14
145	TRANSDERMAL; GEL	14
146	TRANSDERMAL; PATCH	14
147	TRANSDERMAL; PATCH, CONTROLLED RELEASE	14

148	INTRA-ARTICULAR; INJECTABLE	13
149	INTRALESIONAL; INJECTION, SUSTAINED ACTION	13
150	INTRASYNOVIAL; INJECTION, SUSTAINED ACTION	13
151	INTRATHECAL; INJECTION	13
152	ORAL; GRANULE, FOR RECONSTITUTION	13
153	ORAL; TABLET, UNCOATED, TROCHE	13
154	RECTAL; ENEMA	13
155	VAGINAL; GEL	13
156	VAGINAL; INSERT	13
157	ORAL; BAR, CHEWABLE	12
158	ORAL; SOLUTION, LIQUID	12
159	TOPICAL; SOLUTION, DROPS	12
160	DENTAL; GEL	11
161	INTRAOCULAR; SOLUTION	11
162	ORAL; CAPSULE (IMMED./COMP. RELEASE), HARD GELATIN	11
163	ORAL; PASTILLE	11
164	ORAL; TABLET, SUGAR COATED	11
165	RECTAL; AEROSOL, METERED	11
166	INTRALESIONAL; INJECTABLE	10
167	INTRAVIDEAL; SUSPENSION, INJECTION	10
168	ORAL; AEROSOL, METERED	10
169	ORAL; DISPERSIBLE TABLET	10
170	ORAL; TROCHE	10
171	SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION	10
172	URETERAL; SOLUTION	10
173	IM - SC; INJECTION, SUSTAINED ACTION	9
174	INTRACAVITARY; INJECTION	9
175	INTRACAVITARY; POWDER, FOR INJECTION SOLUTION, LYOPHILIZED	9
176	INTRAMUSCULAR; INJECTION, MICROSPHERES	9
177	INTRAPERITONEAL; INJECTION	9
178	INTRATHECAL; INJECTABLE	9
179	INTRAVENOUS; EMULSION, INJECTION	9
180	IRRIGATION; SOLUTION	9
181	OPHTHALMIC; EMULSION	9
182	ORAL; GRANULE, EFFERVESCENT	9
183	ORAL; TABLET, MULTILAYER, COATED	9
184	SOFT TISSUE; INJECTION, SUSTAINED ACTION	9
185	TOPICAL; POWDER, FOR SOLUTION	9
186	INHALATION; INHALANT	8
187	INTRA-ARTICULAR; INJECTION, SUSTAINED ACTION	8



188	INTRADERMAL; INJECTION, SUSTAINED ACTION	8
189	INTRALESIONAL; SUSPENSION, INJECTION	8
190	INTRAMUSCULAR; SUSPENSION, INJECTION	8
191	INTRASYNOVIAL; SUSPENSION, INJECTION	8
192	INTRATRACHEAL; SUSPENSION	8
193	INTRAUTERINE; INTRAUTERINE DEVICE	8
194	INTRAVENOUS; INJECTION, POWDER, LYOPHILIZED, FOR LIPOSOMAL SUSPENSION	8
195	INTRAVENOUS; INJECTION, SUSPENSION, LIPOSOMAL	8
196	IONTOPHORESIS; PATCH, CONTROLLED RELEASE	8
197	NASAL; SOLUTION, SPRAY	8
198	ORAL; CAPSULE (IMMED./COMP. RELEASE), SOFT GELATIN, PERLE	8
199	ORAL; CAPSULE, DELAYED ACTION, COATED, HARD GELATIN	8
200	ORAL; EMULSION	8
----	<b>Grand Total (Route of Administration; Dosage form)</b>	<b>419</b>

**For detailed information you may contact addressing to : The Executive Director, Pharmaceuticals Export Promotion Council of India (Pharmexcil), 101, Aditya Trade Center, Ameerpet, Hyderabad- 500 038. Email: [patents@pharmexcil.com](mailto:patents@pharmexcil.com), [info@pharmexcil.com](mailto:info@pharmexcil.com)**