



# IP Reference Substance Roadmap for 2016-2017

Indian Pharmacopoeia Commission (IPC)  
Ministry of Health and Family Welfare,  
Government of India.

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# Overview

- **Present status of IPRS**
- **New IPRS Targeted for 2016-2017**
- **Roadmap for new IPRS in 2016-2017**
- **Update of Impurity standards**



# Present Status of IPRS

- **The availability of IPRS up to June 2016 : 510 Nos.**
- **The availability of Impurity up to June 2016 : 53 Nos.**
- **The list of available IPRS & Impurity Standards is available at IPC website ([www.ipc.gov.in](http://www.ipc.gov.in))**



# Target of IPRS

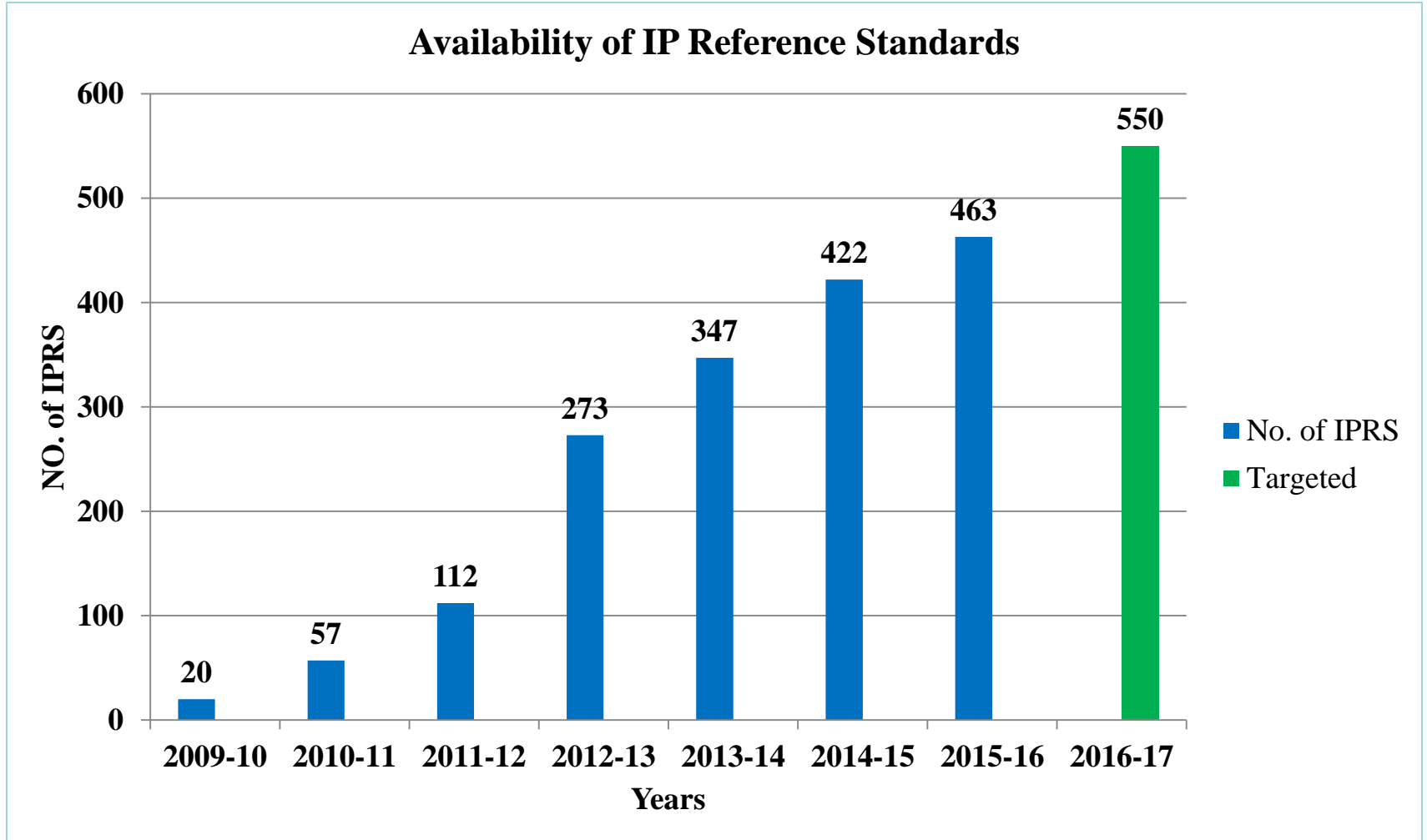
- **The target of total IPRS in year 2016-2017 : 550 Nos.**
  
- **The target of total Impurity in year 2016-2017 : 100 Nos.**



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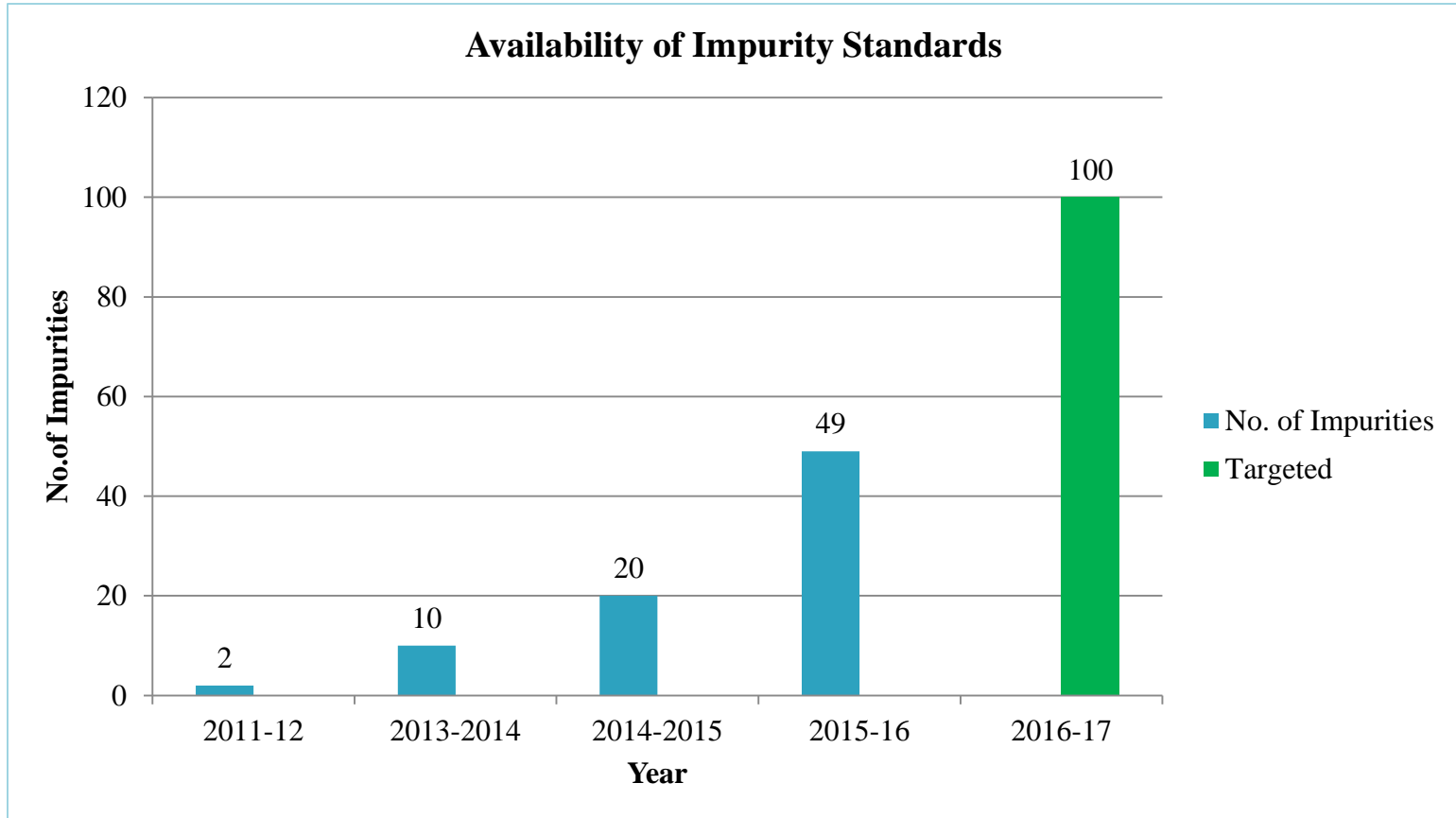


# Indian Pharmacopoeia Reference Substances (IPRS)





# Impurity Standards





# Roadmap for new IPRS & impurity Standard

- 11 New IPRS are under evaluation  
(The list is attached as **Annexure - I**)
- 29 New Impurity standards are issued for characterization in May 2016  
(The list is attached as **Annexure - II**)



# Roadmap for new IPRS & impurity Standard

- 34 New IPRS to be issued in Q 3 2016 for Characterization

(The list is attached as **Annexure III**)

- Another 32 New Impurity to be issued in Q 4 2016

(The list is attached as **Annexure IV**)





# Annexure – I

S.No.	Name of IPRS	LOT NO.
1	Betamethasone Sodium Phosphate	IPRS/154/14
2	Choline Fenofibrate	IPRS/165/14
3	Voglibose	IPRS/07/15
4	Fluphenazine Hydrochloride	IPRS/14/15
5	Flurazepam Hydrochloride	IPRS/15/15
6	Oxazepam	IPRS/16/15
7	Zopiclone	IPRS/17/15
8	Aspartame	IPRS/18/15
9	Diiodohydroxyquinoline	IPRS/63/15
10	Niclosamide	IPRS/64/15
11	Tobramycin Sulphate	IPRS/51/16



# Annexure II

S.No.	Name of the impurity	Name of Monograph	LOT NO.
1	Sodium Propyl Paraben Impurity A	Propyl Paraben	IMP/26/15
2	Noscapine Hydrochloride Impurity A	(Noscapine	IMP/27/15
3	Fexofenadine Hydrochloride Impurity A	Fexofenadine Hydrochloride	IMP/34/15
4	Uridine	Cytarabine	IMP/35/15
5	Hydrochlorothiazide impurity A	Hydrochlorothiazide	IMP/36/15
6	Tris(hydroxymethyl)nitromethane	(Bronopol	IMP/37/15
7	2-methyl-2-nitropropane-1,3-diol	Bronopol	IMP/38/15
8	2-nitroethanol	Bronopol	IMP/39/15
9	2,3-Dimethylaniline	Mefenamic Acid	IMP/01/16
10	2-chlorobenzoic acid / Mesalazine impurity L	Mesalazine)	IMP/02/16



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## Annexure II (Cont....)

S.No.	Name of the impurity	Name of Monograph	LOT NO.
11	2- vinylpyridine / betahistine mesilate impurity A	Betahistine mesilate	IMP/03/16
12	2-chlorobenzophenone / Clotrimazole impurity E	Clotrimazole	IMP/04/16
13	Anilinium chloride/ mesalazine impurity K (Aniline hydrochloride)	Mesalazine	IMP/05/16
14	2-chloro-5-nitrobenzoic acid / Mesalazine impurity M	Mesalazine	IMP/06/16
15	4-chlorobenzoic acid	Indomethacin Suppositories	IMP/07/16
16	Benzhydrol/ diphenylmethanol (Ebastine (impurity- A)/ Diphenhydramine impurity D/ cyclizine impurity B )	Ebastine/ Diphenhydramine hydrochloride/ Cyclizine hydrochloride	IMP/08/16
17	dibenzosuberone / amitriptyline impurity A	Amitriptyline hydrochloride	IMP/09/16
18	oxalic acid dihydrate	Escitalopram oxalate	IMP/10/16
19	S(-) Tyrosine /tyrosine / levodopa impurity B	levodopa	IMP/11/16
20	Iminodibenzyl	carbamazepine/ imipramine Hydrochloride	IMP/12/16



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## Annexure II (Cont....)

S.No.	Name of the impurity	Name of Monograph	LOT NO.
21	Nitrilotriacetic acid	Disodium edetate	IMP/13/16
22	Sodium Bromide	Bronopol	IMP/14/16
23	3-pyridyl acetic acid Hydrochloride	Risedronate sodium	IMP/15/16
24	4-(trifluoromethyl)phenol/ $\alpha,\alpha,\alpha$ -trifluoro-p-cresol	Fluoxetine hydrochloride	IMP/16/16
25	2-methylimidazole	Ondansetron hydrochloriden oral solution Ondansetron Tablets	IMP/17/16
26	N-methylpyrrolidine/1-methyl pyrrolidine	Cefepime hydrochloride	IMP/18/16
27	1-vinyl-2-pyrrolidinone / 1-vinylpyrrolidin-2-one	Povidone	IMP/19/16
28	Vinyl acetate	Povidone	IMP/20/16
29	Diclofenac Impurity A	Diclofenac Sodium	IPRS/53/16



# Annexure – III

S.No.	Name of IPRS	LOT NO.
1	Piperazine Adipate	IPRS/65/15
2	Piperazine Citrate	IPRS/66/15
3	Dorzolamide Hydrochloride	IPRS/67/15
4	Gabapentin	IPRS/99/15
5	Nabumetone	IPRS/100/15
6	Celecoxib	IPRS/101/15
7	Metoprolol Succinate	IPRS/102/15
8	Levetiracetam	IPRS/103/15
9	Brimonidine Tartrate	IPRS/104/15
10	Lactulose Concentrate	IPRS/105/15
11	Methocarbamol	IPRS/106/15



## Annexure – III (cont...)

S.No.	Name of IPRS	LOT NO.
12	Olmesartan Medoxomil	IPRS/107/15
13	Sitagliptin Phosphate	IPRS/108/15
14	Duloxetine Hydrochloride	IPRS/109/15
15	Drotaverine Hydrochloride	IPRS/110/15
16	Mirtazapine	IPRS/111/15
17	Methylphenidate Hydrochloride	IPRS/112/15
18	Tadalafil	IPRS/113/15
19	Cholecalciferol (Vit. D3)	IPRS/128/15
20	Zinc Oxide	IPRS/130/15
21	Formoterol Fumarate Dihydrate	IPRS/30/16
22	Thiotepa	IPRS/31/16



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## Annexure – III (cont...)

S.No.	Name of IPRS	LOT NO.
23	Voriconazole	IPRS/32/16
24	Parecoxib Sodium	IPRS/33/16
25	Diclofenac Diethylamine	IPRS/42/16
26	Terbinafine Hydrochloride	IPRS/43/16
27	Prilocaine	IPRS/44/16
28	Paroxetine Hydrochloride Hemihydrate	IPRS/45/16
29	Mecobalamin	IPRS/46/16
30	Bisoprolol Fumarate	IPRS/47/16
31	Cefdinir USP (Crystal B)	IPRS/48/16
32	Tibolon	IPRS/56/16
33	Trospium Chloride	IPRS/57/16
34	Dexamethasone	IPRS/58/16



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# Annexure – IV

S.No.	Name of the impurity	Name of Monograph	LOT NO.
1	2-methylbenzophenone / Orphenadrine impurity B / (RS)-(2- methylphenyl)phenylmethanone	Orphenadrine citrate	IMP/21/16
2	2,3,4-trimethoxybenzaldehyde / trimetazidine impurity C	Trimetazidine hydrochloride	IMP/22/16
3	2,3,4-trimethoxybenzyl alcohol / (2,3,4-trimethoxyphenyl) methanol/ (trimetazidine impurity D)	Trimetazidine hydrochloride	IMP/23/16
4	4-aminomethylbenzoic acid / tranexamic impurity D	Tranexamic acid	IMP/24/16
5	4-hydroxybenzoic acid (aspirin impurity A)	Aspirin	IMP/25/16
6	Uracil (Lamivudine impurity F) (pyrimidine-2,4(1H,3H)-dione)	Lamivudine	IMP/26/16
7	Cytosine (Lamivudine impurity E) (4-aminopyrimidin-2(1H)-one)	Lamivudine	IMP/27/16
8	Adenine (Adenosine impurity A)	Adenosine	IMP/28/16





## Annexure – IV (cont...)

S.No.	Name of IPRS	Name of Monograph	LOT NO.
9	Inosine (Adenosine impurity G)	Adenosine	IMP/29/16
10	2,5-dimethylphenol/(Gemfibrozil impurity A)/ p-xyleneol	Gemfibrozil	IMP/30/16
11	mandelic acid (sertraline impurity E)	Setraline hydrochloride	IMP/31/16
12	Sodium benzene sulphonate	Amlodipine besylate	IMP/32/16
13	3,4,5-trimethoxybenzoic acid (Trimethoprim impurity J)	Trimethoprim	IMP/33/16
14	Thioacetic acid (Racecadotril impurity A)	Racecadotril	IMP/34/16
15	Benzalacetone (warfarin impurity C) (benzylideneacetone)	Warfarin sodium	IMP/35/16
16	2-pyrrolidinone / 2-pyrrolidone	Piracetam	IMP/36/16



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## Annexure – IV (cont...)

S.No.	Name of IPRS	Name of Monograph	LOT NO.
17	D(-) - $\alpha$ phenylglycine/ D-phenylglycine	(Cephalexin)	IMP/37/16
18	sodium azide (sodium salt of irbesartan impurity B)	Irbesartan)	IMP/38/16
19	5-methyl-3-phenylisoxazole-4-carboxylic acid (Oxacillin impurity C)	Oxacillin sodium	IMP/39/16
20	4-hydroxycoumarin (warfarin impurity B)	(Warfarin sodium)	IMP/40/16
21	1-naphthaleneacetic acid / 1-naphthylacetic acid (naphazoline impurity B)	(Naphazoline nitrate)	IMP/41/16
22	(+)-6-aminopenicillanic acid (Oxacillin impurity A)	(Oxacillin sodium)	IMP/42/16
23	2-methylbenzhydrol (Orphenadrine impurity A)	(Orphenadrine citrate)	IMP/43/16
24	Glutaric acid	(Adipic acid)	IMP/44/16



# Annexure – IV (cont...)

S.No.	Name of IPRS	Name of Monograph	LOT NO.
25	Methyl nicotinate	Nicorandil	IMP/45/16
26	4-(4-Hydroxyphenyl)-2-butanone/ Dobutamine impurity B/ 4-(4-hydroxyphenyl)butan-2-one	Dobutamine Hydrochloride	IMP/46/16
27	Methyl benzenesulphonate	Atracurium besylate	IMP/47/16
28	3-ethoxy-4-hydroxybenzaldehyde	Mitomycin	IMP/48/16
29	Cyclobutane-1,1-dicarboxylic acid/carboplatin impurity B	Carboplatin Injection	IMP/49/16
30	p-Anisaldehyde / Mepyramine impurity B/ anisaldehyde	Mepyramine maleate/ Dobutamine Hydrochloride	IMP/50/16
31	Tramadol Hydrochloride impurity E	Tramadol Hydrochloride	IMP/51/16
32	Flavoxate Hydrochloride impurity A	Flavoxate Hydrochloride	IMP/52/16

***Thank you !!***