BUYER TENDER DOCUMENT

FOR

Supply of "PHARMACEUTICAL IMPURITIES"
at IPC, Ghaziabad

TENDER NO. IPC/5507/2023-24

INDIAN PHARMACOPOEIA COMMISSION

MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
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सत्यमेव जयते

INDEX

SECTION-I

NOTICE INVITING TENDER (NIT)

No. IPC/5507/2023-24 **Dated: 14.12.2023**

Sub: Supply of "PHARMACEUTICAL IMPURITIES" at IPC, Ghaziabad

Indian Pharmacopoeia Commission (IPC), under the Ministry of Health & Family Welfare, Govt. of India invites sealed and super-scribed Bids as per noted subject from reputed and experienced Manufacturers at Indian Pharmacopoeia Commission (IPC). Details of procurement and terms and conditions are mentioned below.

This bid is reserved for Class I and Class II bidders only as per Make in India Policy (DPIIT Order dated 16th September 2020). Participating bidders need to submit an Affidavit regarding Local Content claim on Rs. 100/- Stamp Paper as per ANNEXURE-F under Preference to "MAKE IN INDIA" Policy.

Sl.No.	Particulars	Time for Delivery
1.	Supply of "Pharmaceutical Impurities" at IPC, Ghaziabad	60 Days

Earnest Money Deposit (EMD) Details

Sl. No.	Items	Quantity	Amount of EMD (in Rs.)
1	Supply of "Pharmaceutical Impurities" at IPC, Ghaziabad	As per the Schedule of Requirement	As per GeM Tender Document

- **The bidder should be reputed and experienced Manufacturer.**
- The valid **Manufacturing License/ Approval Document including undertaking** must be enclosed along with the technical Bid.

TERMS & CONDITIONS

1. This Tender Document can also be downloaded from our website **www.ipc.gov.in** .

2. Indian Pharmacopoeia Commission (IPC), reserves the right to accept/ reject any or all tenders without assigning any reason whatsoever.

IMPORTANT DATES

PRE-BID MEETING DATE & TIME	**As per GeM Tender Document**
LAST DATE FOR DOWNLOADING TENDER FORM	**As per GeM Tender Document**
LAST DATE FOR SUBMISSION OF TENDERS	**As per GeM Tender Document**
DATE OF OPENING OF TECHNICAL BIDS	**As per GeM Tender Document**

SECTION-II

SCHEDULE OF REQUIREMENT (SOR)

The below mentioned pharmaceutical Impurities are required:

Tender Schedule No.	Monographs	Impurities IPRS used for SST preparation	IUPAC Names	Purity Greater than & equal to	Qty. (Gram)
1	**Azilsartan medoxomil Potassium API and Tablets**	Azilartan Kamedoxomil impurity A	**IMP A**-2-oxo-3((2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)-[1,1'-biphenyl]-4-yl)methyl)-2,3-dihydro-1H-benzo[d] imidazole-4-carboxylic acid. (Desethyl Asilsartan).	90%	10 G
2	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity B	**IMP B**-2-ethoxy-1-{[2-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)biphenyl-4-yl}methyl)-1H-benzo[d]imidazole-7-carboxylic acid. (Asilsartan).	90%	10 G
3	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity C	**IMP C**- (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl 2hydroxy-1-((2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3yl)-[1,1'-biphenyl]-4-yl)methyl)-1H-benzo[d] imidazole-7-carboxylate. (Desethyl Azilsartan Medoxomil).	90%	10 G
4	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity D	**IMP D-** (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl 1-((2'carbamoyl-[1,1'-biphenyl]-4-yl)methyl)-2-ethoxy-1H-benzo[d] imidazole -7-carboxylate.	90%	10 G
5	**Azilsartan medoxomil Potassium API and Tablets**	Azilartan Kamedoxomil impurity E	**IMP E-** methyl 2-ethoxy-1-((2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)-[1,1'-biphenyl]-4-yl)methyl)-1H-benzo[d] imidazole-7-carboxylate. (methyl Ester).	90%	10 G
6	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity F	**IMP F-** ethyl 2-ethoxy-1- ((2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)-[1,1'-biphenyl]-4-yl)methyl)-1H-benzo[d] imidazole-7-carboxylate.	90%	10 G
7	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity G	**IMP G-** (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl) 2-ethoxy-1-((2'-(4-((5methyl-2-oxo-1,3-dioxol-4-yl)methyl5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)-[1,1'-biphenyl]-4yl)-4-yl)methyl)-1H-benzo[d]imidazole-7-carboxylate. (Bis impuity).	90%	10 G
8	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity H	**IMP H-** 7-(((5-methyl-2-oxo-1,3-dioxol-4-yl)methoxy)carbonyl)-1-((2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3yl)-[1,1'-biphenyl]-4-yl)methyl)-1H-benzo[d] midazole-2yl 2-etoxy-1-((2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)-[1,1'-biphenyl]-4yl)-4-yl)methyl)-1H-benzo[d]imidazole-7-carboxylate. (Azilsartan Medoxomil Dimer-4).	90%	10 G
9	**Cabozantinib S-malate API and Tablets**	Cabozantinib impurity A	**Cabozantinib impurity A -(**1-({4-[(6,7-dimethoxyquinolin-4-yl)oxy]phenyl} carbamoyl)cyclopropanecarboxylic acid)	90%	10 G
10	**Levetiracetam**	Levetiracetam Related Compound A	((S)-N-(1-Amino-1-oxobutan-2-yl)-4-chlorobutanamide)	90%	10 G
11	**Ketoconazole Shampoo**	Ketoconazole impurity D	**IMP D**- (1-[4-[[(2RS,4SR)-2-(2,4-dichlorophenyl)-2-[(1H-imidazol-1-yl)methyl]-1,3-dioxolan-4-yl]methoxy]phenyl]piperazine,)	90%	10 G

12	**Ketoconazole Shampoo**	Ketoconazole impurity 1	**IMP 1**- (rac-4-acetyl-1-[4-({(2R,4S)-2-(2,4-dichlorophenyl)-2-[(1H-imidazol-1-yl)methyl]-1,3-dioxolan-4-yl}methoxy)phenyl]piperazine N1-oxide)	90%	10 G
13	**Ketoconazole Shampoo**	Ketoconazole impurity 2	**IMP 2**-(rac-{(2R,4S)-2-(2,4-dichlorophenyl)-2-[(1H-imidazol-1-yl)methyl]-1,3-dioxolan-4-yl}methanol.)	90%	10 G
14	**Moxifloxacin Tablets**	Moxifloxacin related compound F	**IMP F-** (1-Cyclopropyl-6-fluoro-8-methoxy-7-[(4aS,7aS)-1- methylhexahydro-1H-pyrrolo[3,4-b]pyridin-6(2H)-yl]- 4-oxo-1,4-dihydroquinoline-3-carboxylic acid)	90%	10 G
15	**Moxifloxacin Tablets**	Moxifloxacin related compound A	**IMP A-(**1-Cyclopropyl-6,8-difluoro-1,4-dihydro-7-[(4aS,7aS)- octahydro-6H-pyrrolo[3,4-b]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid)	90%	10 G
16	**Perampanel API and Tablets**	Perampanel impurity A	**IMP A-** 1-Phenyl-5-pyridin-2-yl-2(*1H*)-pyridone	90%	10 G
17	**Perampanel API and Tablets**	Perampanel impurity B	**IMP B-** 3-Bromo-1-phenyl-5-pyridin-2-yl-2(*1H)*-pyridone.	90%	10 G
18	**Perampanel API and Tablets**	Perampanel impurity C	**IMP C-** 3-(2-Oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl)benzonitrile.	90%	10 G
19	**Perampanel API and Tablets**	Perampanel impurity D	**IMP D**- 2-Bromo-6-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl)benzonitrile.	90%	10 G
20	**Perampanel API and Tablets**	Perampanel impurity E	**IMP E-** 3-(2-Oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl)-1,1'-biphenyl-2,2'-dicarbonitrile.	90%	10 G
21	**Perampanel API and Tablets**	Perampanel impurity F	**IMP F-** (methyl 2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl)benzoate)	90%	10 G
22	**Remogliflozin Etabonate API and Tablets**	Remogliflozin etabonate impurity A	(5-methyl-1-(propan-2-yl)-4-[4-(propan-2-yloxy)benzyl]-1H-pyrazol-3-yl β-D-glucopyranoside)	90%	10 G
23	**Rifaximin API and Tablets**	Rifaximin impurity D	**IMP D-** rifaximin Y ([(7S,9E,11S,12R,13S,14R,15S,16S,18R,19E,21Z)-2,15,18,36-tetrahydroxy-11-methoxy-3,7,12,14,16,18,22,30-octamethyl-6,17,23-trioxo-8,37-dioxa-24,27,33-triazahexacyclo[23.10.1.14,7.05,35.026,34.027,32]heptatriaconta-1(35),2,4,9,19,21,25(36),26(34),28,30,32-undecaen-13-yl] acetate	90%	10 G
24	**Rifaximin API and Tablets**	Rifaximin Impurity H	**IMP H-** (2S,16Z,18E,20S,21S,22R,23R,24R,25S,26R,27S,28E)-5,6,21,23-tetrahydroxy-16-(hydroxymethyl)-27-methoxy-2,4,11,20,22,24,26-heptamethyl1,15-dioxo-1,2-dihydro2,7-(epoxypentadeca[1,11,13]trienoimino)[1]benzofuro[4,5-e]pyrido[1,2-a]benzimidazol-25-yl acetate (16-desmethyl-16-(hydroxymethyl)rifaximin).	90%	10 G
25	**Velpatasvir**	Velpatasvir impurity A	**IMP A-**methyl {(2S)-1[(2S,5S)-2-(9-{2-[(2S,4S)-4-(methoxymethyl)pyrrolidine-2-yl]-1H-imidazol-5-yl}-1,11-dihydroisochromeno[4',3':6,7]naphthol[1,2-d]imidazole-2- yl)-5-methylprrolidin-1-yl]-3-methyl-1-oxobutan-2-yl}carbamate. (amine free base.	90%	10 G
26	**Velpatasvir**	Velpatasvir impurity B	**IMP B-** methyl {(2S)-1-[(2S,5S)-2-(9-[2-[(2S,4S)-1-(4,6-dimethoxy-1,3,5-triazin-2-yl)-4-(methoxymethyl)pyrrolidin-2-yl]-1H-imidazol-5yl]-1,11-dihydroisochromeno{4',3':6'7'} naphthol[1,2-d]imidazole-2-yl)-5-methylpyrrolidin-1-yl]-3-	90%	10 G

			methyl-1-oxobutan-2-yl} carbamate. (CDMT impurity)		
27	**Velpatasvir**	Velpatasvir impurity C	**IMP C-**methyl {(1R)-2-[(2S,4S]-2-(5-[2-[(2S,5S)-1-[(2S)-2[(methoxycarbonyl)amino]-3-methylbutanoyl]-5-methylpyrrolidin-2-yl]-1,4,5,11-tetrahydro isochromeno[4',3':6',7'] naphthol[1,2-d]imidazole-9-yl}-1H-imidazol-2-yl)-4-(methoxymethyl)pyrrolidin-1-yl]-2-oxo-1-phenylethyl]carbamate. (Diimidazole impurity).	90%	10 G
28	**Velpatasvir**	Velpatasvir impurity D	**IMP D-**methyl {1S)-2-[(2S,4S)-2-(5-{2-[(2S,5S)-1-{(2S)-2-[(methoxycarbonyl)amino]-3-methylbutanoly}-5methylpyrrolidin-2-yl}-1,11-dihydroiso chromeno[4',3':6',7'}naphtho[1,2-d]imidazol-9-yl}-1H-imidazol-2-yl)-4-(methoxymethyl)pyrrolidin-1-yl]-2-oxo-1-phenylethyl}carbamate. (S-Moc phenyl glycine isomers)	90%	10 G
29	**Velpatasvir**	Velpatasvir impurity E	**IMP E-** methyl {(1R)-2-[(2S,4S]-2-(5-[2-[(2S,4S)-1-[(2R)-2[(methoxycarbonyl)amino]-2-phenylacetyl}-4-(methoxymethyl)pyrrolidin-2-yl]-1,11-dihydro isochromeno[4',3':6',7'] naphthol-1,2-d]imidazole-9-yl}-1H-imidazol-2-yl)-4-(methoxymethyl)pyrrolidin-1-yl]-2-oxo-1-phenylethyl]carbamate. (Intermediate-I Dimer impurity)	90%	10 G
30	**Velpatasvir**	Velpatasvir impurity F	**IMP F-** methyl {(1R)-2-[(2S,4S]-2-(5-[2-[(2S,5S)-1-[(2S)-2[(methoxycarbonyl)amino]-3-methylbutanoyl]-5-methylpyrrolidin-2-yl]-11-oxo-1,11- dihydroisochromeno[4',3':6',7'] naphthol[1,2-d]imidazole-9-yl}-1H-imidazol-2-yl)-4-(methoxymethyl)pyrrolidin-1-yl]-2-oxo-1-phenylethyl]carbamate. (Lactone impurity)	90%	10 G
31	**Velpatasvir**	Velpatasvir impurity G	**IMP G-** methyl {(1R)-2-({(1R)-2-[(2S,4S)-2-(5-{5-2-[(2S,5S)-1-{(2S)-2[(methoxycarbonyl) amino]-3-methylbutanoyl}-5-methylpyrrolidin-2yl}-1,11-dihydroisochromeno[4',3':6',7'] naphthol[1,2-d]imidazole-9-yl}-1H-imidazol-2-yl)-4-(methoxymethyl)pyrrolidin-1-yl]-2-oxo-1-phenylethyl}amino)-2- oxo-1-phenylethyl]carbamate. (Glycine dimer impurity)	90%	10 G
32	**Bilastine API and Tablets**	Bilastine impurity A	**Impurity A** -2-(4-(2-(4-(1-(2-hydroxyethyl)-1H-benzo[d]imidazol-2-yl)piperidine-1-yl)ethyl)phenyl)-2-methylpropanoic acid	90%	10 G
33	**Bilastine API and Tablets**	Bilastine impurity B	**Impurity B**-1-(4-(2-carboxypropan-2-yl)phenethyl)-4-(1-(2-ethoxyethyl)-1H-benzo[d]imidazol-2-yl)piperidine 1-oxide.	90%	10 G
34	**Bilastine API and Tablets**	Bilastine impurity C	**Impurity C**-2-(4-(2-(4-(1-(2-ethoxyethyl)-1H-benzo[d]imidazol-2-yl)piperidine-1-yl)ethyl)phenyl)-N-(1-hydroxy-2-methylpropan-2-yl)-2-methylpropanamide	90%	10 G
35	**Bilastine API and Tablets**	Bilastine impurity D	**Impurity D**-2-(4-(2-(4-(1-(2-ethoxyethyl)-1H-benzo[d]imidazole-2-yl)piperidine-1-yl)ethyl) phenyl) propan-2-yl)-4,4-dimethyl-4,5-dihydrooxazole	90%	10 G
36	**Bilastine API and Tablets**	Bilastine impurity E	**Impurity E**-Methyl-2-(4-(2-(4-(1-(2-ethoxyethyl)-1H-benzo[d]imidazol-2-	90%	10 G

			yl)piperidine-1-yl)ethyl)phenyl)-2-methylpropanoate		
37	**Bilastine API and Tablets**	Bilastine impurity F	**Impurity F**-2-(4-(2-(4-(1-(2-methoxyethyl)-1H-benzo[d]imidazol-2-yl)piperidine-1-yl)ethyl)phenyl)-2-methylpropanoic acid	90%	10 G
38	**Miltefosine API and Capsules**	Miltefosine impurity A	**IMP A-**dodecyl(2-(trimethylammonio)ethyl)phosphate.	90%	10 G
39	**Miltefosine API and Capsules**	Miltefosine impurity B	**IMP B**-tetradecyl(2-(trimethylammonio)ethyl)phosphate.	90%	10 G
40	**Miltefosine API and Capsules**	Miltefosine impurity C	**IMP C**-pentadecyl(2-(trimethylammonio)ethyl)phosphate.	90%	10 G
41	**Miltefosine API and Capsules**	Miltefosine impurity D	**IMP D**-2-aminoethyl hexadecyl hydrogen phosphate.	90%	10 G
42	**Miltefosine API and Capsules**	Miltefosine impurity E	**IMP E**-heptadecyl(2-(trimethylammonio)ethyl)phosphate.	90%	10 G
43	**Miltefosine API and Capsules**	Miltefosine impurity F	**IMP F**-octadecyl(2-(trimethylammonio)ethyl)phosphate.	90%	10 G
44	**Miltefosine API and Capsules**	Miltefosine impurity G	**IMP G**-hexadecyl dihydrogen phosphate.	90%	10 G
45	**Nepafenac and Nepafenac Ophthalmic Suspension**	Nepafenac impurity A	**IMP A** -2-amino-3 benzoylbenzeneacetate sodium salt	90%	10 G
46	**Nepafenac and Nepafenac Ophthalmic Suspension**	Nepafenac impurity B	**IMP B**-2-[2-amino-3-(phenylcarbonyl)phenyl]-N-methylacetamide,	90%	10 G
47	**Nepafenac and Nepafenac Ophthalmic Suspension**	Nepafenac impurity C	**IMP C**- 7-(phenylcarbonyl)-1,3-dihydro-2H-indol-2-one.	90%	10 G
48	**Atropine Opthalmic Solution**	Atropic Acid	2-Phenylacrylic Acid	90%	10 G
49	**Copovidone**	Vinyl Acetate	Vinyl Acetate	90%	10 G
50	**Doxycycline HCl /Cap/Dis Tab**	Doxycycline for system suitability IPRS (containing impurity A)	**Impurity A:** (4S,4aR,5S,5aR,6S,12aS)-4-(dimethylamino)-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide (6-epidoxycycline).	90%	10 G
51	**Doxycycline HCl /Cap/Dis Tab**	Doxycycline for system suitability IPRS (containing impurity C)	**Impurity C:** (4R,4aR,5S,5aR,6R,12aS)-4-(dimethylamino)-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo1,4,4a,5,5a,6,11,12a-octahydrotetracene-2- carboxamide (4-epidoxycycline).	90%	10 G
52	**Doxycycline HCl /Cap/Dis Tab**	Doxycycline for system suitability IPRS (containing impurity F)	**Impurity F:**(4S,4aR,5S,5aR,6R,12aS)-2-acetyl-4-(dimethylamino)-3,5,10,12,12a-pentahydroxy-6-methyl-4a,5a,6,12a-tetrahydrotetracene-1,11(4H,5H)- dione (2-acetyl-2-decarbamoyldoxycycline)	90%	10 G
53	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity A).	**IMP-A:-** ent-(24SR, 17Z)-16α-(acetyloxy)-3β, 11 β, 24, 25-tetrahydroxy-4 β,8, 14-trimethyl-18-nor-5 β,10 α -cholest-17(20)-en-21-oic acid (24,25-dihydro-24,25-dihydroxyfusidic acid)	90%	10 G
54	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity B).	**IMP-B:-**ent-(17Z)-3β,11 βdihydroxy-17-[(6SR)-6-hydroxy-7,7-dimethyl-2-oxooxepan-3-ylidene]-4β,8,14-trimethyl-18-nor-5β,10α-androstan-16α-yl acetate (24,25- dihydro-24,25-dihydroxyfusidic acid 21,25-lactone).	90%	10 G

55	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity C).	**IMP-C:**ent-(17Z)-3β,11 βdihydroxy-17-[(6S)-6-(1-hydroxy-1-methylethyl)-2-oxodihydro-2H-pyran-3(4H)-ylidene]-4β,8,14-trimethyl-18-nor-5β,10α-androstan-16α-yl acetate ((24R),24,25- dihydro-24,25-dihydroxyfusidic acid 21,24-lactone).	90%	10 G
56	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity D).	**IMP-D:**ent-(17Z)-3β,11 βdihydroxy-17-[(6R)-6-(1-hydroxy-1-methylethyl)-2-oxodihydro-2H-pyran-3(4H)-ylidene]-4β,8,14-trimethyl-18-nor-5β,10α-androstan-16α-yl acetate ((24S),24,25- dihydro-24,25-dihydroxyfusidic acid 21,24-lactone).	90%	10 G
57	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity F).	**IMP-F:**ent-(17Z,24EZ)-16α-(acetyloxy)-3β,11β-dihydroxy-4β,8,14-trimethyl-26-oxo-18-nor-5β,10α-cholesta-17(20),24-dien-21-oic acid(26-oxofusidic acid).	90%	10 G
58	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity G).	**IMP-G:** ent-(17Z)-16α-(acetyloxy)-11β-hydroxy-4β,8,14-trimethyl-3-oxo-18-nor-5β,10α-cholesta-17(20),24-dien-21-oic acid (3-didehydrofusidic acid)	90%	10 G
59	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity H).	**IMP- H:** ent-(17Z)-16α-(acetyloxy)-3β-hydroxy-4β,8,14-trimethyl-11-oxo-18-nor-5β,10α-cholesta-17(20),24-dien-21-oic acid (11-didehydrofusidic acid).	90%	10 G
60	**Sodium Fusidate**	Fusidic acid impurity mixture IPRS (containing impurity I)	**IMP-I:**ent-(17Z)-3β, 11β, 16β-trihydroxyl-4β,8,14-trimethyl-18-nor-5β,10α-cholesta-17(20),24-dien-21-oic acid (16-epi-deacetylfusidic acid).	90%	10 G
61	**Sodium Fusidate**	Fusidic acid impurity mixture IPRS (containing impurity K)	**IMP-K:**ent-(17Z)-3β,11β-dihydroxy-4β,8,14-trimethyl-18-nor-5β,10α-cholesta-17(20),24-dieno-21(16α) lactone (deacetylfusidic acid 21,16-lactone).	90%	10 G
62	**Sodium Fusidate**	Fusidic acid impurity mixture IPRS (containing impurity L)	**IMP-L:** ent-(17Z)-16α-(acetyloxy)-3β-hydroxy-4β,8,14-trimethyl-18-nor-5β,10α-cholesta-9(11),17(20),24-trien-21-oic acid (9,11-anhydrofusidic acid).	90%	10 G
63	**Sodium Fusidate**	Fusidic acid impurity mixture IPRS (containing impurity M)	**IMP-M:** ent-(17Z)-16α-(acetyloxy)-3β-hydroxy-4β,8,14-trimethyl-18-nor-5β,10α-cholesta-17(20),24-dien--21-oic acid (11-deoxyfusidic acid).	90%	10 G
64	**Zoledronic Acid**	Zoledronic acid related compound A	**Zoledronic acid related compound A:** 2-(1H-Imidazol-1-yl) acetic acid.	90%	10 G
65	**Zoledronic Acid**	Zoledronic acid related compound B	**Zoledronic acid related compound B:** 1-Hydroxy-2-[1-(2-hydroxy-2,2-diphosphonoethyl)-1H-imidazol-3-ium-3-yl]-1-phosphonoethylphosphonate	90%	10 G
66	**Olmesartan Medoxomil/Tab/ Olmesartan Medoxomil and Hydrochlorothiazide Tablets**	Olmesartan medoxomil RC A	**Olmesartan medoxomil related compound A:** 1-{[2′-(1H-Tetrazol-5-yl)biphenyl-4-yl]methyl}-4,4-dimethyl-2-propyl-1H-furo[3,4-d]imidazol-6(4H)-one	90%	10 G
67	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity A	**Beclomethasone dipropionate impurity A:** 9-chloro-11β,17-dihydroxy-16β-methyl-3,20-dioxopregna-1,4-dien-21-yl propanoate (beclomethasone 21-propionate).	90%	10 G
68	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity B	**Beclomethasone dipropionate impurity B:** 21-(acetyloxy)-9-chloro-11β-hydroxy-16β-methyl-3,20-dioxopregna-1,4-dien-17-yl propanoate (beclomethasone 21-acetate 17-propionate).	90%	10 G
69	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity C	**Beclomethasone dipropionate impurity C:** 9-chloro-11β-hydroxy-16β-methyl-3,20-dioxo-17-(propanoyloxy)-pregna-1,4-dien-21-yl butanoate (beclomethasone 21-butyrate 17-propionate)	90%	10 G

70	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity D	**Beclomethasone dipropionate impurity D:** 9-bromo-11β-hydroxy-16β-methyl-3,20-dioxopregna-1,4-diene-17,21-diyl dipropanoate.	90%	10 G
71	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity F	**Beclomethasone dipropionate impurity F:** 6α-bromo-9-chloro-11β-hydroxy-16β-methyl-3,20-dioxopregna-1,4-diene-17,21-diyl dipropanoate.	90%	10 G
72	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity L	**Beclomethasone dipropionate impurity L:** 9-chloro-11β-hydroxy-16β-methyl-3,20-dioxopregn-4-ene-17,21-diyl dipropanoate.	90%	10 G
73	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity M	**Beclomethasone dipropionate impurity M:** 9-chloro-11β-hydroxy-16β-methyl-3,20-dioxopregna-4,6-diene-17,21-diyl dipropanoate.	90%	10 G
74	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity N	**Beclomethasone dipropionate impurity N:** 2-bromo-9-chloro-11β-hydroxy-16β-methyl-3,20-dioxopregna-1,4-diene-17,21-diyl dipropanoate.	90%	10 G
75	**Amorolfine Hydrochloride**	Amorolfine impurity D	**Amorolfine impurity D:** (2RS,6SR)-2,6-dimethyl-4-[(2RS)-3-(4-tert-butylphenyl)-2-methylpropyl]morpholine,	90%	10 G
76	**Amorolfine Hydrochloride**	Amorolfine impurity E	**Amorolfine impurity E:** mixture of (2RS,6RS]-2,6-dimethyl-4-[(2R)-2-methyl-3-[4-(2-methylbutan-2-yl)phenyl]propyl]morpholine and (2RS,6RS) -2,6-dimethyl-4-[(2S]-2-methyl-3-[4-(2-methylbutan- 2-yl)phenyl]propyl]morpholine.	90%	10 G
77	**Amorolfine Hydrochloride**	Amorolfine impurity I	**Amorolfine impurity I:(**2RS,6SR)-2,6-dimethyl-4-[(2RS)-2-methyl-3-[4-[(2E)-3-methylbutan-2-yl]phenyl]propyl]morpholine,	90%	10 G
78	**Amorolfine Hydrochloride**	Amorolfine impurity J	**Amorolfine impurity J:** (2RS,6SR)-2,6-dimethyl-4-[(2RS)-2-methyl-3-[3-(2-methylbutan-2-yl)phenyl]propyl]morpholine.	90%	10 G
79	**Amorolfine Hydrochloride**	Amorolfine impurity M	**Amorolfine impurity M:** mixture of (1RS,2RS)-3-[(2RS,6SR)-2,6-dimethylmorpholin-4-yl]-2-methyl-I-[4-(2-methylbutan-2-yl) phenyl]propan-1-ol and (1RS,2SR)-3-[(2RS,6SR)-2,6-dimethylmorpholin-4-yl]-2-methyl-1-[4-(2-methylbutan-2yl)phenyl]propan-1-ol.	90%	10 G
80	**Cefepime Hydrochloride**	Cefepime Related Compound D	**RC-D.**(Z)-2-(2-Aminothiazol-4-yl)-2-(methoxyimino)acetic acid	90%	10 G
81	**Cefepime Hydrochloride**	Cefepime Related Compound E	**RC-E.**1-{[(6R,7R)-7-Amino-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl}-1-methylpyrrolidin-1-ium chloride.	90%	10 G
82	**Mexiletine Hydrochloride**	Mexiletine impurity D	**Mexiletine impurity D:** ((2RS)-2-(2,6-dimethylphenoxy)propan-1-amine)	90%	10 G
83	**Neostigmine Bromide**	Neostigmine impurity A	**Neostigmine impurity A:** 3-hydroxy-N,N,N-trimethylanilinium,	90%	10 G
84	**Carboprost Tromethamine**	15-epicarboprost	**15-epicarboprost :** (Z)-7-[(1R,2R,3R,5S)-3,5-Dihydroxy-2-[(E)-(3R)-3-hydroxy-3-methyloct-1-enyl]cyclopentyl]-5-heptenoic acid	90%	10 G
85	**Flurbiprofen/Tab**	Flurbiprofen impurity A	**Flurbiprofen impurity A:** (2RS)-2-([1,1'-biphenyl]-4-yl)propanoic acid;	90%	10 G
86	**Flurbiprofen/Tab**	Flurbiprofen impurity B	**Flurbiprofen impurity B:** (2E,3E)-2-(2-fluoro[1,1'-biphenyl]-4-yl)-2,3-dimethylbutanedioic acid	90%	10 G
87	**Phenindione/Tab**	Phenindione impurity A	**Phenindione impurity A:** 2-hydroxy-2-phenyl-1H-indene-1,3(2H)-dione	90%	10 G
88	**Terbutaline Sulphate**	Terbutaline RC A	**Terbutaline related compound A:** (3,5-Dihydroxy-ω-t-butylaminoacetophenone sulphate)	90%	10 G

89	**Cyclobenzaprine Hydrochloride /Tab**	Cyclobenzaprine related compound A	**RC-A:**5-[3-(Dimethylamino)propyl]-5*H*-dibenzo[*a,d*]-cyclohepten-5-ol,	90%	10 G
90	**Cyclobenzaprine Hydrochloride /Tab**	Cyclobenzaprine related compound B	**RC-B:** 3-(5*H*-Dibenzo[*a,d*]cyclohepten-5-ylidene)-*N*-methyl-1-propanamine hydrochloride	90%	10 G
91	**Ropinirole Prolonged-release Tablets**	Ropinirole impurity B	**IMP-B:**4-[2-(Dipropylamino)ethyl]indoline-2,3-dione hydrochloride.	90%	10 G
92	**Aciclovir/ Tab/ IV/Oral sol/Cream/Eye ointment/Dis Tab**	Imp-K	**Imp-K:** 2,2'-(methylenediazanediyl) bis[9-[(2-hydroxyethoxy)methyl]-1 ,9-dihydro-6H-purin-6-one],	90%	10 G
93	**Aciclovir/ Tab/ IV/Oral sol/Cream/Eye ointment/Dis Tab**	Imp-C	**Imp-C:** 2-amino-7-[(2-hydroxyethoxy)methyl]-1,7-dihydro-6H purin-6-one,	90%	10 G
94	**Dithranol Ointment**	Dithranol impurity C	**Dithranol impurity C: 4,**4',5,5'-tetrahydroxy-9,9'-bianthracenyl10,10'(9H,9'H)dione)	90%	10 G
95	**Ketoconazole**	ketoconazole impurity C	**ketoconazole impurity C:**1-[4-[4-[[(2RS,4RS)-2-(2,4-dichlorophenyl)-2-[(1H-imidazol-1-yl)methyl]-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethan-1-one,	90%	10 G
96	**Ketoconazole**	ketoconazole impurity D	**ketoconazole impurity D:** 1-[4-[[(2RS,4SR)-2-(2,4-dichlorophenyl)-2-[(1H-imidazol-1-yl)methyl]-1,3-dioxolan-4-yl]methoxy]phenyl]piperazine.	90%	10 G
97	**Methotrexate**	Methotrexate impurity I	**Methotrexate impurity I:** (4S)-4-[[4-[[(2,4-diaminopteridin-6-yl)methyl]methylamino]benzoyl]amino]-5-methoxy-5-oxopentanoic acid (methotrexate 1-methyl ester),	90%	10 G
98	**Carbamazepine/Tab**	Carbamazepine related compound B IPRS	**Carbamazepine related compound B IPRS:**5*H*-Dibenz[*b,f*]azepine	90%	10 G
99	**Chlorthalidone**	Chlorthalidone RC-B	**Chlorthalidone RC-B:** 2-(4-chloro-3-sulfamoylbenzoyl)benzoic acid	90%	10 G
100	**Chlorthalidone**	Chlorthalidone RC-G	**Chlorthalidone RC-G:** (3*RS*)-3-(3,4-dichlorophenyl)-3-hydroxy-2,3-dihydro-I*H*-isoindol- l-one	90%	10 G
101	**Cilostazol**	Cilostazol impurity A	**Cilostazol impurity A:**6-hydroxy-3,4-dihydro-1H-quinolin-2-one	90%	10 G
102	**Cilostazol**	Cilostazol impurity C	**Cilostazol impurity C:**1-(4-(5-cyclohexyl-1H-tetrazol-1-yl)butyl)-6-(4-(1-cyclohexyl-1Htetrazol-5-yl)butoxy)-3,4-dihydroquinolin-2(1H)-one	90%	10 G
103	**Ketorolac Tromethamine Injection/Tab**	Ketorolac related compound A	**Ketorolac related compound A:** 5-Benzoyl-*N*-[1,3-dihydroxy-2-(hydroxymethyl)propan-2-yl]-2,3-dihydro-1H-pyrrolizine-1-carboxamide	90%	10 G
104	**Ketorolac Tromethamine Injection/Tab**	Ketorolac related compound B	**Ketorolac related compound B:**5-Benzoyl-2,3-dihydro-1*H*-pyrrolizin-1-ol	90%	10 G
105	**Ketorolac Tromethamine Injection/Tab**	Ketorolac related compound C	**Ketorolac related compound C:**5-Benzoyl-2,3-dihydro-1*H*-pyrrolizin-1-one	90%	10 G
106	**Ketorolac Tromethamine Injection/Tab**	Ketorolac related compound D	**Ketorolac related compound D:**5-Benzoyl-2,3-dihydro-1H-pyrrolizine	90%	10 G
107	**Ascorbic Acid**	Ascorbic acid impurity C	**Ascorbic acid impurity C:** L-xylo-hex-2-ulosonic acid (L-sorbosonic acid)	90%	10 G
108	**Ascorbic Acid**	Ascorbic acid impurity D	**Ascorbic acid impurity D:**methyl L-xylo-hex-2-ulosonate (methyl L-sorbosonate)	90%	10 G
109	**Clindamycin Hcl/ Cap**	Clindamycin imp-B	**Imp-B:**methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R}-4-ethyl-l-methylpyrrolidin-2-yl]carbonyl] amino] -1-thio-L-*threo*-*α*-*D*-galacto-octopyranoside	90%	10 G

110	**Clindamycin Hcl/ Cap**	Clindamycin imp-C	**Imp-C:**methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl] amino)-1-thio-D-erythro- α -D-galacto-octopyranoside (7-epiclindamycin),	90%	10 G
111	**Atropine Sulphate**	Atropine impurity A	**Atropine impurity A:** (1R,3r,5S)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl2-phenylpropenoate (apoatropine).	90%	10 G
112	**Atropine Sulphate**	Atropine impurity B	**Atropine impurity B:** (1R,3r,5S)-8-azabicyclo[3.2.1]oct-3-yl (2RS)-3-hydroxy-2-phenylpropanoate(noratroplne).	90%	10 G
113	**Atropine Sulphate**	Atropine impurity D	**Atropine impurity D:**(1R,3S,5R,6RS)-6-hydroxy-8-methyl-8-azabicyclo[3.2.1]oct-3-yl (2S)-3-hydroxy-2-phenylpropanoate(6-hydroxyhyoscyamine).	90%	10 G
114	**Atropine Sulphate**	Atropine impurity E	**Atropine impurity E:** (1S,3R,5S,6RS)-6-hydroxy-8-methyl-8-azabicyclo[3.2.1]oct-3-yl (2S)-3-hydroxy-2-phenylpropanoate(7-hydroxyhyoscyamine).	90%	10 G
115	**Atropine Sulphate**	Atropine impurity F	**Atropine impurity F:** (1R,2R,4S,5S,7s)-9-methyl-3-oxa-9-azatricyclo[3.3.1.0.^{2,4}]non-7-yl (2S)-3-hydroxy-2-phenylpropanoate (hyoscine).	90%	10 G
116	**Atropine Sulphate**	Atropine impurity G	**Atropine impurity G:** (1R,3r,5S)-8-methyl-8-azabicyclo[3.2.1] oct-3-yl (2RS)-2-hydroxy-3-phenylpropanoate (littorine).	90%	10 G
117	**Dextrose**	Maltotriose	Maltotriose	90%	10 G
118	**Neostigmine Bromide**	Neostigmine impurity B	**Neostigmine impurity B:** 3-dimethylaminophenol	90%	10 G
119	**Phenindione/Tab**	Phenindione impurity C	**Phenindione impurity C:** phenylacetic acid	90%	10 G
120	**Phenindione/Tab**	Phenindione impurity D	**Phenindione impurity D:** 3-benzylidene-2-benzofuran-(3H)-one (benzalphthalide)	90%	10 G
121	**Phenindione/Tab**	Phenindione impurity E	**Phenindione impurity E:** phthalic acid	90%	10 G
122	**Temozolomide Capsules**	Dacarbazine related compound A	**Dacarbazine related compound A:**5-aminoimidazole-4-carboxamide	90%	10 G
123	**Benzyl Alcohol**	Benzyl alcohol impurity B	***benzyl alcohol impurity B:*** *cyclohexyl-methanol*	90%	10 G
124	**Folic Acid**	Folic Acid IMP A	N-(4-aminobenzoyl)-L-glutamic acid	90%	10 G
125	**Tolbutamide**	Tolbutamide IMP B	Toluenesulphonamide	90%	10 G
126	**Levetiracetam**	Levetiracetam IMP B	((S))-2-Aminobutanamide Hydrochloride	90%	10 G
127	**Sodium Fusidate**	impurity N		90%	10 G
128	**Dextrose**	Maltose Monohydrate	4-*O*-α-D-Glucopyranosyl-D-glucose monohydrate	90%	10 G
129	**Cefepime Hydrochloride**	N-methylpyrrolidine	N-methylpyrrolidine	90%	10 G
130	**Vildagliptin and Metformin Tablets**	1 -amino-admantan-3-ol	1-amino-admantan-3-ol	90%	10 G
131	**Dolutegravir Sodium**	isomer-1	Sodium(4S,12aS)-9-[(2,4-difluorobenzyl)carbamoyl]-4- methyl-6,8-dioxo-3,3,6,8,12a- hexahydro-2H-pyrido[1,2:4,5]pyrazino[2,1-b][1,3]oxazin-7-olate	90%	10 G
132	**Dolutegravir Sodium**	enantiomer	sodium (4S,12aR)-9-((2,4-difluorobenzyl)carbamoyl)-4- methyl-6,8-dioxo- 3,4,6,8,12,12a- hexahydro- 2H-pyrido[1',2':4,5]pyrazino[2,1- b][1,3]oxazin-7-olate	90%	10 G
133	**Dolutegravir Sodium**	isomer-2	(4R,12aR)-N-[(2,4-difluorobenzyl)7 hydroxy-4- methyl-6,8-dioxo-3,4,6,8,12a- hexahydro- 2H-pyrido[1,2:4,5]pyrazino[2,1- b][1,3]oxazine-9-carboxamide	90%	10 G
134	**Lactulose**	Lactulose Impurity A	Epilactose	90%	10 G
135	**Metformin HCl**	Melamine	1,3,5-triazine-2,4,6-triamine	90%	10 G

136	**Buprenorphine HCl API/ Injection**	Imp.-G	Imp.-G: 17,17′-di(cyclopropylmethyl)-4,5α;4′,5α′-diepoxy- 7α,7α′-di[(1S)-1-hydroxy-1,2,2-trimethylpropyl]-6,6′- dimethoxy-2,2′-bi(6α,14- ethano-14α-morphinan)-3,3′-diol (2,2′-bibuprenorphine),	90%	10 G
137	**Buprenorphine HCl API/ Injection**	Imp.-H	Imp.-H: (2S)-2-[17-butyl-4,5α-epoxy-3-hydroxy-6- methoxy-6α,14-ethano-14α-morphinan-7α-yl]3,3- dimethylbutan-2-ol,	90%	10 G
138	**Buprenorphine HCl API/ Injection**	Imp.- J	Imp.- J: (2S)-2-[17-(cyclopropylmethyl)-4,5α-epoxy-3- hydroxy-6-methoxy-6α,14-etheno-14α-morphinan-7α-yl]- 3,3-dimethylbutan-2-ol.	90%	10 G
139	**Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets**	Tenofovir disoproxil impurity H	1-methylethylpropyl (5RS)-5- {[(1R)-2-(6-amino-9H-purin- 9yl)-1-methylethoxy]methyl}- 5-oxo-2,4,6,8-tetraoxa-5λ5- phosphano-nanedioate.	90%	10 G
140	**Rivastigmine Tartrate Rivastigmine Capsules**	Rivastigmine tartrate R-Isomer RS	(R)-Rivastigmine tartrate, (R)-3-[1-(Dimethylamino)ethyl]ph enyl ethylmethylcarbamate hydrogen tartrate	90%	10 G
141	**Lamivudine and Zidovudine Tablets**	Lamivudine diastereomer	4-amino-1-((2RS,5RS)-2- (hydroxymethyl)-1,3-oxathiolan-5-yl)pyrimidin- 2(1H)-one	90%	10 G
142	**Tenoxicam Tenoxicam Tablets**	Tenoxicam impurity G	4-hydroxy-2-methyl-2H- thieno[2,3-e]1,2-thiazine-3- carboxamide 1,1-dioxide	90%	10 G
143	**Doxycycline HCl /Cap/Dis Tab**	Impurity B	Impurity B: (4S,4aR,5S,5aR,12aS)-4-(dimethylamino)-3,5,10,12,12a-pentahydroxy-6-methylene-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide **(metacycline).**	90%	10 G
144	**Doxapram HCl**	Impurity B	((4RS)-1-ethyl-4-[2-[(2 hydroxyethyl) amino] ethyl]-3,3-diphenylpyrrolidin-2- one	90%	10 G
145	**Sumatriptan Injection**	Sumatriptan impurity H	([3-[2-(dimethylamino)ethyl -1-[[3-[2-(dimethylamino)ethyl -1H-indol-5 yl]methyl]-1H-indol 5-yl]-N- methylmethanesulph namide	90%	10 G
146	**Tetracycline**	4- epitetracycline HCl	4- epitetracycline HCl	90%	10 G
147	**Paclitaxel**	10-deacetyl-7-epipaclitaxel	10-deacetyl-7-epipaclitaxel	90%	10 G
148	**Vildagliptin**	R-enantiomer of vildagliptin	(1-[(3-Hydroxyadamant-1- ylamino)-acetyl]-pyrrolidine- (2R)-carbonitrile)	90%	10 G
149	**Paroxetine HCl**	Impurity E	(3S,4S)-3- ((benzo[d][1,3]dioxol-5-yloxy)methyl)- 4-(4-fluorophenyl)piperidine HCl	90%	10 G
150	**Sumatriptan**	Impurity A	[3-[2-(dimethylamino)ethyl]-2-[[3- [2-(dimethylamino)ethyl] -1H-indol-5-yl]methyl]-1H-indol-5- yl] -N-methylmethanesulphonamide	90%	10 G
151	**Tranexamic Imp.C**	Impurity C	(RS)-4- (aminomethyl)cyclohex-1-enecarboxylic acid	90%	10 G
152	**Thiamine Hydrochloride Thiamine Mononitrate**	Thiamine impurity B	2-Northiamin ; 3-[(4- aminopyrimidin-5-yl)methyl]- 5-(2-hydroxyethyl)-4-methyl- 1,3-thiazol-3-ium (desmethylthiamine) bromide hydrobromide	90%	10 G
153	**Finasteride**	Impurity C	N-(1,1- di-methylethyl) -3- oxo-4-aza-androsta-1,5-diene-17β-(dihydrofinasteride).	90%	10 G
154	**Phenytoin Sodium**	Impurity E	(carbamoylamino)(diphenyl)acetic acid.	90%	10 G
155	**Indapamide**	Impurity B	4-chloro-N-(2-methyl-[H-indol-1-yl)-3-sulphamoylbenzamide	90%	10 G
156	**Ceftriaxone Sodium (E isomer)**	E isomer	E isomer	90%	10 G
157	**Pantoprazole Sodium API And Pantoprazole Sodium delayed Release Tablets**	Pantoprazole RC-E	RC-E: 6,6′-Bis(difluoromethoxy)-2,2′-bis[[(3,4-dimethoxypyridin-2-yl)methyl]sulfinyl]-1H,1′H-5,5′- bibenzimidazole	90%	10 G

158	**Dicyclomine HCl**	Dicyclomine RC-A	Dicyclomine RC-A: [1,1'-Bi(cyclohexane)]-1-carboxylic acid	90%	10 G
159	**Sulphamethoxazole**	sulfamethoxazole RC-C	Sulfamethoxazole RC-C: 5-Methylisoxazol-3-amine.	90%	10 G
160	**Buprenorphine Hcl/Inj**	IMPURITY A	Imp.-A: (2S)-2-[17-(but-3-enyl)-4,5α-epoxy-3-hydroxy-6-methoxy-6α,14-ethano-14α-morphinan-7α-yl]-3,3-dimethylbutan-2-ol,	90%	10 G
161	**Terazosin HCl**	Impurity N	1-[[(2RS)-tetrahydrofuran-2-yl]carbonyl]piperazine	90%	10 G
162	**Testosterone propionate**	Testerone acetate	Testerone acetate	90%	10 G
163	**Ibuprofen Tablets**	Ibuprofen RC-J	Ibuprofen RC-J: (2RS)-2-[4-(2-methylpropanoyl)phenyl]propanoic acid,	90%	10 G
164	**Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets**	tenofovir disoproxil impurity I	Bis(1-methylethyl)5-{[(1R)-2-(6-{[({9-[(2R)-5-hydroxy-2,11-dimethyl-5,9-dioxo- 3,6,8,10- tetraoxa-5-λ5- phosphadodecyl]- 9H- purin-6-yl}amino)methyl]amino}-9H- purin-9yl)-1-methylethoxy]methyl}- 5-0xo- 2,4,6,8-tetraoxa-5- λ5-phosphanonedioate	90%	10 G
165	**Buprenorphine HCl API/ Injection**	Imp.-B	Imp.-B: (2S)-2-(4,5α-epoxy-3-hydroxy-6-methoxy-6α,14- ethano-14α-morphinan-7α-yl)-3,3-dimethylbutan-2-ol (norbuprenorphine),	90%	10 G
166	**Ipratropium**	Ipratropium impurity B	(1R,3r,5S,8s)-3-[[(2RS)-3-hydroxy-2-phenylpropanoyl]oxy]-8-methyl-8-(1-methylethyl)-8- azoniabicyclo[3.2.1]octane	90%	10 G

1. **The bidders are advised to quote preferably for all tender items(s)/ Pharmaceutical Impurities. However, they are not bound to quote for all items/ Pharmaceutical Impurities.**

2. **BIDDERS ARE ADVISED TO NOT CHANGE THE TENDER SCHEDULE NUMBER. IT MUST BE SAME THROUGHOUT THEIR TECHNICAL BID & PRICE BID AS MENTIONED IN SCHEDULE OF REQUIREMENT (SOR).**

3. **BID Security/ Earnest Money Deposit (EMD)**

The value of Earnest Money (BID SECURITY) to be deposited by the bidder. A Demand Draft towards total **E**arnest **M**oney **D**eposit, must be made in favor of **"Indian Pharmacopoeia Commission"**, and payable at **Ghaziabad**, and must accompany Technical Bid. Failing which, the Tender will be summarily rejected.

OR

The Micro and Small Enterprises (MSE/NSIC) and Startup Firm as defined under Govt. Procurement Policy may claim for exemption from submission of Earnest Money Deposit (EMD) and must submit scanned copy of their latest **Udyog Aadhaar Memorandum (UAM)/NSIC/ Startup Certificate** for the same and **Bid Security Declaration (Annexure-G) certificate in lieu of EMD**.

SECTION-III

INSTRUCTION TO BIDDERS (ITB)

1. **The Bids are intended for Supply of "Pharmaceutical Impurities" at IPC, Ghaziabad as per Schedule of Requirement (SOR).**

2. **Validity of Tender Quoted Rates must be valid for 18 Months from the Last date of Tender.**

   If required, the competent authority may extend the contract for another 18 Months on same rates and terms & conditions subjected to the satisfactory performance of the manufacturer.

3. **This bid is reserved for Class I and Class II bidders only as per make in India Policy (DPIIT Order dated 16th September 2020). Participating bidders need to submit relevant make in India authorization certificate.**

4. Bidding Document may be amended any time prior to closing date & time for submission of tenders. Therefore, Bidders are advised to regularly check GeM Portal for tender relevant amendment/ changes (if any).

5. **A Pre-Bid meeting may be attended by authorized representative of prospective Bidders for any doubt/ clarifications as per scheduled date & time. The Meeting will be held remotely via Video Conferencing facility. The link for same will be shared thru IPC Website.**

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7. This is a TWO BID system comprising of:

   (a) Technical Bid **(b) Price Bid**

8. The bidders are advised to quote preferably for all tendered items. However, the bidders are not bound to quote for all items/ Pharmaceutical Impurities.

9. The Bidder is expected to examine all requirements, Instructions, Forms, Terms and Conditions given in the bidding documents. Failure to furnish information as required in the Bidding documents or submission of a Bid not compliance to the bidding documents in every respect will be at the Bidder risk and may result in rejection of the Bid.

10. **Bidding Preparation Cost:** The bidder will solely bear all costs associated with preparation and submission of bids including site visit etc. regardless of the conduct or outcome of the tender process. In no case, such cost will be reimbursed by the Commission.

11. The Technical Bid should accompany:

    (i) **A Copy of** Demand Draft towards **E**arnest **M**oney **D**eposit, drawn in favor of **"Indian Pharmacopoeia Commission"**, and payable at **Ghaziabad**, failing which the Tender will be summarily rejected. The EMD of unsuccessful bidder will be returned back to them, without any interest after expiration of bid validity or conclusion of contract (whichever is later) on the request from bidders. In the event of Awardee Bidder backing out to any terms & conditions of the Bid Documents, EMD of that bidder will be forfeited.

    OR

The Micro and Small Enterprises (**MSE**/NSIC) and Startup Firms as defined under Govt. Procurement Policy may claim for exemption from submission of Earnest Money Deposit (EMD) and must submit scanned copy of their **latest Udyam Registration Certificate/ Udyog Aadhaar Memorandum (UAM)/ NSIC/ Startup Certificate** and **Bid Security Declaration (Annexure-G) certificate in lieu of EMD**.

12. **Power of Attorney/Authorization Letter in favour of Tender Signatory:** The bids may be submitted by the Bidder or thru Competent Representative, as the case may be. In case the Bids are submitted by competent representative/ official, the **Authorization Letter** (on firm letter head) shall be submitted with Technical Bid for tender signing person.

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15. Deleted

16. The bidders are not permitted to change, edit or withdraw their bids after submission. No communication in this regard will be entertained.

17. **Bids Price & its Validity Period:** Prices must be quoted in inclusive of all charges i.e. GST, cost of the stores, freight, transit insurance, packing and forwarding and **Prices must be kept valid for acceptance for 18 Months from the date of the opening of bids.**

(i) Price must be quoted inclusive of all charges upto goods delivery at the Commission.

(ii) Goods & Service Taxes (GST) shall be paid at actual at the time of invoice generation.

18. Deleted

19. **At first stage,** the Technical Bids shall be scrutinized/ evaluated with respect to parameters prescribed in bid documents or at the discretion of competent authority at IPC.

In case of any clarifications is required during evaluation of bids, wherever necessary, IPC will convey its finding/ observation to the bidder thru GeM only, asking the bidder to respond by a specified date. If the bidder does not reply by the specified date or gives evasive reply without clarifying the point in clear terms, that bid may be ignored at the discretion of competent authority.

20. **In second stage,** the price bids of successful bidders shall be opened for further scrutiny on scheduled date & time. The price bids would also be evaluated for its correctness, responsiveness and L-1 rate.

21. **Bids comparison/ evaluation will be done on basis of All inclusive Total Price of an individual tendered item basis.** However, the commission is not bound to accept the lowest or any bid.

22. Deleted

23. The commission will notify the accepted successful bidders thru GeM Only

24. **Performance Security:** Successful bidder shall also furnish **Performance Security within 15 days from the date of Supply Order i.e. Security Deposit equivalent to 5.0% of the contract/ order value OR as applicable by Govt. Notification at the time of Order Placement,** in form of **demand draft/ Bank Guarantees** in favor of "**Indian Pharmacopoeia Commission"** and **payable at**

Ghaziabad that shall remain Valid for 26 Months.

(i) Performance Security shall be refunded only after successful completion of contract in all respects

25. **INTEGRITY PACT:**

(i) Integrity Pact Performa (Provided as **Annexure- A**) is an agreement that is self-explanatory and mandatory in nature. **Only those vendors/ BIDDERs, who commit themselves to this pact with this commission, would be considered competent to participate in the bidding process.**

(ii) **In other words, entering into this pact would be a preliminary qualification to participate in this Tender.**

(iii) The said Integrity Pact (IP) would be implemented/ monitor thru Secretary-cum-Scientific Director, IPC. The Secretary-cum-Scientific Director, IPC would examine all complaints received by them.

(iv) The contractor shall not sublet (sub contract) the tender without written permission of IPC. In case of Sub-contracting, the principal contractor shall be liable of adoption of Integrity Pact (IP) by the sub-contractor.

26. A declaration as given in **ANNEXURE – B on the firm's letter head** stating that "ALL TERMS AND CONDITIONS with respect to this tender" is acceptable to tenderer, should accompany the tender. Failing which the tender will be summarily rejected. Their tender shall be rejected if any tampering in the tender document is found to be done at the time of opening of tender and later thereon.

27. **Non-blacklist Declaration** by the firm given in **ANNEXURE- C, on the firm's letter head** stating that the firm have not been blacklisted /debarred for dealing by Government of India or any State Govt./ PSU/Banks in any manner.

28. Each Impurity must be supplied along with "**Impurity Material Information Form"** (which is provided in **ANNEXURE -D**) and other supporting documents such as Certificate of Analysis, MSDS etc.

29. Deleted

30. **An affidavit of Self Certification regarding Local Content claim for quoted items, to be provided on Rs. 100/- Stamp Paper as given in ANNEXURE-F under Preference to "MAKE IN INDIA" Policy.**

31. Bidders, who do not meet the required Qualification Criteria prescribed, will be treated as non-responsive and will not be considered further. However, this Commission reserves the right to relax the Norms on prior turnover and prior experience for all Start-ups **and** MSE firms as per extant Govt. policies, subject to meeting of quality and technical specifications. The Startups are defined in Annexure-A of the "Action Plan for Startups India". The same is available on the website of Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce & Industry.

32. IPC reserves the right to allow the purchase preference as per the instruction in vogue while evaluating, comparing and ranking the responsive tenders.

i. In exercise of powers conferred in Section 11 of the Micro, Small and Medium Enterprises Development (MSMED) Act 2006, the Government has notified a new Public Procurement Policy for Micro & Small Enterprises effective from 1st April 2012. The policy mandates that 25% of procurement of annual requirement of goods and services by all Central Ministries/Public Sector Undertakings will be from the micro and small enterprises. The Government has also earmarked a sub-target of 4% procurement of goods & services from MSEs owned by SC/ST entrepreneurs out of above said 25% quantity.

ii. In accordance with the above said notification, the participating Micro and Small Enterprises (MSEs) in a tender, quoting price within the band of L 1+15% would also be allowed to supply a portion of the requirement by bringing down their price to the L 1 price, in a situation where L 1 price is from someone other than an MSE. Such MSEs would be allowed to supply up to 25% of the total tendered value. In case there are more than one such eligible MSE, the 25% supply will be shared equally. Out of 25% of the quantity earmarked for supply from MSEs, 4% quantity is earmarked for procurement from MSEs owned by SC/ST entrepreneurs. However, in the event of failure of such MSEs to participate in the tender process or meet the tender requirements and the L 1 price, the 4% quantity earmarked for MSEs owned by SC/ST entrepreneurs will be met from other participating MSEs.

iii. The MSEs fulfilling the prescribed eligibility criteria and participating in the tender shall enclose with their tender a copy of their valid registration certificate with District Industries Centres or Khadi and Village Industries Commission or Khadi and Village Industries Board or Coir Board or National Small Industries Corporation or any other body specified by Ministry of Micro and Small enterprises in support of their being an MSE, **failing which their tender will be liable to be ignored.**

iv. Special provision for Micro and Small Enterprise owned by women. Out of the total annual procurement from Micro and Small Enterprises, 3% from within the 25% target shall be earmarked for procurement from Micro and Small Enterprise owned by women.

Note: "If the bidder is a MSE, it shall declare in the bid document the Udyog Aadhaar Memorandum Number issued to it under the MSMED Act, 2006. If a MSME bidder do not furnish the UAM Number along with bid documents, such MSE unit will not be eligible for the benefits available under Public Procurement Policy for MSEs Order 2012."

33. **Preference to Make in India**: If applicable, as per the order issued by Department of Industrial Policy and Promotion (DIPP) vide No. P-45021/2/2017-PP (BE-II), dated 16.09.2020; the purchaser reserves the right to give preference to the local supplier. Order copy will form a part of this TED for evaluation and ranking of bids. A local supplier (definition of "local supplier" is given in clause 2 of the aforesaid order of DPIIT) has to submit the following along with their tender(s) **failing which their bid will be evaluated without considering such preference** mentioned in the DIPP order dated 15.06.2017:

i. The local supplier at the time of tender, bidding or solicitation shall be required to provide **self-certification that the item offered meets the minimum local content and shall give details of the location(s) at which the local value addition is made.**

ii. In cases of procurement for a value in excess of Rs. 10 crores. the local supplier shall be required to provide a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content.

iii. The DIPP has notified a Public Procurement (Preference to Make in India) Order, 2017 vide Order no P-45021/2/2017-B.E-II dated 15th June 2017. The procurement policy for Micro & Small Enterprises 2012 has been notified under MSMED Act, 2006. The orders mandates that purchase preference shall be given to local suppliers and MSEs in all procurement undertaken by procuring entities. General principles as per above orders and criteria fixed by MoH&FW shall be followed for various scenarios for award of contract.

34. In case of any inadvertent errors, the Commission reserves the right to correct it at later stage whenever it comes in the notice of this commission.

35. Any dispute arising in the matter shall be resolved through an arbitrator to be nominated by the competent authority at IPC, Ghaziabad.

36. The decision of Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission will be final and binding.

37. Bids & associated documents/ Catalogue/ technical details shall be written or translated in English Language.

38. Statutory deductions if any will be recovered from the Manufacturer/ Supplier.

39. Quantity mentioned in the schedule is approximate and can be increased, decreased and cancelled as per the requirement of this commission.

40. **Twenty Five Percentage (25%) Quantity can be increased or decreased without any change in the unit price and other terms & conditions, as per tender validity mentioned under clause 2, of this section.**

41. IPC reserve the right to cancel the tendering process at any time before award of Supply Order without assigning any reason thereof.

42. If successful bidder fails to deliver or perform any obligations as laid down under the Tender document and contract, then the Commission reserves the right to forfeit the EMD, Performance security and reserve the right to terminate the contract in whole or in part by written notice of default to the bidder/Supplier.

43. If at anytime during the course of contract, it is found that information or documents provided by Tenderer to IPC, either in Tender or otherwise, is false. The commission reserve right for forfeit the EMD, Performance security and to terminate the contract.

SECTION-IV

SPECIAL CONDITIONS OF CONTRACT (SCC)

1. Basic Eligibility Criteria for Bidders are as under:-

1.1. Bidders shall be a registered Sole Proprietor/Partnership Firm/ Company/ Government Organization.

1.2. Bidder must have GST & PAN CARD registration certificate issued by competent authority.

1.3. Average Annual Financial Turnover during the last three years ending on **31.03.2022 i.e. 2019-20, 2020-21 & 2021-22 should be atleast 30% of the Estimated Cost/ Quoted Prices.**

1.4. Bidders should have successfully completed similar Purchase Order for supply of Pharmaceutical Impurities for Impurities/ Reference Substances to B.P, U.S.P, I.P, Any Pharmaceutical Government Organization or Any Pharmaceutical Private Organization **during last Seven years** ending on **31.03.2023** as per following:-

One similar completed Order of not less than **80% of the Estimated Cost/Quoted Prices**.

OR

Two similar completed Order of not less than **50% of the Estimated Cost/Quoted Prices**

OR

Three similar completed Order of not less than **40% of the Estimated Cost/Quoted Prices.**

1.5. **The bidder should be reputed and experienced Manufacturer**

1.6. The Bidder must have possession of Requisite Quality Assurance Certificate/ other certificates.

1.7. The bidder should not be black listed by the any office/department of Central/State Government/Public Undertaking.

1.8. Other Documents asked in tender documents.

2. Selection/Qualification Criteria for Pharmaceutical Impurities:-

2.1 **Impurity Purity/ Potency should be greater than or equal to 90% (Ninety Percentage)**

2.2 In no case, Minimum Purity/ Potency of Supplied Impurities must not be found lesser than the aforementioned percentage criteria.

2.3 For the Offered Impurities, **Supporting COA/ Drafted COA Documents** as per bidder discretion & convenience must be annexed with Technical Bid.

2.1 **Purity/Potency Variation Criteria for the Supplied Pharmaceutical Impurities**:-

In case of tie of price/ rates for any impurity, the order preference may be given to the bidder quoted high purity /criteria for such impurity, at the discretion of competent authority.

2.2 **Shelf Life of all Pharmaceutical Impurities:-**

(i) It is recommended that the stability/ Shelf Life of Pharmaceutical Impurities offered and supplied **must be minimum (02) Two Years**. Specify Storage conditions also for the requisite shelf life.

(ii) To substantiate the same, Each Ordered Impurity should be supplied along with its "Stability Report"

(iii) The Performance Security would be refunded on condition of successful completion of shelf life period for all supplied Pharmaceutical Impurities or on expiry of performance Security validity period, whichever is later. The bidder shall have to produce No-Objection Certificate issued from user Division for release of performance security amount.

(iv) In case, Shelf Life of any Impurity is found lesser than (02) Two Years Period from date of supply to this commission. The supplier would be liable to replace the remaining Impurity available at IPC with afresh Ordered Impurity, which would once again be subjected to its acceptance after In-house Testing & Acceptance at IP Commission.

3. Terms & Conditions for non-delivery & Rejection of ordered Impurities:-

3.1 In case any successful bidder non-deliver any ordered impurity on account of any unprecedented reasons whatsoever, **then this commission reserves the right to levy a penalty of 10.00% of said item value** and the same may be deducted from the bidders' invoices due for payment at the discretion of competent authority.

In case, no accepted item invoices remain due for payment, then such penalty amount may be deducted from the "Performance Security" submitted against said order.

3.2 In case any Impurity found reject due to not matching the acceptance criteria after testing, **then this commission reserves the right to levy a penalty of 10.00% of said Rejected item's value** and the same may be deducted from the bidders' invoices due for payment at the discretion of competent authority. Moreover, if any replaced Impurity found Re- rejected in testing, then no further replacement for that compound would be accepted.

SECTION-V

OTHER TERMS & CONDITIONS (OTC):

1. **PRICES:** Prices quoted should be "Firm & Final" all other applicable charges (i.e. GST, packing, forwarding, postage, transportation, loading and unloading etc.) at F.O.R. IPC, Ghaziabad. Overwriting should be avoided in the Price-Bid/ Quotation. **(Section-X)**

   Bidders must ensure that the Prices Bids must not contain any computational errors and discrepancies. Amount in numeral and words should be same and correct.

2. **Delivery:** The ordered goods must be delivered at this commission within **60 Days periods** in well packed consignment without any extra cost.

   Freight, Insurance charges, if any will be borne by the Bidder/ supplier, Similarly shortage, pilferage in transit will be sole responsibility of the supplier and the same will be intimated to the supplier on receipt of goods by this commission for re-supply.

   Each Impurity must be supplied along with "**Impurity Material Information Form"** (which is provided in **Annexure-D**) and other supporting documents such as Certificate of Analysis, Stability Report and Material Safety Data Sheet etc.

3. **INSPECTION:** IPC reserves the right to inspect & Test the quality & standards of the stores for assessment of quality before dispatch to the consignee or at the consignee end or intermediate inspections during manufacturing stage or transit.

   Further, each delivered Impurity, would be subjected to its Identity, quality /purity testing at IPC for its acceptance at the discretion of competent authority. The invoice shall be processed only after accepted (RoA/COA) from user division.

4. **REPLACEMENT:** Manufacturer/Bidder shall have to replace rejected stores **within 30 days** from date of rejection notification AND shall have to lift back the Rejected Pharmaceutical Impurities thru their authorized Representative with Stamp on their own expenses. **Rejected Pharmaceutical Impurities shall be liable for 10% Penalty Deduction from the bidder's invoices, at the discretion of competent authority.**

5. **PAYMENT TERMS:** IPC payment term will be as below.

   "PAYMENT WILL BE RELEASED WITHIN 30 DAYS AFTER ACCEPTANCE OF GOODS BY COMPETENT AUTHORITY"

   Kindly note that the delivered Pharmaceutical Impurities would be subjected to their identity, quality/ purity testing and acceptance from user division and therefore the payment would be processed only after accepted Result of Analysis (RoA/CoA) Report from IPC.

6. **LIQUIDATED DAMAGES:** In the event of placement of Supply Order, if the contractor fails to complete the order as per the schedule given/ agreed, then IPC reserves the right to levy **liquidated damages @ 0.5% of the undelivered Impurity Order Value per week delay, subject to maximum of 10%.** Once the maximum is reached IPC will be at liberty to terminate the Impurity Order/ contract and to get the order done from alternate source at the cost & risk of the Bidder/Supplier.

7. **VALIDITY:** The offer should be valid for **minimum 18 Months** from the closing date of Tender.

8. The Bidder/Supplier must ensure to deliver only approved brands/ genuine quality of materials. If necessary, the samples may be submitted to get it approved from the competent authority at IPC. Sub-standard quality/ inferior quality of items will be rejected forth with.

9. **Bidder/Supplier should supply the goods as per Tender Specification. Any deviations in the quality are not acceptable.**

10. The Bidder/Supplier shall not sublet (sub contract) the tender without written permission of IPC.

11. **FORCE MAJEURE:** If at any time, during the currency of the contract, the performance in whole or in part by either party or any obligation under this contract shall be prevented or delayed by reasons of any war, natural calamities, hostility, or acts of public enmity, civil commotion, strikers, lock-outs, OR acts of God damage against the other in respect of such non-performance, deliveries under the contract shall be resumed as soon as possible if any of the events have caused to exist.

12. **COURT OF COMPETENT JURIDICTION:** Any legal action taken or proceeding initiated on any term of the tender shall be only in **Delhi/ Ghaziabad jurisdiction.**

13. **The Bidder should Sign & Stamp on each page of the tender as a token of having read, understood & agreed to the terms & conditions contained herein.**

14. **Further, the Bidder should Sign & Stamp each page of documents/ certificate enclosed in their Bid.**

Signature of the Bidder with seal

Date:

SECTION-VI

COMMERCIAL/ TECHNICAL BID

A.	COMMERICAL (General Information)			
(i)	Name of Firm/ Company			
(ii)	Number of years in Operation			
(iii)	Registered Address			
(iv)	Operating Address			
(v)	Telephone No (Country Code) (Area Code) Tel. No.			
(vi)	Tele fax (Country Code) (Area Code) Tel. No			
(vii)	Email Addresses			
(viii)	Constitution - (Tick the appropriate) **(Enclose copy of Certificate of Registration/Incorporation)**	o Partnership Firm o Sole Proprietorship Concern o Private Ltd.company o Public Ltd.Company o Others		
(ix)	Names of Partners/ Directors			
(x)	Authorized contact Persons with Contact Details			
(xi)	GST No. **(Enclose copy of same)**			
(xii)	PAN No. **(Enclose copy of same)**			
(xiii)	NSIC/ Udyog Aadhaar Memorandum (UAM)/ Startup Registration No. (if any) **(Enclose copy of same)**			
(xiv)	**Financial Reports:** Provide copies of last 3 year's Annual report/ Balance Sheet/ Profit and loss statement **Certified by Chartered Accountant**	**Mention Annual Turnover (INR Amount in Crores)**		
		2019-20	**2020-21**	**2021-22**
	Trade within India			
	Export			
	Total Rs. (in Crores)			
(xv)	Bank with full address and Account Details			

B. A BRIEF PROFILE OF THE FIRM MENTIONING ITS SUB-HEADINGS AS FOLLOWS from (i) to (ix) ;

(Kindly ensure Write-up should not be more than 03-05 Pages)

(i) Registered Office and R&D Units across India

(ii) Global Office details (if any)

(iii) Main Area of Business:
(Mentioning Ratio /Percentage of Reference/ Impurity Standard)

(iv) List of Hi-end Equipment/ Instruments (with capacities & Nos.) at Synthesis labs & Analytical/ Quality Control Labs etc.

(v) Organisation Chart of Key Personnel's along with Nos. of qualified professionals, scientists and Competent Technical Staff.

(vi) Business Activities, in domestic as well as Global Market during last five years

(vii) Total Nos. of Manufactured Impurities/ Reference Substance

(viii) List of Impurities/ Reference Substance supplied to other Pharmacopoeia such as i.e. EP, USP, BP etc

(ix) Brief list of some prominent clients/ customers

C. EXPERIENCE:

Details of successfully completed similar Purchase Orders for **supply of Impurities/ Reference Substances** to B.P, U.S.P, I.P, Any Pharmaceutical Government Organization or Any Pharmaceutical Private Organization during **last seven years** ending on **31.03.2023 (Refer Clause 1.4 of Section IV)**

Doc. Ref No. And Date	Description and quantity of ordered goods and services	PO/ CONTRACT VALUE (INR) (For Impurities/ Reference Substances)	Date of Completion of Contract	Have the Goods/ Stores been supplied to entire satisfaction of client [Attach Performance Certificate from Client (if any)]	CLIENT NAME & REFER-ENCE	Specify the page number in bid documents

- **Furnish data in prescribed format, in separate sheet (if required)**
- **In support of the above, the copy of the supporting documents (such as PO copies with proof of delivery/ acceptance/ payment receipt against respective PO to be submitted) should be furnished along with technical bids.**
- **These details may also be verified from the client.**
- **May USE PROFORMA-II to furnish the performance Certificate from client.**

D. TECHNICAL COMPLIANCE SHEET:-

Selection Criteria:-

1. **Impurity Purity must ≥ 90%**

2. **Shelf life of the Impurity- Minimum (02) Years from date of delivery**

3. **In case any Bidder has not offered/ quoted price for any Tendered item/Impurity, such Impurity row must be strikeout completely and mentioned as NO OFFER such as depicted below:-**

Azilartan Kamedoxomil impurity A	----------NO OFFER----------

Tender Sch. No.	Monographs	Impurities IPRS used for SST preparation	Manufactured in India (Yes/No)	Specify Purity/ Potency of Offered Impurity	Attached (CoA/ Drafted CoA) (Yes/ No)	Specify Page Numbers of Attached Documents	Remark for Deviation (if any)
1	**Azilsartan medoxomil Potassium API and Tablets**	Azilartan Kamedoxomil impurity A					
2	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity B					
3	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity C					
4	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity D					
5	**Azilsartan medoxomil Potassium API and Tablets**	Azilartan Kamedoxomil impurity E					
6	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity F					
7	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity G					
8	**Azilsartan medoxomil Potassium API and Tablets**	Azilsartan Kamedoxomil impurity H					
9	**Cabozantinib S-malate API and Tablets**	Cabozantinib impurity A					
10	**Levetiracetam**	Levetiracetam Related Compound A					
11	**Ketoconazole Shampoo**	Ketoconazole impurity D					
12	**Ketoconazole Shampoo**	Ketoconazole impurity 1					
13	**Ketoconazole Shampoo**	Ketoconazole impurity 2					
14	**Moxifloxacin Tablets**	Moxifloxacin related compound F					
15	**Moxifloxacin Tablets**	Moxifloxacin related compound A					
16	**Perampanel API and Tablets**	Perampanel impurity A					

17	**Perampanel API and Tablets**	Perampanel impurity B					
18	**Perampanel API and Tablets**	Perampanel impurity C					
19	**Perampanel API and Tablets**	Perampanel impurity D					
20	**Perampanel API and Tablets**	Perampanel impurity E					
21	**Perampanel API and Tablets**	Perampanel impurity F					
22	**Remogliflozin Etabonate API and Tablets**	Remogliflozin etabonate impurity A					
23	**Rifaximin API and Tablets**	Rifaximin impurity D					
24	**Rifaximin API and Tablets**	Rifaximin Impurity H					
25	**Velpatasvir**	Velpatasvir impurity A					
26	**Velpatasvir**	Velpatasvir impurity B					
27	**Velpatasvir**	Velpatasvir impurity C					
28	**Velpatasvir**	Velpatasvir impurity D					
29	**Velpatasvir**	Velpatasvir impurity E					
30	**Velpatasvir**	Velpatasvir impurity F					
31	**Velpatasvir**	Velpatasvir impurity G					
32	**Bilastine API and Tablets**	Bilastine impurity A					
33	**Bilastine API and Tablets**	Bilastine impurity B					
34	**Bilastine API and Tablets**	Bilastine impurity C					
35	**Bilastine API and Tablets**	Bilastine impurity D					
36	**Bilastine API and Tablets**	Bilastine impurity E					
37	**Bilastine API and Tablets**	Bilastine impurity F					
38	**Miltefosine API and Capsules**	Miltefosine impurity A					
39	**Miltefosine API and Capsules**	Miltefosine impurity B					
40	**Miltefosine API and Capsules**	Miltefosine impurity C					
41	**Miltefosine API and Capsules**	Miltefosine impurity D					
42	**Miltefosine API and Capsules**	Miltefosine impurity E					
43	**Miltefosine API and Capsules**	Miltefosine impurity F					
44	**Miltefosine API and Capsules**	Miltefosine impurity G					
45	**Nepafenac and Nepafenac Ophthalmic Suspension**	Nepafenac impurity A					

46	**Nepafenac and Nepafenac Ophthalmic Suspension**	Nepafenac impurity B					
47	**Nepafenac and Nepafenac Ophthalmic Suspension**	Nepafenac impurity C					
48	**Atropine Opthalmic Solution**	Atropic Acid					
49	**Copovidone**	Vinyl Acetate					
50	**Doxycycline HCl /Cap/Dis Tab**	Doxycycline for system suitability IPRS (containing impurity A)					
51	**Doxycycline HCl /Cap/Dis Tab**	Doxycycline for system suitability IPRS (containing impurity C)					
52	**Doxycycline HCl /Cap/Dis Tab**	Doxycycline for system suitability IPRS (containing impurity F)					
53	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity A).					
54	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity B).					
55	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity C).					
56	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity D).					
57	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity F).					
58	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity G).					
59	**Sodium Fusidate**	Fusidic acid for peak identification IPRS (containing impurity H).					
60	**Sodium Fusidate**	Fusidic acid impurity mixture IPRS (containing impurity I)					
61	**Sodium Fusidate**	Fusidic acid impurity mixture IPRS (containing impurity K)					
62	**Sodium Fusidate**	Fusidic acid impurity mixture IPRS (containing impurity L)					
63	**Sodium Fusidate**	Fusidic acid impurity mixture IPRS (containing impurity M)					
64	**Zoledronic Acid**	Zoledronic acid related compound A					
65	**Zoledronic Acid**	Zoledronic acid related compound B					

66	**Olmesartan Medoxomil/Tab/ Olmesartan Medoxomil and Hydrochlorothiazide Tablets**	Olmesartan medoxomil RC A					
67	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity A					
68	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity B					
69	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity C					
70	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity D					
71	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity F					
72	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity L					
73	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity M					
74	**Beclomethasone dipropionate**	Beclomethasone dipropionate impurity N					
75	**Amorolfine Hydrochloride**	Amorolfine impurity D					
76	**Amorolfine Hydrochloride**	Amorolfine impurity E					
77	**Amorolfine Hydrochloride**	Amorolfine impurity I					
78	**Amorolfine Hydrochloride**	Amorolfine impurity J					
79	**Amorolfine Hydrochloride**	Amorolfine impurity M					
80	**Cefepime Hydrochloride**	Cefepime Related Compound D					
81	**Cefepime Hydrochloride**	Cefepime Related Compound E					
82	**Mexiletine Hydrochloride**	Mexiletine impurity D					
83	**Neostigmine Bromide**	Neostigmine impurity A					
84	**Carboprost Tromethamine**	15-epicarboprost					
85	**Flurbiprofen/Tab**	Flurbiprofen impurity A					
86	**Flurbiprofen/Tab**	Flurbiprofen impurity B					
87	**Phenindione/Tab**	Phenindione impurity A					
88	**Terbutaline Sulphate**	Terbutaline RC A					
89	**Cyclobenzaprine Hydrochloride /Tab**	Cyclobenzaprine related compound A					

90	**Cyclobenzaprine Hydrochloride /Tab**	Cyclobenzaprine related compound B					
91	**Ropinirole Prolonged-release Tablets**	Ropinirole impurity B					
92	**Aciclovir/ Tab/ IV/Oral sol/Cream/Eye ointment/Dis Tab**	Imp-K					
93	**Aciclovir/ Tab/ IV/Oral sol/Cream/Eye ointment/Dis Tab**	Imp-C					
94	**Dithranol Ointment**	Dithranol impurity C					
95	**Ketoconazole**	ketoconazole impurity C					
96	**Ketoconazole**	ketoconazole impurity D					
97	**Methotrexate**	Methotrexate impurity I					
98	**Carbamazepine/Tab**	Carbamazepine related compound B IPRS					
99	**Chlorthalidone**	Chlorthalidone RC-B					
100	**Chlorthalidone**	Chlorthalidone RC-G					
101	**Cilostazol**	Cilostazol impurity A					
102	**Cilostazol**	Cilostazol impurity C					
103	**Ketorolac Tromethamine Injection/Tab**	Ketorolac related compound A					
104	**Ketorolac Tromethamine Injection/Tab**	Ketorolac related compound B					
105	**Ketorolac Tromethamine Injection/Tab**	Ketorolac related compound C					
106	**Ketorolac Tromethamine Injection/Tab**	Ketorolac related compound D					
107	**Ascorbic Acid**	Ascorbic acid impurity C					
108	**Ascorbic Acid**	Ascorbic acid impurity D					
109	**Clindamycin Hcl/ Cap**	Clindamycin imp-B					
110	**Clindamycin Hcl/ Cap**	Clindamycin imp-C					
111	**Atropine Sulphate**	Atropine impurity A					
112	**Atropine Sulphate**	Atropine impurity B					
113	**Atropine Sulphate**	Atropine impurity D					
114	**Atropine Sulphate**	Atropine impurity E					
115	**Atropine Sulphate**	Atropine impurity F					
116	**Atropine Sulphate**	Atropine impurity G					
117	**Dextrose**	Maltotriose					

118	**Neostigmine Bromide**	Neostigmine impurity B					
119	**Phenindione/Tab**	Phenindione impurity C					
120	**Phenindione/Tab**	Phenindione impurity D					
121	**Phenindione/Tab**	Phenindione impurity E					
122	**Temozolomide Capsules**	Dacarbazine related compound A					
123	**Benzyl Alcohol**	Benzyl alcohol impurity B					
124	**Folic Acid**	Folic Acid IMP A					
125	**Tolbutamide**	Tolbutamide IMP B					
126	**Levetiracetam**	Levetiracetam IMP B					
127	**Sodium Fusidate**	impurity N					
128	**Dextrose**	Maltose Monohydrate					
129	**Cefepime Hydrochloride**	N-methylpyrrolidine					
130	**Vildagliptin and Metformin Tablets**	1 -amino-admantan-3-ol					
131	**Dolutegravir Sodium**	isomer-1					
132	**Dolutegravir Sodium**	Enantiomer					
133	**Dolutegravir Sodium**	isomer-2					
134	**Lactulose**	Lactulose Impurity A					
135	**Metformin HCl**	Melamine					
136	**Buprenorphine HCl API/ Injection**	Imp.-G					
137	**Buprenorphine HCl API/ Injection**	Imp.-H					
138	**Buprenorphine HCl API/ Injection**	Imp.- J					
139	**Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets**	Tenofovir disoproxil impurity H					
140	**Rivastigmine Tartrate Rivastigmine Capsules**	Rivastigmine tartrate R-Isomer RS					
141	**Lamivudine and Zidovudine Tablets**	Lamivudine diastereomer					
142	**Tenoxicam Tenoxicam Tablets**	Tenoxicam impurity G					
143	**Doxycycline HCl /Cap/Dis Tab**	Impurity B					
144	**Doxapram HCl**	Impurity B					
145	**Sumatriptan Injection**	Sumatriptan impurity H					

146	**Tetracycline**	4- epitetracycline HCl					
147	**Paclitaxel**	10-deacetyl-7-epipaclitaxel					
148	**Vildagliptin**	R-enantiomer of vildagliptin					
149	**Paroxetine HCl**	Impurity E					
150	**Sumatriptan**	Impurity A					
151	**Tranexamic Imp.C**	Impurity C					
152	**Thiamine Hydrochloride Thiamine Mononitrate**	Thiamine impurity B					
153	**Finasteride**	Impurity C					
154	**Phenytoin Sodium**	Impurity E					
155	**Indapamide**	Impurity B					
156	**Ceftriaxone Sodium (E isomer)**	E isomer					
157	**Pantoprazole Sodium API And Pantoprazole Sodium delayed Release Tablets**	Pantoprazole RC-E					
158	**Dicyclomine HCl**	Dicyclomine RC-A					
159	**Sulphamethoxazole**	sulfamethoxazole RC-C					
160	**Buprenorphine Hcl/Inj**	IMPURITY A					
161	**Terazosin HCl**	Impurity N					
162	**Testosterone propionate**	Testerone acetate					
163	**Ibuprofen Tablets**	Ibuprofen RC-J					
164	**Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets**	tenofovir disoproxil impurity I					
165	**Buprenorphine HCl API/ Injection**	Imp.-B					
166	**Ipratropium**	Ipratropium impurity B					

Total Nos. of Tender items for which, price offer has been provided in price bid_____Nos.

Total No. of Tender items are "Manufactured in India"_____Nos.

<u>Kindly Note:</u>

1. **Valid Manufacturing License/ Approval Document including undertaking must be attached by the bidder with the technical bid.**

2. **Attach Self Certification Affidavit for Local Content in the offered Tender items (Annexure-F on Rs. 100/- Stamp Paper)**

3. **Attach CoA/ Drafted CoA documents for Quoted Tender items for Corroboration Purpose.**

4. **Attach the separate sheet (if required)**

5. **Bidders are advised to quote their offer only for those Pharmaceutical Impurities, whose shelf life meets the criteria of minimum 02 Years.**

E. QUALITY ASSURANCE:

1. The Bidder should have valid ISO 9001/ ISO 17025, Kindly furnish the below mentioned details accordingly;

Certification	Standard	Specify	Certificate No.	Valid Upto
ISO Certification	**ISO 9001**	❑ Yes ❑ no		
	ISO 14001	❑ Yes ❑ no		
	ISO17034	❑ Yes ❑ no		
	ISO/IEC 17025	❑ Yes ❑ no		
	Other ISO/TS Certification	_____ _____		
Other Certification	WHO-GMP/CoPP Certification	❑ Yes ❑ no		
Any Other Relevant	NABL			
QUALITY POLICY/ POLICIES (Please provide ink signed copy also (if any)				

SECTION-VII

ANNEXURE– A

Date:_____ Tender No. _____

INTEGRITY PACT

Between

hereinafter referred to as **"The Principal"**,
and

..... hereinafter referred to as **"The Bidder/ Contractor"**

Preamble

The Principal intends to award, under laid down organizational procedures, contract/s for.....The Principal values full compliance with all relevant laws of the land, rules, regulations, economic use of resources and of fairness / transparency in its relations with its Bidder(s) and / or Contractor(s).

In order to achieve these goals, the Principal will appoint Independent External Monitors (IEMs) who will monitor the tender process and the execution of the contract for compliance with the principles mentioned above.

Section 1 – Commitments of the Principal

(1) The Principal commits itself to take all measures necessary to prevent corruption and to observe the following principles:-

a. No employee of the Principal, personally or through family members, will in connection with the tender for , or the execution of a contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the person is not legally entitled to.

b. The Principal will, during the tender process treat all Bidder(s) with equity and reason. The Principal will in particular, before and during the tender process, provide to all Bidder(s) the same information and will not provide to any Bidder(s) confidential / additional information through which the Bidder(s) could obtain an advantage in relation to the tender process or the contract execution.

c. The Principal will exclude from the process all known prejudiced persons.

(2) If the Principal obtains information on the conduct of any of its employees which is a criminal offence under the IPC/PC Act, or if there be a substantive suspicion in this regard, the Principal will inform the Chief Vigilance Officer and in addition can initiate disciplinary actions.

Section 2 – Commitments of the Bidder(s)/ Contractor(s)

(1) The Bidder(s)/ Contractor(s) commit themselves to take all measures necessary to prevent corruption. The Bidder(s)/ Contractor(s) commit themselves to observe the following principles during participation in the tender process and during the contract execution.

a. The Bidder(s)/ Contractor(s) will not, directly or through any other person or firm, offer, promise or give to any of the Principal's employees involved in the tender process or the execution of the contract or to any third person any material or other benefit which he/she is not legally entitled to, in order to obtain in exchange any advantage of any kind whatsoever during the tender process or during the execution of the contract.

b. The Bidder(s)/ Contractor(s) will not enter with other Bidders into any undisclosed agreement or understanding, whether formal or informal. This applies in particular to prices, specifications, certifications, subsidiary contracts, submission or non-submission of bids or any other actions to restrict competitiveness or to introduce cartelisation in the bidding process.

c. The Bidder(s)/ Contractor(s) will not commit any offence under the relevant IPC/PC Act; further the Bidder(s)/ Contractor(s) will not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the Principal as part of the business relationship, regarding plans, technical proposals and business details, including information contained or transmitted electronically.

d. The Bidder(s)/Contractors(s) of foreign origin shall disclose the name and address of the Agents/representatives in India, if any. Similarly the Bidder(s)/Contractors(s) of Indian Nationality shall furnish the name and address of the foreign principals, if any. Further details as mentioned in the "Guidelines on Indian Agents of Foreign Suppliers" shall be disclosed by the Bidder(s)/Contractor(s).Further, as mentioned in the Guidelines all the payments made to the Indian agent/representative have to be in Indian Rupees only.

e. The Bidder(s)/ Contractor(s) will, when presenting their bid, disclose any and all payments made, is committed to or intends to make to agents, brokers or any other intermediaries in connection with the award of the contract.

f. Bidder(s) /Contractor(s) who have signed the Integrity Pact shall not approach the Courts while representing the matter to IEMs and shall wait for their decision in the matter.

(2) The Bidder(s)/ Contractor(s) will not instigate third persons to commit offences outlined above or be an accessory to such offences.

Section 3 - Disqualification from tender process and exclusion from future contracts

If the Bidder(s)/Contractor(s), before award or during execution has committed a transgression through a violation of Section 2, above or in any other form such as to put their reliability or credibility in question, the Principal is entitled to disqualify the Bidder(s)/Contractor(s) from the tender process or take action as per the procedure

Section 4 – Compensation for Damages

(1) If the Principal has disqualified the Bidder(s) from the tender process prior to the award according to Section 3, the Principal is entitled to demand and recover the damages equivalent to Earnest Money Deposit/ Bid Security.

(2) If the Principal has terminated the contract according to Section 3, or if the Principal is entitled to terminate the contract according to Section 3, the Principal shall be entitled to demand and recover from the Contractor liquidated damages of the Contract value or the amount equivalent to Performance Bank Guarantee.

Section 5 -- Previous transgression

(1) The Bidder declares that no previous transgressions occurred in the last three years with any other Company in any country conforming to the anti-corruption approach or with any Public Sector Enterprise in India that could justify his exclusion from the tender process.

(2) If the Bidder makes incorrect statement on this subject, he can be disqualified from the tender process or action can be taken as per the procedure

Section 6 – Equal treatment of all Bidders / Contractors / Subcontractors

(1) In case of Sub-contracting, the Principal Contractor shall take the responsibility of the adoption of Integrity Pact by the Sub-contractor.

(2) The Principal will enter into agreements with identical conditions as this one with all Bidders and Contractors.

(3) The Principal will disqualify from the tender process all bidders who do not sign this Pact or violate its provisions.

Section 7 – Criminal charges against violating Bidder(s) / Contractor(s) / Subcontractor(s)

If the Principal obtains knowledge of conduct of a Bidder, Contractor or Subcontractor, or of an employee or a representative or an associate of a Bidder, Contractor or Subcontractor which constitutes corruption, or if the Principal has substantive suspicion in this regard, the Principal will inform the same to the Chief Vigilance Officer.

Section 8 – Independent External Monitor

(1) The Principal appoints competent and credible Independent External Monitor for this Pact after approval by Central Vigilance Commission. The task of the Monitor is to review independently and objectively, whether and to what extent the parties comply with the obligations under this agreement.

(2) The Monitor is not subject to instructions by the representatives of the parties and performs his/her functions neutrally and independently. The Monitor would have access to all Contract documents, whenever required. It will be obligatory for him / her to treat the information and documents of the Bidders/Contractors as confidential. He/ she reports to the Chairman,

(3) The Bidder(s)/Contractor(s) accepts that the Monitor has the right to access without restriction to all Project documentation of the Principal including that provided by the Contractor. The Contractor will also grant the Monitor, upon his/her request and demonstration of a valid interest, unrestricted and unconditional access to their project documentation. The same is applicable to Sub-contractors.

(4) The Monitor is under contractual obligation to treat the information and documents of the Bidder(s)/ Contractor(s)/ Sub-contractor(s) with confidentiality. The Monitor has also signed declarations on 'Non-Disclosure of Confidential Information' and of 'Absence of Conflict of Interest'. In case of any conflict of interest arising at a later date, the IEM shall inform Chairman, SAIL and recuse himself / herself from that case.

(5) The Principal will provide to the Monitor sufficient information about all meetings among the parties related to the Project provided such meetings could have an impact on the contractual relations between the Principal and the Contractor. The parties offer to the Monitor the option to participate in such meetings.

(6) As soon as the Monitor notices, or believes to notice, a violation of this agreement, he/she will so inform the Management of the Principal and request the Management to discontinue or take corrective action, or to take other relevant action. The monitor can in this regard submit non-binding recommendations. Beyond this, the Monitor has no right to demand from the parties that they act in a specific manner, refrain from action or tolerate action.

(7) The Monitor will submit a written report to the within 8 to 10 weeks from the date of reference or intimation to him by the Principal and, should the occasion arise, submit proposals for correcting problematic situations.

(8) If the Monitor has reported to the Chairman , a substantiated suspicion of an offence under relevant IPC/ PC Act, and the Chairman has not, within the reasonable time taken visible action to proceed against such offence or reported it to the Chief Vigilance Officer, the Monitor may also transmit this information directly to the Central Vigilance Commissioner.

(9) The word **'Monitor'** would include both singular and plural.

Section 9 – Pact Duration

This Pact begins when both parties have legally signed it. It expires for the Contractor 12 months after the last payment under the contract, and for all other Bidders 6 months after the contract has been awarded. Any violation of the same would entail disqualification of the bidders and exclusion from future business dealings.

If any claim is made / lodged during this time, the same shall be binding and continue to be valid despite the lapse of this pact as specified above, unless it is discharged / determined by Chairman

Section 10 – Other provisions

(1) This agreement is subject to Indian Law. Place of performance and jurisdiction is the Registered Office of the Principal.

(2) Changes and supplements as well as termination notices need to be made in writing. Side agreements have not been made.

(3) If the Contractor is a partnership or a consortium, this agreement must be signed by all partners or consortium members.

(4) Should one or several provisions of this agreement turn out to be invalid, the remainder of this agreement remains valid. In this case, the parties will strive to come to an agreement to their original intentions.

(5) Issues like Warranty / Guarantee etc. shall be outside the purview of IEMs.

(6) In the event of any contradiction between the Integrity Pact and its Annexure, the Clause in the Integrity Pact will prevail.

(For & On behalf of the Principal)	(For & On behalf of Bidder/ Contractor)
(Office Seal)	(Office Seal)

Place ----------

Date ----------

Witness 1:

(Name & Address) _____

_____

_____

_____

Witness 2:

(Name & Address) _____

_____

_____

_____

ANNEXURE – B

(On Agency/ Firm Letter Head)

DECLARATION

I/ We Confirm having read and understood all the work requirements, instruction forms, terms & conditions and all other requirements of the above tender (both expressed and implied) in full and the offer being abide by all without any deviation.

SIGNATURE:

NAME & ADDRESS OF BIDDER

(Seal of the Bidder)

ANNEXURE-C

(On Agency/ Firm Letter Head)

NON-BLACKLIST DECLARATION

Undertaking by the firm on the firm's letter head stating that **the firm have not been blacklisted /debarred** for dealing by Government of India or any State Govt./ PSU/ RBI / Banks in any manner.

SIGNATURE:

NAME & ADDRESS OF BIDDER

(Seal of the Bidder)

ANNEXURE-D

IMPURITY MATERIAL INFORMATION FORM

1. Impurity Material Information				
Impurity Name				
CAS Registry Number (if available)				
Supplier lot/Batch number				
2. Supplier Information				
Supplier				
Contact Name				
Phone number		E-mail address		
Signature		Date		
3. Origin of Material – Required				
Country of Manufacture		Biologically Derived?	Yes/No	
Synthetically Derived?	Yes/No	Source [e.g. fermentation, recombinant (provide expression system, e.g. plasmid, *E. coli*, Yeast, CHO cells)]		
4. Basis of Purity or Value Assignment				
☐	Official IP Method	IP_____, page_____		
☐	In-House Assay Method	Reference Standard used		
		Number of assay replicates		
	Comments:			
☐	Loss On Drying or TGA			
☐	Related substance by HPLC			
5. Storage Conditions				
☐	Room temperature			
☐	Cool Room (between 8° and 15° C)			
☐	Refrigerator (between 2° and 8° C)			
☐	Freezer (between -25° and -10° C)			
☐	Other			
☐	Not known			

6.	**Directions for Use**
☐	Dry before use Temperature:___°C time:___hrs vacuum:_____mm Hg:_____ desiccant:_____
☐	Do not dry, correct for volatiles (___LOD) or correct for moisture (___KF)
☐	Do not dry, use as-is
☐	Not known
7.	**Sample Preparation Recommendations**
☐	Use immediately (solutions are unstable)
☐	Protect from light
☐	Refrigerate
☐	Other_____
☐	Not known
8.	**Material Information**
☐	Material is stable under stated storage conditions for_____years
☐	Material is hygroscopic
☐	Material is air sensitive
☐	Material is light sensitive
☐	Solvents used during the last stage (e.g., reaction, workup, purification): _____
☐	Information regarding salt, solvent, hydrate ratios
☐	Information regarding known polymorphs
☐	Not known
9.	**Packaging Recommendations**
☐	Ambient temperature and humidity conditions
☐	Rooms with a reduced relative humidity
☐	Inert gas-filled glove box
☐	Package under low actinic light
☐	Not known
10.	**Shipping Documentation**
☐	Certificate of Analysis (CoA)
☐	Material Safety Data Sheet (MSDS)
☐	Supporting analytical data
☐	Stability Report

1. **Dept. of Pharmaceutical Order for Minimum Local Content for all Pharma products (Pharmaceutical Formulation) for reference of Prospective Bidders**

2. **Procedure for Calculating Local Content would remain same as mentioned in clause 6 of the order:**

No.31026/4/2018-Policy
Government of India
Ministry of Chemicals& Fertilizers
Department of Pharmaceuticals
*****

Shastri Bhawan, New Delhi
Dated the 1st January, 2019

ORDER

Subject:- Public Procurement (Preference to Make in India), Order, 2017 (revised) -Notifying provisions about Pharmaceutical Formulations in furtherance to the Order.

Reference:- Department of Industrial Policy & Promotion (DIPP) Order No. P-45021/2/2017-PP (BE-II) dated 28.05.2018.

The Government has issued revised Public Procurement (Preference to Make in India), Order 2017 vide the Department of Industrial Policy & Promotion (DIPP) Order No. P-45021/2/2017-PP(BE-II) dated 28.05.2018 to encourage 'Make in India' and to promote manufacturing and production of goods and services in India with a view to enhancing income and employment.

2. DIPP has identified Department of Pharmaceuticals as the nodal Department for implementing the provisions related to goods, services or works related to Pharmaceutical sector.

3. In furtherance of the above mentioned order of DIPP, the Department of Pharmaceuticals (DoP) hereby notifies that purchase preference shall be provided by all Government Procuring Entities to local suppliers of Pharmaceutical Formulations in various dosage forms, as per the minimum local content prescribed in this order.

4. This Order comes into effect immediately and shall remain valid till revised.

5. Minimum local content and Phased Manufacturing Programme (PMP).

5.1 For formulations which are manufactured in India, the minimum local content for all Pharma products shall be as per the table below:-

Pharma Products	Minimum Local Content (%)			
	2018-19	2019-21	2021-23	2023-25
All Pharmaceutical formulations in different dosage forms and strengths	75	80	85	90

5.2 For formulations which are not manufactured in India, the minimum local content for all Pharma products shall be as per the table below:-

Pharma Products	Minimum Local Content (%)			
	2018-19	2019-21	2021-23	2023-25
All Pharmaceutical formulations in different dosage forms and strengths	10	15	20	30

6. Procedure for calculating local content for Pharmaceutical Formulations.

6.1 Bill of Material sourced from domestic manufacturers (Dom-BOM) may be calculated based on one of the following depending on data available. Each of these calculations should provide consistent result:-

(a) Sum of the costs of all inputs which go into the product (including duties and taxes levied on procurement of inputs except those for which credit/ set-off can be taken) and which have not been imported directly or through a domestic trader or an intermediary.

(b) Ex-Factory Price of product minus profit after tax minus sum of imported Bill of material used (directly or indirectly) as inputs in producing the product (including duties and taxes levied on procurement of inputs except those for which credit/ set-off can be availed).

(c) Market price minus post-production freight, insurance and other handling costs minus profit after tax minus warranty costs minus sum of Imported Bill of material used as inputs in producing the product (including duties and taxes levied on procurement of inputs except those for which credit / set-off can be taken) minus sales and marketing expenses.

6.2 Total bill of Material (Total-BOM) may be calculated based on one of the following depending on data available. Each of these calculations should provide consistent result:-

(a) Sum of the costs of all inputs which go into the product (including duties and taxes levied on procurement of inputs except those for which credit / set-off can be availed).

(b) Ex-factory Price of product minus profit after tax.

(e) Market price minus post-production freight, insurance and other handling costs minus profit after tax, minus sales and marketing expenses.

6.3 The percentage of local content value-addition may be calculated as per the following formula:-

Percentage of local content= (Dom-BOM/Total-BOM) x100

It is recommended that each assessing agency should calculate the domestic local content/value addition using at least two of the above formulae so as to validate the assessments in this regard and ensure that the local content that is claimed is consistent.

7. It is clarified that this order shall also be applicable to procurement of medicines made by State Governments or PSUs under State Governments or local bodies under Centrally Sponsored schemes that are fully or partially funded by Government of India.

8. Every procuring entity shall constitute a Committee with internal and external experts for independent verification of self-declaration and auditors /accountants certificates on random basis and for the complaints that are received/ referred. In case any clarification is needed by this committee on any particular point, the matter may be referred to the following committee in the Department of Pharmaceuticals:-

(i) Chairperson - Joint Secretary (Policy)
(ii) Member - Joint Secretary (PSU) or representative thereof.
(iii) Member - Member Secretary (NPPA) or representative thereof.

9. In case a complaint is received by a procuring entity against the claim of a bidder regarding local content, the same shall be referred to the committee of the procuring entity as referred to in para- 8 above. The Committee should dispose of the complaint within 4 weeks, as far as possible, from the date of receipt of complaint alongwith all necessary documentation in support of local content claimed by the bidder.

10. There will be a complaint fee of Rs. 10,000/- per complaint to be deposited with the said procuring entity alongwith the complaint by the complainant. In case, the complaint is found to be incorrect, the complaint fee shall be forfeited. In case, the complaint is upheld in part or full, deposited fee of the complaint will be refunded without any interest.

11. All other terms & conditions will be as per the Department of Industrial Policy & Promotion (DIPP) Order no. P-45021/2/2017-PP(BE-II) dated 28.05.2018.

(Navdeep Rinwa)
Joint Secretary to the Govt. of India
Ph. 23385131

Copy to:-

1. All Ministries/Departments of Government of India
2. Cabinet Secretariat
3. Prime Minister's Office
4. NITI Aayog
5. Comptroller & Auditor General of India
6. Internal Circulation in the Department of Pharmaceuticals
7. Senior Director, NIC, DoP with request to upload the same on the Department's website.

Format for Affidavit of Self Certification regarding Local Content to be provided on Rs. 100/- Stamp Paper under Preference to "MAKE IN INDIA" Policy

Date:

I_____**S/o, D/o, W/o**_____Resident of _____ hereby certify that we M/s_____ _____ (Manufacturer/Supplier name) are local supplier (Class-I/ Class-II) meeting the requirement of minimum Local content for the below mentioned items against Govt. Tender No._____:

Schedule. No.	Items Particulars	Percentage of Local Content Claimed (%)	Details of Locations at which local value addition is made
1.			
2.			
3.			
4.			
5.			
.			
.			
So on For all the quoted items			

I do hereby solemnly affirm and declare as under:

That I will agree to abide by the terms and conditions of the policy of Government of India issued by Department of Industrial Policy and Promotion (DIPP) vide Notification No. P-45021/2/2017-PP (BE-II), dated 16.09.2020, and its amendments as applicable on the date of submission of tender.

That the information furnished hereinafter is correct to best of my knowledge and belief and I undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals. Government of India for the purpose of assessing the local content.

That the local content for all inputs which constitute the said items/ goods has been verified by me and I am responsible for the correctness of the claims made therein.

That in the event of the domestic value addition of the product mentioned herein is found to be incorrect and not meeting the prescribed value-addition norms, based on the assessment of an authority so nominated by the Department of Pharmaceuticals. Government of India for the purpose of assessing the local content, action will be taken against me as per DOP Order No. P-45021/2/2017-B.E.-II dated 15.06.2017 and Guidelines issued vide letter no. 31026/36/2016- MD dated 18.05.2018.

I also understand, false declarations will be in breach of the Code of Integrity under Rule 175(1)(i)(h) of the General Financial Rule for which for which a bidder or its successors can be debarred for up two years as per Rule 151 (iii) of the General Financial Rules along with such other actions as may be permissible under law.

I agree to maintain the following information in the Company's record for a period of 8 years and shall make this available for verification to any statutory authority:

i) Name and details of the Domestic Manufacturer (Registered Office. Manufacturing unit location, Nature of legal entity)
ii) Date on which this certificate is issued
iii) Item/ Goods for which the certificate is produced
iv) Procuring entity to whom the certificate is furnished
v) Percentage of local content claimed
vi) Name and contact details of the unit of the manufacturer
vii) Sale Price of the product
viii) Ex-Factory Price of the product
ix) Freight, insurance and handling
x) Total Bill of Material
xi) List and total cost value of inputs used for manufacture of the goods.
xii) List and total cost of inputs which are domestically sourced. Value addition certificates from suppliers, if the input is not in- house to be attached.
xiii) List and cost of inputs which are imported. directly or indirectly

For and on behalf of_____(Name of firm/entity)

Authorized signatory (To be duly authorized by the Board of Director or Equivalent)

ANNEXURE-G

Bid Security Declaration Form

Date:_____ Tender No. _____

To,

(insert complete name and address of the purchaser)

I/We. The undersigned, declare that:

I/We understand that, according to your conditions, bids must be supported by a Bid Securing Declaration.

I/We accept that I/We may be disqualified from bidding for any contract with you for a period of one year from the date of notification if I am /We are in a breach of any obligation under the bid conditions because I/We

a) have withdrawn/modified/amended, impairs or derogates from the tender, my/our Bid during the period of bid validity specified in the form of Bid; or
b) having been notified of the acceptance of our Bid by the purchaser during the period of bid validity

i. fail or refuse to execute the contract, if required, or
ii. fail or refuse to furnish the Performance Security, in accordance with the Instructions to Bidders.

I/We understand this Bid Securing Declaration shall cease to be valid if I am/we are not the successful Bidder, upon the earlier of

a) the receipt of your notification of the name of the successful Bidder; or
b) thirty days after the expiration of the validity of my/our Bid.

Signature of Tenderer

Name: Designation:

Organization Name:

Contact No.:

SECTION-VIII

PERFORMA-I

MANUFACTURER'S AUTHORISATION FORM

- ***DELETED (AS NOT APPLICABLE FOR THIS TENDER)***

PERFORMA-II

FORMAT OF PERFORMANCE CERTIFICATE
(FROM CLIENTS)

TO WHOM IT MAY CONCERN

Ref. No._____ Date_____

Certified that M/s_____(name & address of bidder/ Supplier) supplied us_____Nos (specify name of goods/ stores) manufactured by _____ (specify name of the equipment) against our order no _____dt_____(please specify order no & date as furnished in the experience statement). The goods/ stores were supplied over to us and accepted by us on_____(specify date) to our entire satisfaction to this effect.

Place:_____ Name & Designation of Officer with Seal

Date:_____ _____

(in capital letters)

Kindly Note:

IPC has right to call for original to verify and also has right to cross verify from the issuer and concerned organization.

To be made on Rs. 100.00 Non-Judicial Stamp

AGREEMENT/ CONTRACT FORM

THIS AGREEMENT is made on the____day of_____(Month)_____(Year)

BETWEEN

Indian Pharmacopoeia Commission that is an autonomous institution under Ministry of Health & Family Welfare (MoH&FW) and having its premises at Sector-23, Raj Nagar, Ghaziabad-201002, (Hereinafter called **"the Institution"**) and,

AND M/s_____(Name of the Bidder/ Supplier), a corporation incorporated under the laws of [insert: country of Supplier] and having its principal palace of Business at _____(Address of Supplier) (hereinafter called **"the Supplier"**).

WHEREAS the Institution invited bids for certain Goods/ stores and ancillary services viz, _____[brief description of Goods/ stores and Services] and has accepted a bid by the Supplier for the supply of those goods/ stores and services in the sum of Rs. _____[contract unit price in the words and figures] (hereinafter called **"the Contract Price"**).

NOW THIS AGREEMENT WITNESSTH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Condition of Contract referred to.

2. The following documents shall constitute the Contract between the Institution and the Supplier, and each shall be read and construed as an integral part of the Contract:

   (a) Tender Document No._____dated._____
   (b) Amendment/ Corrigendum (if any)
   (c) This Contract Agreement
   (d) Technical Requirements (including Functional Requirements and Implementation Schedule)
   (e) The Supplier's bid and original Price Schedules
   (f) The Schedule of Requirements
   (g) The Institution's Letter of Award (LOA)
   (h) Supply Order
   (i) [Specify: any other documents]

3. In consideration of the payments to be made by the Institution to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Institution to provide the Goods/ stores and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

The Institution hereby covenants to pay the Supplier in consideration of the provision of the Goods/ stores and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the contract.

Sl NO.	**BRIEF DESCRIPTION OF GOODS/ STORES**	**UNIT PRICE**	**DELIVERY TERMS**

DELIVERY SCHEDULE:

WITNESS WHEREOF the parties hereto have signed the Agreement the day and the year first above written.

For and on behalf of the Supplier

Signature of the authorized official
Name of the official
Stamp/Seal of the Supplier

By the said_____
Name on behalf of the Supplier
in the presence of :

Witness_____
Name_____
Address _____

_____
_____
Contact No._____

For and on behalf of the Institution

Signature of the authorized Officer
Name of the Officer
Stamp/Seal of the Institution

By the said _____
Name on behalf of the Institution
in the presence of :

Witness_____
Name_____
Address_____

_____
_____
Contact No._____

BANK GUARANTEE FORM
FOR PERFORMANCE SECURITY

To,

Indian Pharmacopoeia Commission (IPC),
Sec-23, Raj Nagar,
Ghaziabad- 201002
Uttar Pradesh

WHEREAS_____(Name and address of the Bidder/ Supplier) (Hereinafter called "the supplier") has undertaken, in pursuance of Tender/ Contract No._____dated____to supply (description of goods and services) (herein after called "the contract").

AND WHEREAS it has been stipulated by you in the said contract that the supplier shall furnish you with a bank guarantee by a scheduled commercial bank recognized by you for the sum specified therein as security for compliance with its obligations in accordance with the contract;

AND WHEREAS we have agreed to give the supplier such a bank guarantee;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you, on behalf of the supplier, up to a total of_____(Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the supplier to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the supplier before presenting us with the demand.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the supplier shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

This guarantee shall be valid up to_____months from the date of Notification of Award i.e up to ---- - (indicate date)

……
(Signature with date of the authorized officer of the Bank)
……
Name and designation of the officer
……
……
Seal, name & address of the Bank and address of the Branch

PROVISIONAL RECEIPT CERTIFICATE

Received intact the entire material in full and good condition and the goods/ stores have been taken into account entering in the stock register. The details are certified as under;

The following stores (s) has/have been received in good condition:

1) Contract No. & date : _____

2) Supplier's Name : _____

3) Name of Item supplied : _____

4) Quantity Supplied : _____

5) Date of Receipt by the Consignee : _____

6) Name and designation of IPC Officials : _____

7) Signature of IPC Officials with date : _____

8) Seal of Institution : _____

PERFORMA -VI

FINAL ACCEPTANCE CERTIFICATE (FAC)

1. IPC Order No. and date : _____

2. Name of Supplier : _____

3. Name of the item received in full and good condition (in units) with details as under

Item	Quantity	Quality

SEAL & SIGNATURE OF
IPC OFFICIAL

Proforma As per DoP Order No. 31026/36/2016-MD, Dated. 18th May, 2018 for reference only

Enclosure-II

Format for Affidavit of Self Certification regarding Local Content in a Medical Device to be provided on Rs. 100/- Stamp Paper

Date:_____

I_____ **S/o,D/o,W/o**_____, Resident of

_____

do hereby solemnly affirm and declare as under:

That I will agree to abide by the terms and conditions of the policy of Government of India issued vide Notification No:

That the information furnished hereinafter is correct to best of my knowledge and belief and I undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content.

That the local content for all inputs which constitute the said medical device has been verified by me and I am responsible for the correctness of the claims made therein.

That in the event of the domestic value addition of the product mentioned herein is found to be incorrect and not meeting the prescribed value-addition norms, based on the assessment of an authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content, action will be taken against me as per Order No. P-45021/2/2017-B.E.-II dated 15.06.2017 and Guidelines issued vide letter no. 31026/36/2016-MD dated 18.05.2018.

I agree to maintain the following information in the Company's record for a period of 8 years and shall make this available for verification to any statutory authority:

i) Name and details of the Domestic Manufacturer (Registered Office, Manufacturing unit location, nature of legal entity)
ii) Date on which this certificate is issued
iii) Medical devices for which the certificate is produced
iv) Procuring entity to whom the certificate is furnished
v) Percentage of local content claimed
vi) Name and contact details of the unit of the manufacturer
vii) Sale Price of the product
viii) Ex-Factory Price of the product
ix) Freight, insurance and handling
x) Total Bill of Material
xi) List and total cost value of inputs used for manufacture of the medical device
xii) List and total cost of inputs which are domestically sourced. Value addition certificates from suppliers, if the input is not in- house to be attached.
xiii) List and cost of inputs which are imported, directly or indirectly

For and on behalf of **(Name of firm/entity)**

Authorized signatory (To be duly authorized by the Board of Director)

SECTION-IX

QUICK CHECKLIST GUIDE

Note: Except Demand Drafts, each & every document must be numbered, starting with Page No. 62. The document should be in sequence as listed below and writes their Page Numbers in respective column.

Sr. No.	Particulars	Please Specify (Yes/ No)	Page No. in Bidding Documents
1.	Enclosed EMD Demand Draft for **Rs._____/- (Rupees: _____)** DD No. Date: Drawn on Bank:		**N/A**
2.	**OR** **If claimed exemption for MSE/ Startup,** **(i) Attached latest Udyog Aadhaar Memorandum (UAM)/ Startup Certificate and** **(ii) Attached Bid Security Declaration Form (Annexure- G)**		**N/A**
3.	Enclosed Power of Attorney/Authorization Letter in favour of Tender signing person		
4.	**Duly Filled & Annexed "SECTION VI Technical / Commercial Bids" containing Sub-sections A,B,C,D & E etc.**		
5.	Enclosed copy of Certificate of Registration/Incorporation.		
6.	Enclosed copy of GST Certificate		
7.	Enclosed copy of PAN Card		
8.	Enclosed copy of latest NSIC/ Udyog Aadhaar Memorandum (UAM)/ Startup Certificate (if any)		
9.	Enclosed Annual Turnover Report/ Balance Sheet/ Profit & Loss Statement of the firm, duly **certified by Chartered Accountant** for last 03 years **(F.Y 2019-20, 2020-21 & 2021-22)**		
10.	**A brief profile of the firm mentioning various sub-headings in line of Sub-Section B of Section- VI**		
11.	Enclosed Relevant Experience supporting documents (such as PO copies with proof of delivery/ acceptance/ payment receipt etc. against respective PO)		

12.	Enclosed **Manufacturing License/ Approval Document including undertaking** for Offered impurities (If Applicable)		
13.	**Have you submitted requisite Affidavit on Rs. 100/- Stamp Paper for Local Content (Annexure-F) under Preference to "MAKE IN INDIA" Policy,** for quoted impurities.		
14.	Enclosed CoA/ Drafted CoA documents for Quoted Impurities		
15.	Enclosed Requisite Quality Assurance Certificates (valid ISO 9001/ ISO 17025)		
16.	Annexed duly filled **Annexure-A (Integrity Pact)**		
17.	**Annexure- B & C on Company Letter Head**		
18.	**Annexed duly Signed & Stamped Copy of Buyer Tender Document**		
19.	**Have you signed & stamped each/every enclosed documents, certificate etc.**		