



# **TENDER DOCUMENT FOR**

**Supply of “PHARMACEUTICAL IMPURITIES”  
at IPC, Ghaziabad**

**TENDER NO. IPC/5533/2022-23,  
DATED: 16.11.2022**

**Bid Submission Last Date: 09<sup>th</sup> Dec. 2022, till 11:00 Hrs.  
Technical Bid Opening Date: 09<sup>th</sup> Dec. 2022, 11:30 Hrs.**

## **INDIAN PHARMACOPOEIA COMMISSION**

**MINISTRY OF HEALTH & FAMILY WELFARE**

**GOVERNMENT OF INDIA**

**SECTOR 23, RAJ NAGAR, GHAZIABAD-201002**

**TEL NO: 0120-2783392, 2783400, 2800500**

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# SECTION-I

## NOTICE INVITING TENDER (NIT)

No. IPC/5533/2022-23

Dated: 18.11.2022

**Sub: Supply of “PHARMACEUTICAL IMPURITIES” at IPC, Ghaziabad**

Indian Pharmacopoeia Commission (IPC), under 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 16<sup>th</sup> September 2020). Participating bidders need to submit 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	Cost of Tender Form (Non-Refundable)
1.	Supply of “PHARMACEUTICAL IMPURITIES” at IPC	60 Days	(i) 560/- each (upto 24 Nos.)  (ii) If quoting for 25 Nos. or more than Rs. 14,000/-

### Earnest Money Deposit (EMD) Details

Sl. No.	Items	Quantity	Amount of EMD(in Rs.)
1	Supply of “PHARMACEUTICAL IMPURITIES” at IPC	10 Gms for Each Impurity  AND 200 Gms. For Reference Standard API	5,000/- for each Tender Item

- Refer Schedule of Requirement (SOR) for calculation of Total EMD Amount.
- 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. Tender Forms can be downloaded from our website [www.ipc.gov.in](http://www.ipc.gov.in) only. Downloaded Tender document must be submitted with Demand Draft(s) as mentioned above, in favour of “**Indian Pharmacopoeia Commission**” payable at Ghaziabad.
2. Sealed tender duly super scripted can be submitted to the office of the Indian Pharmacopoeia Commission, Ghaziabad **through Post/ Courier also**, on or before the due date mentioned below. The tenders received before due date shall be opened on scheduled date of opening.
3. Indian Pharmacopoeia Commission (IPC), reserves the right to accept/ reject any or all tenders without assigning any reason whatsoever.

### **IMPORTANT DATES**

<b>PRE-BID MEETING DATE &amp; TIME</b>	<b>23<sup>rd</sup> Nov. 2022, 11:00 Hrs.</b>
<b>LAST DATE FOR DOWNLOADING TENDER FORM</b>	<b>08<sup>th</sup> Dec. 2022 (Upto 17:00 Hrs)</b>
<b>LAST DATE FOR SUBMISSION OF TENDERS</b>	<b>09<sup>th</sup> Dec. 2022, till 11:00 Hrs.</b>
<b>DATE OF OPENING OF TECHNICAL BIDS</b>	<b>09<sup>th</sup> Dec. 2022, 11:30 Hrs.</b>
<b><u>TENTATIVE DATE</u> OF OPENING OF PRICE BIDS</b>	<b>WILL BE INTIMATED LATER TO THE TECHNICALLY QUALIFIED/ RESPONSIVE TENDERERS</b>
<b><u>Venue</u></b>	<b>INDIAN PHAMACOPOEIA COMMISSION, MINISTRY OF HEALTH &amp; FAMILY WELFARE, GOVERNMENT OF INDIA SECTOR 23, RAJ NAGAR, GHAZIABAD-201002</b>

## SECTION-II

### SCHEDULE OF REQUIREMENT (SOR) & EMD Workout Sheet

**#RC stands for Reference Compound**

#### LIST OF REQUIRED API FOR PREPARATION OF REFERENCE SUBSTANCES

<u>Tender Schedule No.</u>	<u>Monographs</u>	<u>Impurities IPRS used for SST preparation</u>	<u>IUPAC Names</u>	<u>Purity Greater than &amp; equal to</u>	<u>Qty. (Gram)</u>	<u>EMD Amount (Rs.)</u>	<u>Specify EMD Furnished (YES/N.A)</u>
1.	Ibuprofen Tablets	Ibuprofen RC-A	Ibuprofen RC-A: (2RS)-2-[3-(2-methylpropyl)phenyl]propanoic acid,	90%	10	5,000/-	
2.	Ibuprofen Tablets	Ibuprofen RC-B	Ibuprofen RC-B: (2RS)-2-(4-butylphenyl)propanoic acid,	90%	10	5,000/-	
3.	Ibuprofen Tablets	Ibuprofen RC-E	Ibuprofen RC-E: 1-[4-(2-methylpropyl)phenyl]ethanone,	90%	10	5,000/-	
4.	Ibuprofen Tablets	Ibuprofen RC-J	Ibuprofen RC-J: (2RS)-2-[4-(2-methylpropanoyl)phenyl]propanoic acid,	90%	10	5,000/-	
5.	Ibuprofen Tablets	Ibuprofen RC-N	Ibuprofen RC-N: (2RS)-2-(4-ethylphenyl)propanoic acid,	90%	10	5,000/-	
6.	Phenylephrine Hydrochloride	Norphenylephrine	Norphenylephrine: 3-(2-Amino-1-hydroxyethyl)phenol hydrochloride.	90%	10	5,000/-	
7.	Phenylephrine Hydrochloride	Phenylephrine RC-C	Phenylephrine RC-C: 1-(3-Hydroxyphenyl)-2-(methylamino)ethan-1-one hydrochloride.	90%	10	5,000/-	
8.	Phenylephrine Hydrochloride	Phenylephrine RC-D	Phenylephrine RC-D: 1-(3-[Benzyl(methyl)amino]-1-hydroxyethyl)phenol	90%	10	5,000/-	
9.	Phenylephrine Hydrochloride	Phenylephrine RC-E	Phenylephrine RC-E: 2-[Benzyl(methyl)amino]-1-(3-hydroxyphenyl)ethan- 1-one hydrochloride	90%	10	5,000/-	
10.	Phenylephrine Hydrochloride	Phenylephrine RC-F	Phenylephrine RC-F: R)-2-Methyl-1,2,3,4-tetrahydroisoquinoline-4,8-diol hydrochloride monohydrate.	90%	10	5,000/-	
11.	Chlorpheniramine Maleate	Chlorpheniramine RC-B	Chlorpheniramine RC-B : Di(2-ylidene-2-yl)amine	90%	10	5,000/-	
12.	Chlorpheniramine Maleate	Chlorpheniramine RC-C	Chlorpheniramine RC-C : 3-(4-Chlorophenyl)-N-methyl-3-(2-ylidene-2-yl)propan-1-amine maleate	90%	10	5,000/-	
13.	Metronidazole Injection	Tinidazole related compound A	Tinidazole related compound A: 2-Methyl-5-nitroimidazole.	90%	10	5,000/-	
14.	Promethazine hydrochloride API	Promethazine related compound B	Promethazine related compound B: Isopromethazine hydrochloride; N,N-Dimethyl-2-(10H-phenothiazin-10-yl)propan-1-amine hydrochloride.	90%	10	5,000/-	

15.	Linezolid	linezolid RC- D	linezolid RC- D: I-[3-(3-Fluoro-4-morpholinophenyl)-2-oxooxazolidin-5-yl)methylmethanesulfonate	90%	10	5,000/-	
16.	Linezolid	linezolid R-isomer	linezolid R-isomer: <i>N</i> -{[1-3-(3-Fluoro-4-morpholinophenyl)-2-oxo-5-oxazolidinyl)methyl]acetamide.	90%	10	5,000/-	
17.	Sildenafil Citrate	Sildenafil RC- A	Sildenafil RC- A: -[2-Ethoxy-5-[(4-methylpiperazin-1-yl)sulfonyl]phenyl]-1-methyl-3-(2-methylpropyl)-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one; Also known as 1-[[3-(6,7-Dihydro-1-methyl-7-oxo-3-isobutyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine	90%	10	5,000/-	
18.	Mometasone Furoate	Imp. C	IMP. C: 21-chloro-16 $\alpha$ -methyl-3,11,20-trioxopregna-1,4-dien-17-yl furan-2-carboxylate.	90%	10	5,000/-	
19.	Mometasone Furoate	Imp J	IMP. J: 9,21-dichloro-11 $\beta$ -hydroxy-6 $\alpha$ ,16 $\alpha$ -dimethyl-3,20-dioxopregna-1,4-dien-17-yl furan-2-carboxylate.	90%	10	5,000/-	
20.	Miconazole Nitrate (03)	Miconazole RC F	Miconazole RC- F: 1-{2-[(3,4-Dichlorobenzyl)oxy]-2-(2,4-dichlorophenyl)ethyl}-1H-imidazole.	90%	10	5,000/-	
21.	Miconazole Nitrate (03)	Miconazole RC I	Miconazole RC- I: 1-{2-[(2-Chlorobenzyl)oxy]-2-(2,4-dichlorophenyl)ethyl}-1H-imidazole mononitrate.	90%	10	5,000/-	
22.	Miconazole Nitrate (03)	Miconazole RC C	Miconazole RC- C: 2-[(2,4-Dichlorobenzyl)oxy]-2-(2,4-dichlorophenyl)ethan-1-amine hydrochloride.	90%	10	5,000/-	
23.	Ursodeoxycholic Acid	Impurity A	Impurity A: 3 $\alpha$ ,7 $\alpha$ -dihydroxy-5 $\beta$ -cholan-24-oic acid (chenodeoxycholic acid),	90%	10	5,000/-	
24.	Ursodeoxycholic Acid	Impurity H	Impurity H: 3 $\beta$ ,7 $\beta$ -dihydroxy-5 $\beta$ -cholan-24-oic acid	90%	10	5,000/-	
25.	Ursodeoxycholic Acid	Impurity C	Impurity C: Lithocholic acid	90%	10	5,000/-	
26.	Fluconazole	Fluconazole RC- A	Fluconazole RC- A: 2-[2-Fluoro-4-(1H-1,2,4-triazol-1-yl)phenyl]-1,3-bis(1H-1,2,4-triazol-1-yl)-propan-2-ol.	90%	10	5,000/-	
27.	Fluconazole	Fluconazole RC- B	Fluconazole RC- B: 2-(4-Fluorophenyl)-1,3-di(1H-1,2,4-triazol-1-yl)-propan-2-ol.	90%	10	5,000/-	
28.	Fluconazole	Fluconazole RC- C	Fluconazole RC- C: 1,1'-(1,3-Phenylene)di(1H-1,2,4-triazole).	90%	10	5,000/-	
29.	Propranolol HCl / Propranolol Injection/ Tablets	Propranolol imp. A	Propranolol imp. A: (2RS)-3-[(4-yridine4ne-1-yl)oxy]propane-1,2-diol,	90%	10	5,000/-	

30.	Propranolol HCl / Propranolol Injection/ Tablets	Propranolol imp. B	Propranolol imp. B: 1,1'-[(propan-2-yl)azanediyl]bis[(2E)-3-[[4-yridine4ne-1-yl]oxy]propan-2-ol,	90%	10	5,000/-	
31.	Propranolol HCl / Propranolol Injection/ Tablets	Propranolol imp. C	Propranolol imp. C: 1,3-bis[(4-yridine4ne-1-yl)oxy]propan-2-ol.	90%	10	5,000/-	
32.	Dicyclomine HCl	Dicyclomine RC-A	Dicyclomine RC-A: [1,1'-Bi(cyclohexane)]-1-carboxylic acid	90%	10	5,000/-	
33.	Amiodarone HCl	Amiodarone RC-D	Amiodarone RC-D: (2-butylbenzofuran-3-yl)(4-hydroxy-3,5-diiodophenyl) methanone.	90%	10	5,000/-	
34.	Amiodarone HCl	Amiodarone RC-E	Amiodarone RC-E: (2-butylbenzofuran-3-yl)(4-hydroxyphenyl) methanone.	90%	10	5,000/-	
35.	Amiodarone HCl	Amiodarone IMP.-H	Amiodarone IMP.-H : (2-chloroethyl) diethylamine hydrochloride.	90%	10	5,000/-	
36.	Sulphamethoxazole	sulfamethoxazole RC-A	sulfamethoxazole RC-A: N-{4-[N-(5-Methylisoxazol-3-yl)sulfamoyl]phenyl}acetamide.	90%	10	5,000/-	
37.	Sulphamethoxazole	sulfamethoxazole RC-B	Sulfamethoxazole RC-B: 4-Amino-N-{4-[N-(5-methylisoxazol-3-yl)sulfamoyl]phenyl}benzenesulfonamide.	90%	10	5,000/-	
38.	Sulphamethoxazole	sulfamethoxazole RC-C	Sulfamethoxazole RC-C: 5-Methylisoxazol-3-amine.	90%	10	5,000/-	
39.	Sulphamethoxazole	sulfamethoxazole RC-F	Sulfamethoxazole RC-F: 4-Amino-N-(3-methylisoxazol-5-yl)benzenesulfonamide.	90%	10	5,000/-	
40.	Sulphamethoxazole	Sulfanilic acid	Sulfanilic acid: 4-Aminobenzenesulfonamide	90%	10	5,000/-	
41.	Sulphamethoxazole	Sulfanilamide	Sulfanilamide: 4-Aminobenzenesulfonic acid.	90%	10	5,000/-	
42.	Piroxicam	Piroxicam RC-A	Piroxicam RC-A: Pyridin-2-amine	90%	10	5,000/-	
43.	Piroxicam	Piroxicam RC-B	Piroxicam RC-B: 4-Hydroxy-N-(6-yridine-2-yl)-2H-benzothiazine-3-carboxamide 1,1-dioxide.	90%	10	5,000/-	
44.	Piroxicam	Piroxicam RC-D	Piroxicam RC-D: Methyl 2-[1,1-dioxido-3-oxobenzisothiazol-2(3H)-yl]acetate.	90%	10	5,000/-	
45.	Piroxicam	Piroxicam RC-G	Piroxicam RC-G: Methyl 4-hydroxy-2H-benzothiazine-3-carboxylate 1,1-dioxide monohydrate.	90%	10	5,000/-	
46.	Piroxicam	Piroxicam RC-J	Piroxicam RC-J: Methyl 4-hydroxy-2-methyl-2H-benzothiazine-3-carboxylate 1,1-dioxide.	90%	10	5,000/-	
47.	Ketokonazole	Terconazole	Terconazole: Piperazine, 1-[4-[[2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl)methyl]-1,3-dioxolan-4-yl]methoxy]phenyl]-4-(1-methylethyl)-, cis-;cis-1-(p-{[2-(2,4-Dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl)methyl]-1,3-dioxolan-4-yl]methoxy}phenyl)-4-isopropylpiperazine.	90%	10	5,000/-	

48.	Duloxetine HCl	Impurity F	Impurity F: ((3S)-N-methyl-3-(naphthalene-1-yloxy)-3-(thiophene-3-yl) propane- 1 – amine.	90%	10	5,000/-	
49.	Frusemide	Frusemide imp. A	Frusemide imp. A: 2-Chloro-4-N-furfurylamino-5-sulfamoylbenzoic acid	90%	10	5,000/-	
50.	Frusemide	Frusemide imp. B	Frusemide imp. B: 4-Chloro-5-sulfamoylanthranilic acid.	90%	10	5,000/-	
51.	Bisacodyl	Impurity D	sodium (pyridin-2-ylmethylene)bis(4,1-phenylene) bis(sulfate)	90%	10	5,000/-	
52.	Ceftriaxone	E-Isomer	-	90%	10	5,000/-	
53.	Dolutegravir Sodium	Dolutegravir 4- fluoro impurity	(4R,12aS)-N-(4-Fluorobenzyl)-7-hydroxy-4- methyl-6,8-dioxo- 3,4,6,8,12,12a-hexahydro- 2H- pyrido [1',2':4,5] pyrazino[2,1-b] [1,3] oxazine- 9- carboxamide	90%	10	5,000/-	
54.	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	5,000/-	
55.	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	5,000/-	
56.	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	5,000/-	
57.	Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets	dolutegravir impurity E	(4R,12aS)-N-[(4-Fluorophenyl)methyl]-7- hydroxy-4-methyl-6,8-dioxo- 3,4,6,8,12,12a-hexahydro-2H- pyrido[1',2':4,5]pyrazino-[2,1-b][1,3]oxazine-9- carboxamide	90%	10	5,000/-	
58.	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-Oxo- 2,4,6,8-tetraoxa-5- λ5-phosphanonedioate	90%	10	5,000/-	
59.	Haloperidol	Bromperidol	4-(4-(4-bromophenyl)-4- hydroxypiperidin-1-yl) -1-(4-fluorophenyl)butan-1-one	90%	10	5,000/-	
60.	Hydrocortisone acetate	Cortisone acetate	17-hydroxy-3,11,20-trioxopregn- 4-ene-21-ylacetate	90%	10	5,000/-	
61.	Lactulose	Lactulose Impurity A	Epilactose	90%	10	5,000/-	



62.	Lactulose	Lactulose Impurity B	Galactose	90%	10	5,000/-	
63.	Lactulose	Lactulose impurity C	Lactose	90%	10	5,000/-	
64.	Lactulose	Lactulose impurity D	Fructose	90%	10	5,000/-	
65.	Lactulose	Lactulose impurity E	Tagatose	90%	10	5,000/-	
66.	Levocetirizine Hydrochloride	Piperazine RS	Piperazine RS	90%	10	5,000/-	
67.	Luliconazole Luliconazole Cream Luliconazole Lotion	Luliconazole S-E	RS((2E)-[(4S)-4-(2,4-dichlorophenyl)-1,3-dithiolan-2-ylidene](1H-imidazol-1-yl)ethanenitrile)	90%	10	5,000/-	
68.	Luliconazole Luliconazole Cream Luliconazole Lotion	Luliconazole Z formRS	((2Z)-[4-(2,4-dichlorophenyl)-1,3-dithiolan-2-ylidene](1H-imidazol-1-yl)ethanenitrile)	90%	10	5,000/-	
69.	Mefenamic acid	Mefenamic acid impurity C	2-Chlorobenzoic acid	90%	10	5,000/-	
70.	Metformin HCl	Melamine	1,3,5-triazine-2,4,6-triamine	90%	10	5,000/-	
71.	Metronidazole Benzoate	Impurity A	1-(2-hydroxyethyl)-2-methyl-5-nitroimidazole	90%	10	5,000/-	
72.	Naproxen	Racemic Naproxen	Racemic Naproxen	90%	10	5,000/-	
73.	Propofol	Impurity J	2,6-bis(1-methylethyl)benzene-1,4-dione	90%	10	5,000/-	
74.	Propofol	Impurity E (dimer)	3,3',5,5'-tetrakis(1-methylethyl)biphenyl-4,4'-diol	90%	10	5,000/-	
75.	Propofol	Impurity G	2-(1-methylethoxy)-1,3-bis(1-methylethyl)benzene	90%	10	5,000/-	
76.	Simvastatin	Impurity F	(1S,3R,7S,8S,8aR)-8-[2[(2R,4R)-4-hydroxy-6-oxo-tetrahydro-2H-pyran-2-yl]ethyl]-3,7-dimethyl-1,2,3,7,8,8a-hexahydronaphthalen-1-yl(2R)-2-methylbutanoate	90%	10	5,000/-	
77.	Sulbactam Sodium	Sulbactam related substance A	(2S)-2-Amino-3-methyl-3-sulfino-butanoic acid	90%	10	5,000/-	
78.	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	5,000/-	
79.	Terazosin HCl	Impurity B	1-(4-hydroxy-6,7-dimethoxyquinazolin-2-yl)-4-[[[(2RS)-tetrahydrofuran-2-yl]carbonyl]piperazine	90%	10	5,000/-	
80.	Terazosin HCl	Impurity N	1-[[[(2RS)-tetrahydrofuran-2-yl]carbonyl]piperazine	90%	10	5,000/-	
81.	Testosterone propionate	Testosterone acetate	Testosterone acetate	90%	10	5,000/-	
82.	Thyroxine Sodium Thyroxine Tablets	Liothyronine Sodium RS	Liothyronine Sodium RS	90%	10	5,000/-	
83.	Tigecycline Tigecycline Injection	Tigecycline impurity B	9-Aminomincycline	90%	10	5,000/-	
84.	Tolnaftate	Impurity D	N,3-dimethylaniline(N-methyl-m-toluidine)	90%	10	5,000/-	
85.	Topiramate	Impurity A	2,3,4,5-Bis-o-(1-methylethylidene)-beta-D-fructopyranose	90%	10	5,000/-	

86.	Montelukast	Montelukast Styrene	2-[1-[[[(1R)-1-[3-[(E)-2-(7-chloroquinolin-2-yl)ethenyl]phenyl]-3-(2-prop-1-en-2-ylphenyl)propyl]sulfanyl methyl]cyclopropyl]acetic acid	90%	10	5,000/-	
87.	Buprenorphine HCl API/ Injection	Imp.-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	5,000/-	
88.	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	5,000/-	
89.	Buprenorphine HCl API/ Injection	Imp.-F	Imp.-F: 17-(cyclopropylmethyl)-4,5α-epoxy-6-methoxy-7α-[1-(1,1-dimethylethyl)ethenyl]-6α,14-ethano-14α-morphinan-3-ol,	90%	10	5,000/-	
90.	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	5,000/-	
91.	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	5,000/-	
92.	Buprenorphine HCl API/ Injection	Imp.-J	Imp.-J: (2S)-2-[17-(cyclopropylmethyl)-4,5α-epoxy-3-hydroxy-6-methoxy-6α,14-ethano-14α-morphinan-7α-yl]-3,3-dimethylbutan-2-ol.	90%	10	5,000/-	
93.	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	5,000/-	
94.	Cefpodoxime Proxetil	S-epimer	S-epimer	90%	10	5,000/-	
95.	Cefpodoxime Proxetil	R-epimer	R-epimer	90%	10	5,000/-	
96.	Cefuroxime Axetil	Diastereoisomer A	Diastereoisomer A	90%	10	5,000/-	
97.	Cefuroxime Axetil	Diastereoisomer B	Diastereoisomer B	90%	10	5,000/-	
98.	Mupirocin	Impurity C /pseudomonic acid D	pseudomonic acid	90%	10	5,000/-	
99.	Mupirocin	Impurity D	9-[[[(2E)-4-[(2R,3aS,6S,7S)-2-[(2S,3S)-1,3-dihydroxy-2-methylbutyl]-7-hydroxyhexahydro-4H-furo[3,2-c]pyran-6-yl]-3-methylbut-2-enoyl]oxy]nonanoic acid	90%	10	5,000/-	
100.	Mupirocin	Impurity E	9-[[[(2E)-4-R2R,3RS,4aS,7S,8S,8aR)-3,8-dihydroxy-2-[(1S,2S)-2-hydroxy-1-methylpropyl]hexahydro-2H,5H-pyrano[4,3-b]pyran-7-yl]-3-methylbut-2-enoyl]oxy]nonanoic acid	90%	10	5,000/-	
101.	Methylergometrine Maleate	Impurity B	(6aR,9S)-7-methyl-4,6,6a,7,8,9-hexahydroindolo[4.3-fg]quinoline-9-carboxylic acid	90%	10	5,000/-	

102.	Methylephedrine Maleate	Impurity C	6aR,9R)-7-meth y l-4,6,6a ,7,8,9-hexahydroindolo[4,3-fg]quinoline-9-carboxamide	90%	10	5,000/-	
103.	Methylephedrine Maleate	Impurity D	ergometrine	90%	10	5,000/-	
104.	Methylephedrine Maleate	Impurity E	(6aR,9S)-7-meth y l-4,6,6a ,7,8,9-hexahydroindolo[4,3 fg]quinoline-9-carboxiimide	90%	10	5,000/-	
105.	Methylephedrine Maleate	Impurity F/Ergometrine	Ergometrine	90%	10	5,000/-	
106.	Methylephedrine Maleate	Impurity G/Methylephedrine	Methylephedrine	90%	10	5,000/-	
107.	Methylephedrine Maleate	Impurity H/Methyl ergometrine	Methyl ergometrine	90%	10	5,000/-	
108.	Methylephedrine Maleate	Impurity I	1¢-epi-methylephedrine,	90%	10	5,000/-	
109.	Levonorgestrel	Dexronorgestrel	Dexronorgestrel	90%	10	5,000/-	
Tender Schedule No.	Name of Product	Name of Candidate Material for Reference Standards	<u>IUPAC Names</u>	Purity is NLT- % w/w	Qty. (Gram )	EMD Amount (Rs.)	Specify EMD Furnished (YES/N.A)
110.	Prednisone API for IPRS development	Prednisone API	-	99%	200 Gms	5,000/-	
Specify Total Nos. of Tender Items for which, Offer/ Quote have been provided							
Total EMD Amount Calculated (Rs.) i.e. Total Nos. of Offered Tender Item X 5,000/-							

**Total EMD Amount in Words** \_\_\_\_\_

- The bidders are advised to quote preferably for all tendered items/ impurities. However, they are not bound to quote for all items/ impurities.
- 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).
- In case any Bidder has not offered/ quoted price for any Tendered item, such impurity row must be strikeout completely and mentioned as “Not Applicable”
- BID Security/ Earnest Money Deposit (EMD)**
  - The value of Earnest Money (BID SECURITY) to be deposited by the bidder must be obtained according to total Numbers of Tender Items, for which bidders have submitted their offer in Technical & Price Bid. Failing which, their bids would be rejected straightaway.
  - A Demand Draft towards total Earnest Money Deposit, 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.

## **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 IPC Website 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 at the Commission 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.
6.
  - a) Pre Bid Meeting date & time : **23<sup>rd</sup> Nov. 2022, 11:00 Hrs.**
  - b) The last date & time for downloading tender forms : **08<sup>th</sup> Dec. 2022, (Upto 17:00 Hrs).**
  - c) The last date and time for submission of tenders is : **09<sup>th</sup> Dec. 2022, till 11:00 Hrs.**
  - d) The date and time of Opening of Technical Bids is : **09<sup>th</sup> Dec. 2022, 11:30 Hrs.**
  - e) The date and time of Opening of Price Bids is : **would be intimated later**
7. This is a **TWO BID** system comprising of:  
  

<b>(a) Technical Bid</b>	<b>(b) Price Bid</b>
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8. The bidders are advised to quote preferably for all tendered impurities. However, the bidders are not bound to quote for all items/ 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 non-returnable Demand Draft should be accompanied toward cost of tender form in favour of “**Indian Pharmacopoeia Commission**”, and payable at **Ghaziabad** **(As specified on Page No. 03)**. The amount would not be refunded in any case.

- (ii) A Demand Draft towards Earnest Money Deposit, drawn in favor of **“Indian Pharmacopoeia Commission”**, and payable at **Ghaziabad** (As specified on Page No. 11), 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 (MSME/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.

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.
13. **The technical & financial bids shall be kept in separate sealed covers super-scribed as “Technical Bid” and “Price Bid” on the respective covers in order to clearly identify between the two bids. These two separately sealed and super scribed Bids must be kept/ placed in a bigger cover, which should also be sealed and duly super scribed with the respective Tender details & Number.**
14. **The Agency/Firm details along with contact details & e-mail ID shall be clearly written on each covers.**
15. **The bids should be completed in all respect and must be addressed to Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector-23, Raj Nagar, Ghaziabad-201002. The filled Tenders/ Bids must reach us on or before the due date and time mentioned in the Tenders Notification thru Post/ Courier also. IPC shall not be responsible for the delay, if any in the delivery of the bidding documents or non-receipt of the same.**
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 excluding of GST** i.e. 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. **Bids received after the closing date and time for bid submission will not be accepted/ considered. In case the date mentioned above is declared subsequently, as holiday for the office, the due date for submission and opening of bids will be the next working day at the same venue and time.**

19. **At first stage**, the Technical Bids shall be opened at stipulated date & Time, in presence of Bidder or their Authorized Representative, who chooses to be present. The Technical Bids shall be scrutinized/ evaluated with respect to parameters prescribed in bid documents or at the discretion of competent authority at IPC.

**Technical bid openings will be held remotely via Video Conferencing facility. The link for same will be shared thru IPC Website. Bidders may choose to attend the bid opening thru then shared link.**

In case of any clarifications is required during evaluation of bids, wherever necessary, IPC will convey its finding/ observation to the bidder thru e-mails 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 at issue 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.

**Price Bid Opening will also be held remotely via Video Conferencing facility in presence of Technically Qualified Bidders Only, who choose to attend. The Video Conferencing link for same would be shared at their registered e-mail ID.**

21. **Bids comparison/ evaluation will be done on basis of All inclusive Total Price (excluding GST) of an individual tendered item/ impurity wise 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 followed by enclosing Supply Order.

24. **Performance Security:** Successful bidder shall also furnish **Performance Security i.e. Security Deposit equivalent to 3.0% of the contract/ order value within 15 days from the date of Supply Order** in form of **demand draft/ Bank Guarantees** in favor of “Indian Pharmacopoeia Commission” and **payable at Ghaziabad that shall remain Valid for 20 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. **Procedure for Calculating Local Content under Preference to “MAKE IN INDIA” Policy would remain same as mentioned in clause 6 of the order from Dept. of Pharmaceuticals provided in ANNEXURE -E.**
30. **An affidavit of Self Certification regarding Local Content claim 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** MSME 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 MSME, 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 MSME 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 DIPP) 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 15<sup>th</sup> 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.** IPC reserve the right to cancel the tendering process at any time before award of Supply Order without assigning any reason thereof.
- 41.** 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.
- 42.** 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 Impurities to B.P, U.S.P, I.P, Any Pharmaceutical Government Organization or Any Pharmaceutical Private Organization **during last Seven years** ending on **31.03.2022** 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 Manufacturer/ Original Impurity Producer etc.
- 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 Impurities:-**

- 2.1 **Impurity Purity/ Potency should be greater than and 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.

## 2.4 Purity/Potency Variation Criteria for the Supplied Impurities:-

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

It is to ensured by bidder that the purity/ potency of supplied impurity should not be lesser than (2%) Two Percentage, compared to the purity/ potency quoted in their technical bid.

**For Example-** If an Impurity is quoted with purity 95% for the purpose of system suitability in bidder offer against its supporting CoA/ Drafted CoA Document. Then only (2%) Two percentage of downside deviation/ variation i.e. 1.9% is acceptable for supplied impurity. In this case, Impurity of purity found lesser than 93.10% would be liable for rejection at the discretion of competent authority. The decision of Competent Authority would be final and binding.

## 2.5 Shelf Life of all Impurities:-

- (i) It is recommended that the stability/ Shelf Life of 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 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 10 GMS impurity, which would once again be subjected to its acceptance after In-house Testing & Acceptance at IP Commission.

## **SECTION-V**

### **OTHER TERMS & CONDITIONS (OTC):**

1. **PRICES:** Prices quoted should be “Firm & Final” all other applicable charges (i.e. 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 resupply.

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 Impurities thru their authorized Representative with Stamp on their own expenses. **Rejected Impurities/ reference Standards 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 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/ Impurities 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

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

**B. A BRIEF PROFILE OF THE FIRM ON COMPANY LETTER HEAD 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 Ration/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
- (viii)** List of impurities 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** to B.P, U.S.P, I.P, Any Pharmaceutical Government Organization or Any Pharmaceutical Private Organization during **last seven years** ending on **31.03.2022 (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 Impurity/ Reference Standards)	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 & REFERENCE	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 be  $\geq 90\%$ / Candidate Material for Reference Standards NLT 99% w/w
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:-

Ibuprofen Tablets Ibuprofen RC-A	-----NO OFFER-----
-------------------------------------	--------------------

Tender Sch. No.	Name of Monograph/ Impurity Name	Manufactured in India  (Yes/No)	Enclosed Manufacturer License/ Approval Document incl. Undertaking (Yes/ No)	Specify Percentage of Minimum Local Content (%)	Specify Purity/ Potency of Offered Impurity	Attached (CoA/ Drafted CoA)  (Yes/ No)	Specify Page Numbers of Attached Documents	Remark for Deviation (if any)
1.	Ibuprofen Tablets Ibuprofen RC-A							
2.	Ibuprofen Tablets Ibuprofen RC-B							
3.	Ibuprofen Tablets Ibuprofen RC-E							
4.	Ibuprofen Tablets Ibuprofen RC-J							
5.	Ibuprofen Tablets Ibuprofen RC-N							
6.	Phenylephrine Hydrochloride Norphenylephrine							
7.	Phenylephrine Hydrochloride Phenylephrine RC-C							
8.	Phenylephrine Hydrochloride Phenylephrine RC-D							
9.	Phenylephrine Hydrochloride Phenylephrine RC-E							
10.	Phenylephrine Hydrochloride Phenylephrine RC-F							
11.	Chlorpheniramine Maleate Chlorpheniramine RC-B							
12.	Chlorpheniramine Maleate Chlorpheniramine RC-C							
13.	Metronidazole Injection Tinidazole related compound A							
14.	Promethazine hydrochloride API Promethazine related compound B							
15.	Linezolid linezolid RC- D							
16.	Linezolid linezolid R-isomer							
17.	Sildenafil Citrate Sildenafil RC- A							

18.	Mometasone Furoate Imp. C							
19.	Mometasone Furoate Imp J							
20.	Miconazole Nitrate (03) Miconazole RC F							
21.	Miconazole Nitrate (03) Miconazole RC I							
22.	Miconazole Nitrate (03) Miconazole RC C							
23.	Ursodeoxycholic Acid Impurity A							
24.	Ursodeoxycholic Acid Impurity H							
25.	Ursodeoxycholic Acid Impurity C							
26.	Fluconazole Fluconazole RC- A							
27.	Fluconazole Fluconazole RC- B							
28.	Fluconazole Fluconazole RC- C							
29.	Propranolol HCl / Propranolol Injection/ Tablets Propranolol imp. A							
30.	Propranolol HCl / Propranolol Injection/ Tablets Propranolol imp. B							
31.	Propranolol HCl / Propranolol Injection/ Tablets Propranolol imp. C							
32.	Dicyclomine HCl Dicyclomine RC-A							
33.	Amiodarone HCl Amiodarone RC-D							
34.	Amiodarone HCl Amiodarone RC-E							
35.	Amiodarone HCl Amiodarone IMP.-H							
36.	Sulphamethoxazole sulfamethoxazole RC-A							
37.	Sulphamethoxazole sulfamethoxazole RC-B							
38.	Sulphamethoxazole sulfamethoxazole RC-C							
39.	Sulphamethoxazole sulfamethoxazole RC-F							
40.	Sulphamethoxazole Sulfanilic acid							
41.	Sulphamethoxazole Sulfanilamide							
42.	Piroxicam Piroxicam RC-A							
43.	Piroxicam Piroxicam RC-B							
44.	Piroxicam Piroxicam RC-D							
45.	Piroxicam Piroxicam RC-G							
46.	Piroxicam Piroxicam RC-J							
47.	Ketokonazole Terconazole							
48.	Duloxetine HCl Impurity F							
49.	Furosemide Furosemide imp. A							

50.	<b>Frusemide</b> Frusemide imp. B							
51.	<b>Bisacodyl</b> Impurity D							
52.	<b>Ceftriaxone</b> E-Isomer							
53.	<b>Dolutegravir Sodium</b> Dolutegravir 4- fluoro impurity							
54.	<b>Dolutegravir Sodium</b> isomer-1							
55.	<b>Dolutegravir Sodium</b> Enantiomer							
56.	<b>Dolutegravir Sodium</b> isomer-2							
57.	<b>Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets</b> dolutegravir impurity E							
58.	<b>Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets</b> tenofovir disoproxil impurity I							
59.	<b>Haloperidol</b> Bromperidol							
60.	<b>Hydrocortisone acetate</b> Cortisone acetate							
61.	<b>Lactulose</b> Lactulose Impurity A							
62.	<b>Lactulose</b> Lactulose Impurity B							
63.	<b>Lactulose</b> Lactulose impurity C							
64.	<b>Lactulose</b> Lactulose impurity D							
65.	<b>Lactulose</b> Lactulose impurity E							
66.	<b>Levocetirizine Hydrochloride</b> Piperazine RS							
67.	<b>Luliconazole Luliconazole Cream Luliconazole Lotion</b> Luliconazole S-E							
68.	<b>Luliconazole Luliconazole Cream Luliconazole Lotion</b> Luliconazole Z formRS							
69.	<b>Mefenamic acid</b> Mefenamic acid impurity C							
70.	<b>Metformin HCl</b> Melamine							
71.	<b>Metronidazole Benzoate</b> Impurity A							
72.	<b>Naproxen</b> Racemic Naproxen							
73.	<b>Propofol</b> Impurity J							
74.	<b>Propofol</b> Impurity E (dimer)							
75.	<b>Propofol</b> Impurity G							
76.	<b>Simvastatin</b> Impurity F							
77.	<b>Sulbactam Sodium</b> Sulbactam related substance A							
78.	<b>Tenoxicam Tenoxicam Tablets</b> Tenoxicam impurity G							
79.	<b>Terazosin HCl</b> Impurity B							

80.	Terazosin HCl Impurity N							
81.	Testosterone propionate Testosterone acetate							
82.	Thyroxine Sodium Thyroxine Tablets Liothyronine Sodium RS							
83.	Tigecycline Tigecycline Injection Tigecycline impurity B							
84.	Tolnaftate Impurity D							
85.	Topiramate Impurity A							
86.	Montelukast Montelukast Styrene							
87.	Buprenorphine HCl API/ Injection Imp.-A							
88.	Buprenorphine HCl API/ Injection Imp.-B							
89.	Buprenorphine HCl API/ Injection Imp.-F							
90.	Buprenorphine HCl API/ Injection Imp.-G							
91.	Buprenorphine HCl API/ Injection Imp.-H							
92.	Buprenorphine HCl API/ Injection Imp.- J							
93.	Ipratropium Ipratropium impurity B							
94.	Cefpodoxime Proxetil S-epimer							
95.	Cefpodoxime Proxetil R-epimer							
96.	Cefuroxime Axetil Diastereoisomer A							
97.	Cefuroxime Axetil Diastereoisomer B							
98.	Mupirocin Impurity C /pseudomonic acid D							
99.	Mupirocin Impurity D							
100.	Mupirocin Impurity E							
101.	Methylethergometrine Maleate Impurity B							
102.	Methylethergometrine Maleate Impurity C							
103.	Methylethergometrine Maleate Impurity D							
104.	Methylethergometrine Maleate Impurity E							
105.	Methylethergometrine Maleate Impurity F/Ergometrine							
106.	Methylethergometrine Maleate Impurity G/Methylethergide							
107.	Methylethergometrine Maleate							

	Impurity H/Methyl ergometrinine							
<b>108.</b>	<b>Methylethylergometrine Maleate</b> Impurity I							
<b>109.</b>	<b>Levonorgestrel</b> Dextronorgestrel							
<b>Tender Sch. No.</b>	<b>Name of Product/ Candidate Material for Reference Standards</b>	<b>Manufactured in India</b>  (Yes/No)	<b>Enclosed Manufacturer License/ Approval Document incl. Undertaking</b>  (Yes/ No)	<b>Specify Percentage of Minimum Local Content (%)</b>	<b>Purity is NLT- % w/w 99%</b>	<b>Attached (CoA/ Drafted CoA)</b>  (Yes/ No)	<b>Specify Page Numbers of Attached Documents</b>	<b>Remark for Deviation (if any)</b>
<b>110.</b>	<b>Prednisone API for IPRS development</b> Prednisone API				<b>NLT 99%</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.**

**Kindly Note:**

- Valid Manufacturing License/ Approval Document including undertaking must be attached by the bidder with the technical bid.**
- Attach Self Certification Affidavit for Local Content in the offered Tender items**
- Attach CoA/ Drafted CoA documents for Quoted Tender items for Corroboration Purpose.**
- Attach the separate sheet (if required)**
- Bidders are advised to quote their offer only for those Impurities/ Reference Standards, whose shelf life meets the criteria of minimum 02 Years.**

**E. QUALITY ASSURANCE:**

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

Certification	Standard	Specify	Certificate No.	Valid Upto
<b>ISO Certification</b>	ISO 9001	<input type="checkbox"/> Yes <input type="checkbox"/> no		
	ISO 14001	<input type="checkbox"/> Yes <input type="checkbox"/> no		
	ISO17034	<input type="checkbox"/> Yes <input type="checkbox"/> no		
	ISO/IEC 17025	<input type="checkbox"/> Yes <input type="checkbox"/> no		
	Other ISO/TS Certification	_____ _____		
<b>Other Certification</b>	WHO-GMP/CoPP Certification	<input type="checkbox"/> Yes <input type="checkbox"/> no		
<b>Any Other Relevant</b>	NABL			

**QUALITY POLICY/ POLICIES (Please provide ink signed copy also)**

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## **SECTION-VII**

## **ANNEXURE- A**

### **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)/Contractor(s) of foreign origin shall disclose the name and address of the Agents/representatives in India, if any. Similarly the Bidder(s)/Contractor(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)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**(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)

**(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)

**IMPURITY MATERIAL INFORMATION FORM**

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

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

*500 (Arms)*  
*2/20/19*  
*Shastri Bhawan*  
*2/20/19*

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

Shastri Bhawan, New Delhi  
Dated the 1<sup>st</sup> 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

*Praveen*



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.



(c) 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:-

$$\text{Percentage of local content} = (\text{Dom-BOM} / \text{Total-BOM}) \times 100$$

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			

**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 to 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)

## **SECTION-VIII**

### **PERFORMA-I**

#### **MANUFACTURER'S AUTHORISATION FORM**

No. \_\_\_\_\_

dated. \_\_\_\_\_

To,

**Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission (IPC), Sector-23, Raj Nagar,  
Ghaziabad- 201002, Uttar Pradesh**

Sir,

Ref. Your Tender No. \_\_\_\_\_, dated \_\_\_\_\_

We, \_\_\_\_\_ who are proven and reputable manufacturers of \_\_\_\_\_ (*name and description of the goods offered in the tender*) having factories at \_\_\_\_\_, hereby authorise Messrs \_\_\_\_\_ (*name and address of the agent*) to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred Tender document for the above goods manufactured by us.

We further confirm that no supplier or firm or individual other than Messrs. \_\_\_\_\_ (*name and address of the above agent*) is authorized to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred Tender documents for the above goods manufactured by us. Agency agreement with them giving details of agency commission shall be provided.

We also hereby extend our full guarantee & warranty, as specified therein for compliance in accordance with the Tender documents including amendments/ corrigendum (if any), for the goods and services offered for supply by the above firm.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized agent.

We also confirm that the price quoted by our agent shall not exceed than that which we would have quoted directly.

Yours faithfully,  
[Signature with date, name and designation]  
For and on behalf of Messrs

\_\_\_\_\_  
[Name & address of the manufacturers]

**Note: 1.** This letter of authorization should be on the letter head of the manufacturing firm and should be signed by a person competent and having the power of attorney to legally bind the manufacturer.

2. Original letter may be sent.

**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 place 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.

SI 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**

**For and on behalf of the Institution**

Signature of the authorized official

Signature of the authorized Officer

Name of the official

Name of the Officer

Stamp/Seal of the Supplier

Stamp/Seal of the Institution

By the said \_\_\_\_\_

By the said \_\_\_\_\_

Name on behalf of the Supplier

Name on behalf of the Institution

in the presence of :

in the presence of :

Witness \_\_\_\_\_

Witness \_\_\_\_\_

Name \_\_\_\_\_

Name \_\_\_\_\_

Address \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Contact No. \_\_\_\_\_

Contact No. \_\_\_\_\_

**BANK GUARANTEE FORM**  
**FOR PERFORMANCE SECURITY**

To,

**Secretary-cum-Scientific Director,  
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 : \_\_\_\_\_

**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

<u>Item</u>	<u>Quantity</u>	<u>Quality</u>
-------------	-----------------	----------------

**SEAL & SIGNATURE OF  
IPC OFFICIAL**

**Proforma As per DoP Order No. 31026/36/2016-MD, Dated. 18<sup>th</sup> 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:

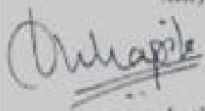
That the information furnished hereinafter is correct to best of my knowledge and belief and I undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content.

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. **66**. 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 Demand Draft for Rs. _____/- (Rupees: _____) for tender document is downloaded from IPC website. DD No. _____ Date: _____ Drawn on Bank		N/A
2.	Enclosed EMD Demand Draft for Rs. _____/- (Rupees: _____) DD No. _____ Date: _____ Drawn on Bank:  Or If claimed exemption, Attach Udyog Aadhaar Memorandum (UAM)/ Startup Certificate		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 NSIC/ Udyog Aadhaar Memorandum (UAM)/ Startup Certificate (if any)		
9.	Enclosed Annual Turnover Report/ Balance Sheet/ Profit & Loss Statement of the firm, duly <b>certified by Chartered Accountant</b> for last 03 years <b>(F.Y 2019-20, 2020-21 &amp; 2021-22)</b>		
10.	<b>A brief profile of the firm <u>on company letter head</u> mentioning various sub-headings in line of Clause B, Section- VI</b>		
11.	Enclosed Relevant Experience supporting documents (such as PO copies with proof of delivery/ acceptance/ payment receipt etc. against respective PO)		

12.	Enclosed <b>Manufacturing License/ Approval Document including undertaking</b> for Offered impurities (If Applicable)		
13.	Have you submitted requisite Affidavit for Local Content (Annexure-F) under Preference to “MAKE IN INDIA” Policy		
14.	Enclosed CoA/ Drafted CoA documents for Quoted Impurities		
15.	Enclosed Quality Assurance Certificates		
16.	Annexed <b>Annexure-A (Integrity Pact)</b>		
17.	<b>Annexure- B &amp; C on Company Letter Head</b>		
18.	Have you signed & stamped each/every enclosed documents, certificate etc.		
19.	<u>Technical Bid Envelope</u> - Kept Page No. <b>01-65</b> with all other supporting documents in Technical Bid Envelope. (without mentioning any price therein, but mentioning the quoted Impurities from <b>Page No. 56-64</b> and striking out Non-Quoted Impurities)		Pg. No. <b>01-65</b>
20.	<u>Price Bid Envelope</u> - Kept Page No. <b>56-65</b> i.e. Price Bid, in Price Bid Envelope only mentioning the prices.		Pg. No. <b>56-65</b>

# SECTION-X

## PRICE BID

(To be kept in separate sealed Envelope)

**Sub: Supply of “PHARMACEUTICAL IMPURITIES” at IPC, Ghaziabad- Reg.**

1. Name of Tenderer/ Bidder :  
(With Address & Contact Details)

A	B	C	D	E	F	G	H
Tender Schedule No.	Name of Product/ Monograph	Impurity Name	Qty.	All Inclusive Total Amount at IPC Site (excluding GST) (Rs.)	GST Extra as applicable (E) X ____% (Rs.)	Total Price at IPC (E) + (F) (Rs.)	Total Price in Words
1.	Ibuprofen Tablets	Ibuprofen RC-A	10 gms				
2.	Ibuprofen Tablets	Ibuprofen RC-B	10 gms				
3.	Ibuprofen Tablets	Ibuprofen RC-E	10 gms				
4.	Ibuprofen Tablets	Ibuprofen RC-J	10 gms				
5.	Ibuprofen Tablets	Ibuprofen RC-N	10 gms				
6.	Phenylephrine Hydrochloride	Norphenylephrine	10 gms				



7.	Phenylephrine Hydrochloride	Phenylephrine RC-C	10 gms				
8.	Phenylephrine Hydrochloride	Phenylephrine RC-D	10 gms				
9.	Phenylephrine Hydrochloride	Phenylephrine RC-E	10 gms				
10.	Phenylephrine Hydrochloride	Phenylephrine RC-F	10 gms				
11.	Chlorpheniramine Maleate	Chlorpheniramine RC-B	10 gms				
12.	Chlorpheniramine Maleate	Chlorpheniramine RC-C	10 gms				
13.	Metronidazole Injection	Tinidazole related compound A	10 gms				
14.	Promethazine hydrochloride API	Promethazine related compound B	10 gms				
15.	Linezolid	linezolid RC- D	10 gms				
16.	Linezolid	linezolid R-isomer	10 gms				
17.	Sildenafil Citrate	Sildenafil RC- A	10 gms				
18.	Mometasone Furoate	Imp. C	10 gms				
19.	Mometasone Furoate	Imp J	10 gms				
20.	Miconazole Nitrate (03)	Miconazole RC F	10 gms				

21.	Miconazole Nitrate (03)	Miconazole RC I	10 gms				
22.	Miconazole Nitrate (03)	Miconazole RC C	10 gms				
23.	Ursodeoxycholic Acid	Impurity A	10 gms				
24.	Ursodeoxycholic Acid	Impurity H	10 gms				
25.	Ursodeoxycholic Acid	Impurity C	10 gms				
26.	Fluconazole	Fluconazole RC- A	10 gms				
27.	Fluconazole	Fluconazole RC- B	10 gms				
28.	Fluconazole	Fluconazole RC- C	10 gms				
29.	Propranolol HCl / Propranolol Injection/ Tablets	Propranolol imp. A	10 gms				
30.	Propranolol HCl / Propranolol Injection/ Tablets	Propranolol imp. B	10 gms				
31.	Propranolol HCl / Propranolol Injection/ Tablets	Propranolol imp. C	10 gms				
32.	Dicyclomine HCl	Dicyclomine RC-A	10 gms				
33.	Amiodarone HCl	Amiodarone RC-D	10 gms				
34.	Amiodarone HCl	Amiodarone RC-E	10 gms				

35.	Amiodarone HCl	Amiodarone IMP.-H	10 gms				
36.	Sulphamethoxazole	sulfamethoxazole RC-A	10 gms				
37.	Sulphamethoxazole	sulfamethoxazole RC-B	10 gms				
38.	Sulphamethoxazole	sulfamethoxazole RC-C	10 gms				
39.	Sulphamethoxazole	sulfamethoxazole RC-F	10 gms				
40.	Sulphamethoxazole	Sulfanilic acid	10 gms				
41.	Sulphamethoxazole	Sulfanilamide	10 gms				
42.	Piroxicam	Piroxicam RC-A	10 gms				
43.	Piroxicam	Piroxicam RC-B	10 gms				
44.	Piroxicam	Piroxicam RC-D	10 gms				
45.	Piroxicam	Piroxicam RC-G	10 gms				
46.	Piroxicam	Piroxicam RC-J	10 gms				
47.	Ketokonazole	Terconazole	10 gms				

48.	Duloxetine HCl	Impurity F	10 gms				
49.	Frusemide	Frusemide imp. A	10 gms				
50.	Frusemide	Frusemide imp. B	10 gms				
51.	Bisacodyl	Impurity D	10 gms				
52.	Ceftriaxone	E-Isomer	10 gms				
53.	Dolutegravir Sodium	Dolutegravir 4- fluoro impurity	10 gms				
54.	Dolutegravir Sodium	isomer-1	10 gms				
55.	Dolutegravir Sodium	Enantiomer	10 gms				
56.	Dolutegravir Sodium	isomer-2	10 gms				
57.	Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets	dolutergravir impurity E	10 gms				
58.	Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets	tenofovir disoproxil impurity I	10 gms				
59.	Haloperidol	Bromperidol	10 gms				
60.	Hydrocortisone acetate	Cortisone acetate	10 gms				
61.	Lactulose	Lactulose Impurity A	10 gms				

62.	Lactulose	Lactulose Impurity B	10 gms				
63.	Lactulose	Lactulose impurity C	10 gms				
64.	Lactulose	Lactulose impurity D	10 gms				
65.	Lactulose	Lactulose impurity E	10 gms				
66.	Levocetirizine Hydrochloride	Piperazine RS	10 gms				
67.	Luliconazole Luliconazole Cream Luliconazole Lotion	Luliconazole S-E	10 gms				
68.	Luliconazole Luliconazole Cream Luliconazole Lotion	Luliconazole Z form RS	10 gms				
69.	Mefenamic acid	Mefenamic acid impurity C	10 gms				
70.	Metformin HCl	Melamine	10 gms				
71.	Metronidazole Benzoate	Impurity A	10 gms				
72.	Naproxen	Racemic Naproxen	10 gms				
73.	Propofol	Impurity J	10 gms				
74.	Propofol	Impurity E (dimer)	10 gms				
75.	Propofol	Impurity G	10 gms				

76.	Simvastatin	Impurity F	10 gms				
77.	Sulbactam Sodium	Sulbactam related substance A	10 gms				
78.	Tenoxicam Tenoxicam Tablets	Tenoxicam impurity G	10 gms				
79.	Terazosin HCl	Impurity B	10 gms				
80.	Terazosin HCl	Impurity N	10 gms				
81.	Testosterone propionate	Testosterone acetate	10 gms				
82.	Thyroxine Sodium Thyroxine Tablets	Liothyronine Sodium RS	10 gms				
83.	Tigecycline Tigecycline Injection	Tigecycline impurity B	10 gms				
84.	Tolnaftate	Impurity D	10 gms				
85.	Topiramate	Impurity A	10 gms				
86.	Montelukast	Montelukast Styrene	10 gms				
87.	Buprenorphine HCl API/ Injection	Imp.-A	10 gms				
88.	Buprenorphine HCl API/ Injection	Imp.-B	10 gms				

89.	Buprenorphine HCl API/ Injection	Imp.-F	10 gms				
90.	Buprenorphine HCl API/ Injection	Imp.-G	10 gms				
91.	Buprenorphine HCl API/ Injection	Imp.-H	10 gms				
92.	Buprenorphine HCl API/ Injection	Imp.- J	10 gms				
93.	Ipratropium	Ipratropium impurity B	10 gms				
94.	Cefpodoxime Proxetil	S-epimer	10 gms				
95.	Cefpodoxime Proxetil	R-epimer	10 gms				
96.	Cefuroxime Axetil	Diastereoisomer A	10 gms				
97.	Cefuroxime Axetil	Diastereoisomer B	10 gms				
98.	Mupirocin	Impurity C /pseudomonic acid D	10 gms				
99.	Mupirocin	Impurity D	10 gms				
100.	Mupirocin	Impurity E	10 gms				
101.	Methylethergometrine Maleate	Impurity B	10 gms				
102.	Methylethergometrine Maleate	Impurity C	10 gms				

<b>103.</b>	<b>Methylergometrine Maleate</b>	<b>Impurity D</b>	10 gms				
<b>104.</b>	<b>Methylergometrine Maleate</b>	<b>Impurity E</b>	10 gms				
<b>105.</b>	<b>Methylergometrine Maleate</b>	<b>Impurity F/Ergometrinine</b>	10 gms				
<b>106.</b>	<b>Methylergometrine Maleate</b>	<b>Impurity G/Methylsergide</b>	10 gms				
<b>107.</b>	<b>Methylergometrine Maleate</b>	<b>Impurity H/Methyl ergometrinine</b>	10 gms				
<b>108.</b>	<b>Methylergometrine Maleate</b>	<b>Impurity I</b>	10 gms				
<b>109.</b>	<b>Levonorgestrel</b>	<b>Dextronorgestrel</b>	10 gms				

<b>Tender Schedule No.</b>	<b>Name of Product</b>	<b>Name of Candidate Material for Reference Standards</b>	<b>Qty.</b>	<b>All Inclusive Total Amount at IPC Site (excluding GST) (Rs.)</b>	<b>GST Extra as applicable (E) X ____% (Rs.)</b>	<b>Total Price at IPC (E) + (F) (Rs.)</b>	<b>Total Price in Words</b>
<b>110.</b>	<b>Prednisone API for IPRS development</b>	<b>Prednisone API</b>	<b>200 GMS.</b>				
	<b>Write Total Numbers of Impurities/Item for which price has been quoted</b>						
	<b>Total Amount of above offer (Rs.) i.e. Sum of (G1+G110)</b>						

**(Total Amount for above offer in Words:.....)**



**Kindly Note:**

- I. The rates must be quoted in prescribed format/ Performa only and in INR only.
- II. **SCHEDULE NUMBER OF IMPURITIES/ TENDER ITEM MUST NOT BE CHANGED. IT MUST BE SAME (AS IT IS) AS PROVIDED BY IPC. IN CASE PRICE FOR ANY IMPURITY/ITEM HAS NOT BEEN QUOTED, SUCH IMPURITY ROW MUST BE STRIKEOUT COMPLETELY AND MENTIONED AS “NO OFFER” IN THAT ROW.**
- III. The items have to be quoted by the bidder strictly in accordance to the technical specifications of the Bidding Document.
- IV. The rate quoted must be inclusive of all charges upto goods delivery at the Commission. No additional charges (i.e. Packing & forwarding, transportation, loading & unloading, insurance charges etc) other than quoted would be paid extra.
- V. **The price competitiveness for each impurities shall be given due consideration while analyzing the commercial/ Price bid.** No Additional Charges other than mentioned would be paid extra.
- VI. Goods & Service Taxes (GST) shall be paid at actual at the time of invoice generation.
- VII. TDS & other taxes shall be deducted as per applicable rules.

It is hereby confirmed that we shall abide by all terms & conditions as specified in this tender.

SIGNATURE OF AUTHORIZED SIGNATORY:

NAME & ADDRESS OF BIDDER

(Seal of the Bidder)

Telephone & Mobile Number:- \_\_\_\_\_