Industry Questionnaire for Pharmaceutical sector

Department of Commerce

Ministry of Commerce and Industry

(Please share your inputs by **28 November, 2024, Thursday – 5 PM)**

**Section 1: Responder details**

|  |  |  |
| --- | --- | --- |
| 1.1 | Responder Name |  |
| 1.2 | Responder Designation |  |
| 1.3 | Responder Organisation Name |  |
| 1.4 | Responder email |  |
| 1.5 | Responder mobile/ contact no. |  |
| 1.6 | Category  (Exporter/ EPC/ Govt. officials/ Private or Industry representative / Experts/ Others) |  |
| 1.7 | In case (Exporter/ Private or Industry representative /) selected in 1.6, please pick one  Scale 1: Annual Turnover **< INR 1 Crs)**  Scale 2: Annual Turnover **INR 1 Crs) < INR 5 Crs)**  Scale 3: Annual Turnover **INR 5 Crs) < INR 50 Crs)**  Scale 4: Annual Turnover **> INR 50 Crs)** |  |

**Section 2: Indian Pharma Market overview.**

|  |  |  |
| --- | --- | --- |
| 2.1 | What percentage of total units in pharmaceutical industry’s clusters are MSMEs? | 1. 5% - 25% 2. 25% - 50% 3. 50% - 75% 4. 75% and above |
| 2.2 | In medical devices, what are the key challenges faced by Indian exporters? | Please choose from the below options:   1. Regulatory 2. Trade Finance 3. Quality 4. Investment in R&D   Please elaborate your response. |
| 2.3 | What is the average R&D spent in countries like Germany, USA, China and India? | Please provide your response here |
| 2.4 | What are the major issues/ challenges facing India’s pharma industry in adhering to Goods Manufacturing Practices (GMP)? | Please provide your response here |
| 2.5 | What is the average share of logistics cost in India’s pharma industry? | Please choose from the below options:   1. 5%-15% 2. 15%-30% 3. 30%-45%   Please elaborate your response. |
| 2.6 | What is the average time taken to get approvals for exporting drugs and pharma products, both State and Central? | Please provide your response here. |
| 2.7 | What is the average time taken to get approval from FDA? Please suggest any related specific insight/ challenge, if any | Please provide your response here. |
| 2.8 | What is the average time taken to get approval from EMA? Please suggest any related specific insight/ challenge, if any | Please provide your response here. |
| 2.9 | What is the average time taken by companies/ MNCs to set up manufacturing facilities in India? | Please provide your response here. |
| 2.10 | What are the challenges faced by MNCs in setting up manufacturing facilities in India, and consequently export to other countries? | Please elaborate your response here. |

**Section 3: Potential Markets for India Pharma Exports**

|  |  |  |
| --- | --- | --- |
| 3.1 | What are the challenges faced by exporters in entering EU members states such as Netherlands, France, Belgium and Germany? | Please provide your response here. |
| 3.2 | In the last 10 years, Italy has become top exporter of Drugs and Pharmaceutical. It climbed from 10th position to 7th position as global exporters. What led to Italy’s rise as global exporters in the market? | Please elaborate your response here. |
| 3.3 | Which specific potential countries/ regions therapeutic areas are experiencing the highest growth globally? Does India have the capability to export to these countries? If no, please elaborate on the challenges faced by Indian pharma companies. | Please type your response. |

**Section 4: Potential products as per Pharma Trade analysis**

|  |  |  |
| --- | --- | --- |
| 4.1 | If exporter, please specify the category of products which are being currently exported. | 1. Bulk drugs, drug intermediates 2. Generic drugs 3. Vaccines 4. Biosimilars and biologics 5. Contract research and manufacturing 6. Surgicals 7. Ayush and herbal products 8. Medical devices   Please specify list of HS codes (6 or 8 digit codes)……………….. |
| 4.2 | What are the top 10 markets for the above category of products? | Please specify country name… |
| 4.3 | Which sector out of the following is expected to grow in next 5 years globally? Please specify HS codes (6 or 8 digit) of the potential sector  As per trade data analysis, the D&P exports has increased at a CAGR of 7% (2015-24) with major exports contributed by Surgicals, Drugs and formulations and biologicals. Among the top 10 globally imported drugs & pharma products, India exports highest contribution was noted in the case of HS 300490, 293399 & 293339 of about~4%. | 1. Bulk drugs, drug intermediates 2. Generic drugs 3. Vaccines 4. Biosimilars and biologics 5. Contract research and manufacturing 6. Surgicals 7. Ayush and herbal products 8. Medical devices   Please specify HS codes (6 or 8 digit codes)….. |
| 4.4 | Which sector out of the following is expected to grow in next 5 years to USA? Please specify HS codes (6 or 8 digit) of the potential sector | 1. Bulk drugs, drug intermediates 2. Generic drugs 3. Vaccines 4. Biosimilars and biologics 5. Contract research and manufacturing 6. Surgicals 7. Ayush and herbal products 8. Medical devices   Please specify HS codes (6 or 8 digit codes)….. |
| 4.5 | As per trade analysis, below is the list of HS codes which shows potential for exports to USA. Does India have the capability to produce the same? If yes, what are the challenges which hinders the growth of each potential commodity. | Please specify in each row for each HS code. |
| |  |  |  | | --- | --- | --- | | **HS Code** | **Description** | **Challenges in production in India** | | 293090 | Organo-sulphur compounds (excl. thiocarbamates and dithiocarbamates, thiuram mono-, di- or ... |  | | 293319 | Heterocyclic compounds with nitrogen hetero-atom[s] only, containing an unfused pyrazole ring, ... |  | | 291899 | Carboxylic acids with additional oxygen function and their anhydrides, halides, peroxides and ... |  | | 291619 | Unsaturated acyclic monocarboxylic acids, their anhydrides, halides, peroxides, peroxyacids ... |  | | 292529 | Imines and their derivatives; salts thereof (excl. chlordimeform [ISO]) |  | | 294000 | Sugars, chemically pure (excl. sucrose, lactose, maltose, glucose and fructose); sugar ethers, ... |  | | 291524 | Acetic anhydride |  | | 291479 | Halogenated, sulphonated, nitrated or nitrosated derivatives of ketones or quinones (excl. ... |  | | 290319 | Saturated chlorinated derivatives of acyclic hydrocarbons (excl. chloromethane [methyl chloride], ... |  | | 290220 | Benzene |  | | 293299 | Heterocyclic compounds with oxygen hetero-atom[s] only (excl. compounds containing unfused ... |  | | 292429 | Cyclic amides, incl. cyclic carbamates, and their derivatives; salts thereof (excl. ureines ... |  | | | |
| 4.6 | In continuation to the above, which of these products can be exported or produced by MSME sector? Do you foresee any challenges which MSME segment may face in domestic production.  Please specify Yes or No for each HS codes.  any challenges which MSME segment may face in domestic production.  Please specify Yes or No for each HS codes. | |
| |  |  |  | | --- | --- | --- | | **HS Code** | **Description** | **Can be produced by MSME segment (Yes/ No)** | | 293090 | Organo-sulphur compounds (excl. thiocarbamates and dithiocarbamates, thiuram mono-, di- or ... |  | | 293319 | Heterocyclic compounds with nitrogen hetero-atom[s] only, containing an unfused pyrazole ring, ... |  | | 291899 | Carboxylic acids with additional oxygen function and their anhydrides, halides, peroxides and ... |  | | 291619 | Unsaturated acyclic monocarboxylic acids, their anhydrides, halides, peroxides, peroxyacids ... |  | | 292529 | Imines and their derivatives; salts thereof (excl. chlordimeform [ISO]) |  | | 294000 | Sugars, chemically pure (excl. sucrose, lactose, maltose, glucose and fructose); sugar ethers, ... |  | | 291524 | Acetic anhydride |  | | 291479 | Halogenated, sulphonated, nitrated or nitrosated derivatives of ketones or quinones (excl. ... |  | | 290319 | Saturated chlorinated derivatives of acyclic hydrocarbons (excl. chloromethane [methyl chloride], ... |  | | 290220 | Benzene |  | | 293299 | Heterocyclic compounds with oxygen hetero-atom[s] only (excl. compounds containing unfused ... |  | | 292429 | Cyclic amides, incl. cyclic carbamates, and their derivatives; salts thereof (excl. ureines ... |  | | | |
| 4.7 | In continuation to the above, which of these products are dependent on imports for production in India (for raw materials/ intermediate goods)?  Please specify HS codes of dependent product and dependent market. | |
| |  |  |  |  | | --- | --- | --- | --- | | **HS Code** | **Description** | **Import dependent (specify HS codes of dependent product – raw material/ intermediate product)** | **Please specify the importing source/ country for the specified import dependent product** | | 293090 | Organo-sulphur compounds (excl. thiocarbamates and dithiocarbamates, thiuram mono-, di- or ... |  |  | | 293319 | Heterocyclic compounds with nitrogen hetero-atom[s] only, containing an unfused pyrazole ring, ... |  |  | | 291899 | Carboxylic acids with additional oxygen function and their anhydrides, halides, peroxides and ... |  |  | | 291619 | Unsaturated acyclic monocarboxylic acids, their anhydrides, halides, peroxides, peroxyacids ... |  |  | | 292529 | Imines and their derivatives; salts thereof (excl. chlordimeform [ISO]) |  |  | | 294000 | Sugars, chemically pure (excl. sucrose, lactose, maltose, glucose and fructose); sugar ethers, ... |  |  | | 291524 | Acetic anhydride |  |  | | 291479 | Halogenated, sulphonated, nitrated or nitrosated derivatives of ketones or quinones (excl. ... |  |  | | 290319 | Saturated chlorinated derivatives of acyclic hydrocarbons (excl. chloromethane [methyl chloride], ... |  |  | | 290220 | Benzene |  |  | | 293299 | Heterocyclic compounds with oxygen hetero-atom[s] only (excl. compounds containing unfused ... |  |  | | 292429 | Cyclic amides, incl. cyclic carbamates, and their derivatives; salts thereof (excl. ureines ... |  |  | | | |
| 4.8 | Please specify the type of challenges which are acting as impediment to growth for the above listed products. | 1. Regulatory challenges (Issues related to ease of compliance & certifications, patents) 2. Access to finance (challenges in trade finance for exporting to specific country/ region) 3. Time and efficiency for drug regulations (from CDSCO or State govt. for business regulations) 4. Time taken for approval from FDA or other similar organisations from target export country 5. Logistics and storage issues   Please select and specify the issues in detail … |
| 4.9 | What are the specific interventions required from Department of commerce for boosting export of the above products to USA?  Any MRA or FTA or other agreements which should be considered on priority | Please specify in detail… |
| 4.10 | Please specify if any support is required from Mission abroad of USA which would support in boosting exports | Please specify in detail… |

**Section 5: Generic Drug Export Promotion.**

|  |  |  |
| --- | --- | --- |
| 5.1 | A total of 600 molecules of APIs and Drug Intermediates are imported to India, of **which 58 molecules are exclusively imported from China. Please suggest, which molecules have a potential for domestic production and/or Export?**  Refer to Annexure 1: | Please type your response |
| 5.2 | Which criterion ( 8 criterion are listed in Slide4) for generic drugs is the most suitable for highlighting India’s export potential? | Please rank on scale below  1 – Highest on India’s export potential  8 – Least on India’s export potential |
|  | **Criteria 1:** Molecules/drugs by Global sales (2019); For details refer to Annexure 2 |  |
|  | **Criteria 2:** Molecules/drug/intermediates based on Imports ( Mainly from China) ; For details refer to Annexure 1 |  |
|  | **Criteria 3:** Molecules based on Off patent drugs in the US FDA orange book listings, ANDA /NDA/ Competitive Generic Therapy Approvals by Indian Pharma; For details refer to Annexure 3 |  |
|  | **Criteria 4:** Molecules based on Drug Shortages in the US market; For details refer to Annexure 4 |  |
|  | **Criteria 5:** Molecules identified in the Atma Nirbhar scheme: Gaz Not. 21 July 2020; For details refer to Annexure 5 |  |
|  | **Criteria 6:** Molecules identified in the ministry of environment, forest and climate change notification dated 23rd January, 2020; For details refer to Annexure 6 |  |
|  | **Criteria 7:** Molecules identified based on Patent expiry; For details refer to Annexure 7 |  |
|  | **Criteria 8:** List of identified Pharmaceutical Products at HS-6 digit (Based on a "India’s Trade in Pharmaceutical Products: A Method for the Classification of Pharmaceutical Products and Recent Trends“. ; For details refer to Annexure 8 |  |
|  | Please suggest, if any other criteria | Please type your text here. |
| 5.3 | Which Therapeutic Class/s ( Acute & Chronic) should be selected among the selected criterion for generic drugs for highlighting India’s export potential? | Please type your text here. |

## **Refer to Annexure 1: APIs and Drug Intermediates are imported to India from China**

**Part 1.1: Major APIs for which India depends excessively on China**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No.** | **APIs** | **Therapeutic Class/ Use** | **Dependence on China (%)** |
| **1** | **Oxytetracycline** | **Antibiotic** | **100** |
| **2** | **Tetracycline** | **Antibiotic** | **100** |
| **3** | **Azithromycin** | **Antibiotic** | **100** |
| **4** | **Norfloxacin** | **Antibiotic** | **100** |
| **5** | **Ofloxacin** | **Antibiotic** | **100** |
| **6** | **Aspirin** | **Pain management** | **100** |
| **7** | **Metformin** | **Anti-diabetic** | **100** |
| **8** | **Ampicillin** | **Antibiotic** | **100** |
| **9** | **Levofloxacin** | **Antibiotic** | **-100** |
| **10** | **Atorvastatin** | **Anti-cholesterol** | **-100** |
| **11** | **Chloroquine** | **Anti-malarial** | **-100** |
| **12** | **Montelukast** | **Asthma treatment** | **-100** |
| **13** | **Telmisartan** | **Anti-hypertensive** | **-100** |
| **14** | **Cephalosporins** | **Antibiotics** | **-100** |
| **15** | **Olmesartan** | **Anti-hypertensive** | **-100** |
| **16** | **Penicillin G** | **Antibiotic** | **-100** |
| **17** | **Streptomycin** | **TB treatment** | **-100** |
| **18** | **Ranitidine** | **Anti-histamine** | **-100** |
| **19** | **Ambroxol** | **Respiratory disease** | **-100** |
| **20** | **Metronidazole** | **Anti-diarrheal** | **99** |
| **21** | **Neomycin** | **Antibiotic** | **98** |
| **22** | **Ciprofloxacin** | **Antibiotic** | **97** |
| **23** | **Rifampicin** | **TB treatment** | **97** |
| **24** | **Amoxicillin** | **Antibiotic** | **93** |
| **25** | **Doxycycline** | **Antibiotic** | **91** |
| **26** | **Paracetamol** | **Analgesic and antipyretic** | **90** |
| **27** | **Gabapentin** | **Antibiotic** | **89** |
| **28** | **Gentamicin** | **Anxiety drug** | **86** |
| **29** | **Vitamin C** | **Antibiotic** | **81** |
| **30** | **Chloramphenicol** | **Antibiotic** | **78** |
| **31** | **Vitamin B6** | **Vitamin** | **77** |
| **32** | **Vitamin B1** | **Vitamin** | **75** |
| **33** | **Ibuprofen** | **Pain Management** | **-75** |
| **34** | **Heparin** | **Anti-coagulant** | **72** |
| **35** | **Vitamin B12** | **Vitamin** | **68** |
| **36** | **Erythromycin** | **Antibiotic** | **63** |

**Part 1.2: Other important APIs, along with their therapeutic class/ use, which are imported from China**

|  |  |  |
| --- | --- | --- |
| **SI. No.** | **APIs** | **Therapeutic Class/ Use** |
| **1** | **Ornidazole** | **Anti-diarrheal** |
| **2** | **Clarithromycin** | **Antibiotic** |
| **3** | **Cefixime** | **Antibiotic** |
| **4** | **Ceftriaxone** | **Antibiotic** |
| **5** | **Meropenem** | **Antibiotic** |
| **6** | **Artemisinin** | **Anti-malarial** |
| **7** | **Lamivudine** | **Antiretroviral** |
| **8** | **Clindamycin** | **Antibacterial** |
| **9** | **Tazobactam** | **Anti-bacterial** |
| **10** | **Rosuvastatin** | **Anti-cholesterol** |
| **11** | **Lopinavir** | **Anti-retroviral** |
| **12** | **Ritonavir** | **Anti-retroviral** |
| **13** | **Sulfadiazine** | **Antibiotic** |
| **14** | **Acyclovir** | **Antiviral** |
| **15** | **Oxcarbazepine** | **Anti-epileptic** |
| **16** | **Carbamazepine** | **Anti-epileptic** |
| **17** | **Levetiracetam** | **Anti-epileptic** |
| **18** | **Carbidopa** | **Decarboxylase inhibitor** |
| **19** | **Diclofenac Sodium** | **Pain management** |
| **20** | **Sulbactam** | **-lactamase inhibitor** |
| **21** | **Valsartan** | **Angiotensin receptor blocker** |
| **22** | **Imipenem** | **Antibiotic** |
| **23** | **Doripenem** | **Antibiotic** |
| **24** | **Valproic acid** | **Seizure disorders treatment** |
| **25** | **Hydroxychloroquine** | **Anti-malarial** |
| **26** | **Clomipramine** | **Anti-depressant** |
| **27** | **Nebivolol** | **Anti-hypertensive** |
| **28** | **Lansoprazole** | **Peptic ulcer treatment** |
| **29** | **Gliptins** | **Anti-diabetic** |
| **30** | **Flozins** | **Anti-diabetic** |
| **31** | **Zoles** | **Anti-fungal** |
| **32** | **Nibs** | **Anti-cancer** |
| **33** | **Abacavir** | **HIV Treatment** |
| **34** | **Progesterone** | **Steroid hormone** |
| **35** | **Levodopa** | **Parkinson disease treatment** |
| **36** | **Aspartame** | **Artificial sweetener** |

## **Annexure 2: Criteria 1: Molecules/drugs by Global sales (2019);**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SI. No. | Active Pharma Ingredient (APIs) | Main Therapeut Indication | SI. No. | Active Pharma Ingredient (APIs) | Main Therapeutic |
| 1 | Lenalidomide | Oncology | 15 | Fingolimod | CNS & Anesthesia |
| 2 | Apixaban | Cardiovascular Diseases | 16 | Osimertinib | Oncology |
| 3 | Dolutegravir | Infectious Diseases | 17 | Abacavir, Dolutegravir and Lamivudine | Infectious Diseases |
| 4 | Palbociclib | Oncology | 18 | Glecaprevir/Pibrentasvir | Infectious Diseases |
| 5 | Ibrutinib | Oncology | 19 | Emtricitabine, and Tenofovir Disoproxil Fumarate | Infectious Diseases |
| 6 | Rivaroxaban | Cardiovascular Diseases | 20 | Abiraterone Acetate | Oncology |
| 7 | Diroximel Fumarate | CNS & Anesthesia | 21 | Budesonide and Formoterol | Respiratory Disorders |
| 8 | Dimethyl Fumarate | CNS & Anesthesia | 22 | Lisdexamfetamine | CNS & Anesthesia |
| 9 | Elvitegravir, Cobicistat | Infectious Diseases | 23 | Empagliflozin | Diabetes |
| 10 | Enzalutamide | Oncology | 24 | Tiotropium bromide | Respiratory Disorders |
| 11 | Sitagliptin | Diabetes | 25 | Tofacitinib Citrate | Immunology |
| 12 | Paliperidone Palmitate | CNS & Anesthesia | 26 | Pomalidomide | Oncology |
| 13 | Pregabalin | CNS & Anesthesia | 27 | Salmeterol | Respiratory Disorders |
| 14 | Liraglutide | Diabetes | 28 | Pemetrexed | Oncology |
| S. No. | Active Pharma Ingredient (APIs) | Main Therapeutic Indication | S. No. | Active Pharma Ingredient (APIs) | Main Therapeutic Indication |
| 29 | Dasatinib | Oncology | 40 | Linagliptin and Metformin Hydrochloride | Diabetes |
| 30 | Darunavir and Cobicistat | Infectious Diseases | 41 | Semaglutide | Diabetes |
| 31 | Nusinersen | Genetic Disorders | 42 | Dabigatran Etexilate | Hematology |
| 32 | Teriflunomide | CNS & Anesthesia | 43 | Emtricitabine, Rilpivirine, and Tenofovir | Infectious Diseases |
| 33 | Metformin and Sitagliptin | Diabetes | 44 | Sodium Oxybate | CNS & Anesthesia |
| 34 | Atorvastatin Calcium | Cardiovascular Diseases | 45 | Octreotide | Oncology |
| 35 | Sofosbuvir &VeIpatasvir | Infectious Diseases | 46 | Ticagrelor | Cardiovascular Diseases |
| 36 | Nilotinib | Oncology | 47 | Dapagliflozin | Diabetes |
| 37 | Tacrolimus | Immunology | 48 | Everolimus | Oncology |
| 38 | Lurasidone | CNS & Anesthesia | 49 | Emtricitabine and Tenofovir Alafenamide | Infectious Diseases |
| 39 | Sacubitril and Valsartan | Cardiovascular Diseases | 50 | Esomeprazole Magnesium | Gastrointestinal Disorders |

## **Annexure 3: Criteria 3: Molecules based on Off patent drugs in the US FDA orange book listings, ANDA /NDA/ Competitive Generic Therapy Approvals by Indian Pharma**

|  |  |  |
| --- | --- | --- |
| **Orange Book Data set- 9799 Approved Formulations of 1254 active molecules/ingredients** | **Active ingredient** | **No of applicants (companies seeling the generic drug formulation in US)** |
| **1** | **DILTIAZEM HYDROCHLORIDE** | **102** |
| **2** | **DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE** | **92** |
| **3** | **LEVOTHYROXINE SODIUM** | **82** |
| **4** | **METHYLPHENIDATE HYDROCHLORIDE** | **81** |
| **5** | **AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE** | **81** |
| **6** | **MORPHINE SULFATE** | **80** |
| **7** | **TEMOZOLOMIDE** | **71** |
| **8** | **TRIAMCINOLONE ACETONIDE** | **70** |
| **9** | **DULOXETINE HYDROCHLORIDE** | **66** |
| **10** | **GABAPENTIN** | **60** |
| **11** | **CELECOXIB** | **58** |
| **12** | **HEPARIN SODIUM** | **56** |
| **13** | **POTASSIUM CHLORIDE** | **54** |
| **14** | **WARFARIN SODIUM** | **54** |
| **15** | **DEXMETHYLPHENIDATE HYDROCHLORIDE** | **53** |
| **16** | **VANCOMYCIN HYDROCHLORIDE** | **51** |
| **17** | **CLOBETASOL PROPIONATE** | **50** |
| **18** | **ATOMOXETINE HYDROCHLORIDE** | **48** |
| **19** | **AMOXICILLIN** | **47** |
| **20** | **FENOFIBRATE** | **46** |
| **21** | **FLUCONAZOLE** | **45** |

## **Annexure 4: Criteria 4: Molecules based on Drug Shortages in the US market;**

|  |  |  |
| --- | --- | --- |
| Ser. No | Generic Name or Active Ingredient | Status |
| 1 | Albuterol Sulfate Solution | Currently in Shortage |
| 2 | Amifostine Injection | Currently in Shortage |
| 3 | Amino Acid Injection | Currently in Shortage |
| 4 | Amoxapine Tablet | Currently in Shortage |
| 5 | Amoxicillin Powder, For Suspension | Currently in Shortage |
| 6 | Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet | Currently in Shortage |
| 7 | Atropa Belladonna, Opium Suppository | Currently in Shortage |
| 8 | Atropine Sulfate Injection | Currently in Shortage |
| 9 | Azacitidine Injection | Currently in Shortage |
| 10 | Bumetanide Injection | Currently in Shortage |
| 11 | Bupivacaine Hydrochloride Injection | Currently in Shortage |
| 12 | Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection | Currently in Shortage |
| 13 | Capecitabine Tablet | Resolved |
| 14 | Carboplatin Injection | Currently in Shortage |
| 15 | Cefotaxime Sodium Injection | Currently in Shortage |
| 16 | Cefotetan Disodium Injection | Resolved |
| 17 | Chloroprocaine Hydrochloride Injection | Currently in Shortage |
| 18 | Cisplatin Injection | Resolved |
| 19 | Clindamycin Phosphate Injection | Currently in Shortage |
| 20 | Clonazepam Tablet | Currently in Shortage |
| 21 | Conivaptan Hydrochloride Injection | Currently in Shortage |
| 22 | Cromolyn Sodium Concentrate | Currently in Shortage |
| 23 | Cyclopentolate Hydrochloride Ophthalmic Solution | Currently in Shortage |
| 24 | Cytarabine Injection | Resolved |
| 25 | Dacarbazine Injection | Currently in Shortage |

## **Annexure 5: Criteria 5: Molecules identified in the Atma nirbhar scheme: Gaz Not. 21 July 2020**

|  |  |  |  |
| --- | --- | --- | --- |
| **S. No.** | **Name of the product** | **S. No.** | **Name of the product** |
| **1.** | **Amoxicillin** | **28.** | **Ciprofloxacin** |
| **2.** | **Azithromycin** | **29.** | **Losartan** |
| **3.** | **Erythromycin Stearate/ Estolate** | **30.** | **Telmisartan** |
| **4.** | **Ceftriaxone** | **31.** | **Artesunate** |
| **5.** | **Cefoperazone** | **32.** | **Norfloxacin** |
| **6.** | **Cefixime** | **33.** | **Ofloxacin** |
| **7.** | **Cephalexin** | **34.** | **Metronidazole** |
| **8.** | **Piperacillin Tazobactam** | **35.** | **Sulfadiazine** |
| **9.** | **Sulbactam** | **36.** | **Levofloxacin** |
| **10.** | **Dexamethasone** | **37.** | **Meropenem** |
| **11.** | **Prednisolone** | **38.** | **Paracetamol** |
| **12.** | **Metformin** | **39.** | **Tinidazole** |
| **13.** | **Gabapentin** | **40.** | **Ornidazole** |
| **14.** | **Rifampicin** | **41.** | **Ritonavir** |
| **15.** | **Vitamin B1** | **42.** | **Diclofenac Sodium** |
| **16.** | **Vitamin B6** | **43.** | **Aspirin** |
| **17.** | **Clindamycin Phosphate** | **44.** | **Levetiracetam** |
| **18.** | **Clindamycin HCL** | **45.** | **Carbidopa** |
| **19.** | **Streptomycin** | **46.** | **Levodopa** |
| **20.** | **Neomycin** | **47.** | **Carbamazepine** |
| **21.** | **Gentamycin** | **48.** | **Oxcarbazepine** |
| **22.** | **Doxycycline** | **49.** | **Valsartan** |
| **23.** | **Potassium Clavulanate** | **50.** | **Olmesartan** |
| **24.** | **Oxytetracycline** | **51.** | **Atorvastatin** |
| **25.** | **Tetracycline** | **52.** | **Acyclovir** |
| **26.** | **Clarithromycin** | **53.** | **Lopinavir** |
| **27.** | **Betamethasone** |  |  |

## **Annexure 6: Criteria 6: Molecules identified in the ministry of environment, forest and climate change notification dated 23rd January, 2020**

* Effluent standards for manufacturing of around 122 Antibiotics

## **Annexure 7: Criteria 7: Molecules identified based on Patent expiry**

## A screenshot of a graph Description automatically generated

## **Annexure 8: Criteria 8: List of identified Pharmaceutical Products at HS-6 digit (Based on a "India’s Trade in Pharmaceutical Products: A Method for the Classification of Pharmaceutical Products and Recent Trends“.**

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| Category | HS 6- digit | Description |
| APIs | 291821 | Salicylic acid & its salts |
| APIs | 291822 | O-Acetylsalicylic acid, its salts & esters |
| APIs | 291823 | Esters of salicylic acid & their salts, other than salicylic acid & its salts/O-acetylsalicylic acid & its salts & esters |
| APIs | 292241 | Lysine & its esters; salts thereof |
| APIs | 292242 | Glutamic acid & its salts |
| APIs | 292310 | Choline & its salts |
| APIs | 292320 | Lecithins & other phosphoaminolipids |
| APIs | 292390 | Quaternary ammonium salts & hydroxides; lecithins & other phosphoaminolipids, whether/not chemically defined (excl. of 2923.10 & 2923.20) |
| APIs | 292411 | Meprobamate (INN) |
| APIs | 292412 | Fluoroacetamide (ISO), monocrotophos (ISO)&phosphamidon (ISO) |
| APIs | 292419 | Acyclic amides (including acyclic carbamates, excl. of 2924.11& 2924.12)&their derivatives; salts thereof |
| APIs | 292423 | 2-Acetamidobenzoic acid (N-acetylanthranilic acid) & its salts |
| APIs | 292424 | Ethinamate (INN) |
| APIs | 292429 | Cyclic amides (incl. cyclic carbamates) & their derivatives (excl. of 2924.21-2924.24); salts thereof |
| APIs | 293229 | Lactones (excl. coumarin, methylcoumarins & ethylcoumarins) |
| APIs | 293311 | Phenazone (antipyrin) & its derivatives |
| APIs | 293319 | Heterocyclic comps. containing an unfused pyrazole ring (whether/not hydrogenated) in the structure (excl. phenazone & its derivatives) |
| APIs | 293321 | Hydantoin & its derivatives |
| APIs | 293352 | Malonylurea (barbituric acid) & its salts |
| APIs | 293353 | Allobarbital (INN), amobarbital (INN), barbital (INN), butalbital (INN), butobarbital, cyclobarbital (INN), methylphenobarbital (INN), pentobarbital (INN), phenobarbital (INN), secbutabarbital (INN), secobarbital (INN) & vinylbital (INN); salts thereof |
| APIs | 293354 | Derivatives of malonylurea (barbituric acid) (excl. of 2933.53); salts thereof |
| APIs | 293355 | Loprazolam (INN), mecloqualone (INN), methaqualone (INN) & zipeprol (INN); salts thereof |
| APIs | 293359 | Heterocyclic comps. containing a pyrimidine ring (whether/not hydrogenated)/piperazine ring in the structure (excl. of 2933.52- 2933.55) |
| APIs | 293369 | Heterocyclic comps. containing an unfused triazine ring (whether/not hydrogenated) in the structure, other than melamine |
| APIs | 293430 | Compounds containing in the structure a phenothiazine ring-system (whether/not hydrogenated), not further fused |

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| *Category* | *HS 6- digit* | *Description* |
| APIs | 293500 | Sulphonamides |
| APIs | 293621 | Vitamins A & their derivatives |
| APIs | 293622 | Vitamin B1 & its derivatives |
| APIs | 293623 | Vitamin B2 & its derivatives |
| APIs | 293624 | D- /DL-Pantothenic acid (Vitamin B3/Vitamin B5) & its derivatives |
| APIs | 293625 | Vitamin B6 & its derivatives |
| APIs | 293626 | Vitamin B12 & its derivatives |
| APIs | 293627 | Vitamin C & its derivatives |
| APIs | 293628 | Vitamin E & its derivatives |
| APIs | 293629 | Vitamins & their derivatives, unmixed (excl. of 2936.10-2936.28) |
| APIs | 293690 | Provitamins&vitamins, natural/reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins,&intermixtures of the foregoing, whether/not in any solvent,n.e.s.in Ch 29.36 |
| APIs | 293711 | Somatotropin, its derivatives & structural analogues |
| APIs | 293712 | Insulin & its salts |
| APIs | 293719 | Polypeptide hormones, protein hormones & glycoprotein hormones, their derivatives & structural analogues (excl. of 2937.11 & 2937.12) |
| APIs | 293721 | Cortisone, hydrocortisone, prednisone (dehydrocortisone) & prednisolone (dehydrohydrocortisone) |
| APIs | 293722 | Halogenated derivatives of corticosteroidal hormones |
| APIs | 293723 | Oestrogens & progestogens |
| APIs | 293729 | Steroidal hormones, their derivatives & structural analogues (excl. of 2937.21-2937.23) |
| APIs | 293731 | Epinephrine |
| APIs | 293739 | Catecholamine hormones other than epinephrine, their derivatives & structural analogues |
| APIs | 293740 | Amino-acid derivatives |
| APIs | 293750 | Prostaglandins, thromboxanes & leukotrienes, their derivatives & structural analogues |
| APIs | 293790 | Hormones, prostaglandins, thromboxanes & leukotrienes, natural/reproduced by synthesis(excl. of 2937.11-2937.50); derivatives & structural analogues thereof, including chain modified polypeptides, used primarily as hormones |
| APIs | 293810 | Rutoside (rutin) & its derivatives, natural/reproduced by synthesis |

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| APIs | 293890 | Glycosides, other than rutoside (rutin) & its derivatives, natural/reproduced by synthesis, & their salts, ethers, esters & other derivatives |
| APIs | 293911 | Concentrates of poppy straw; buprenorphine (INN), codeine, dihydrocodeine (INN), ethylmorphine, etorphine (INN), heroin, hydrocodone (INN), hydromorphone (INN), morphine, nicomorphine (INN), oxycodone (INN), oxymorphone (INN), pholcodine (INN), thebacon |
| APIs | 293919 | Alkaloids of opium (excl. of 2939.11) & their derivatives; salts thereof |
| APIs | 293920 | Alkaloids of cinchona&their derivatives; salts thereof |
| APIs | 293930 | Caffeine & its salts |
| APIs | 293941 | Ephedrine & its salts |
| APIs | 293942 | Pseudoephedrine (INN) & its salts |
| APIs | 293943 | Cathine (INN) & its salts |
| APIs | 293949 | Ephedrines & their salts, other than ephedrine, pseudoephedrine (INN) & cathine (INN) |
| APIs | 293951 | Fenetylline (INN) & its salts |
| APIs | 293959 | Theophylline & aminophylline (theophylline-ethylenedia-mine) & their derivatives (excl. of 2939.51); salts thereof , n.e.s. |
| APIs | 293961 | Ergometrine (INN) & its salts |
| APIs | 293962 | Ergotamine (INN) & its salts |
| APIs | 293963 | Lysergic acid & its salts |
| APIs | 293969 | Alkaloids of rye ergot & their derivatives (excl. of 2939.61-2939.63); salts thereof |
| APIs | 293991 | Cocaine, ecgonine, levometamfetamine, metamfetamine (INN), metamfetamine racemate; salts, esters & other derivatives thereof |
| APIs | 293999 | Vegetable alkaloids, natural/reproduced by synthesis, & their salts, ethers, esters & other derivatives (excl. of 2939.11-2939.91) |
| APIs | 294000 | Sugars, chemically pure, other than sucrose, lactose, maltose, glucose&fructose; sugar ethers, sugar acetals&sugar esters,& their salts (excl. of 29.37/29.38/29.39) |
| APIs | 294110 | Penicillins & their derivatives with a penicillanic acid structure; salts thereof |
| APIs | 294120 | Streptomycins & their derivatives; salts thereof |
| APIs | 294130 | Tetracyclines & their derivatives; salts thereof |
| APIs | 294140 | Chloramphenicol & its derivatives; salts thereof |
| APIs | 294150 | Erythromycin & its derivatives; salts thereof |
| APIs | 294190 | Antibiotics & their derivatives (excl. of 2941.10-2941.50); salts thereof |

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| *Category* | *HS 6- digit* | *Description* |
| Bulk Medicines | 300310 | Medicaments containing penicillins/derivatives thereof with a penicillanic acid structure/streptomycins/their derivatives, not put up in measured doses/forms/packagings for RS |
| Bulk Medicines | 300320 | Medicaments consisting of 2/more constituents, containing other antibiotics (excl. of 3003.10), not put up in measured doses/forms/packagings for RS |
| Bulk Medicines | 300331 | Medicaments containing insulin, not put up in measured doses/forms/packagings for RS |
| Bulk Medicines | 300339 | Medicaments containing hormones/other products of 29.37 but not containing antibiotics (excl. meds. containing insulin), not put up in measured doses/forms/packagings for RS |
| Bulk Medicines | 300390 | Medicaments (excluding goods of heading 30.02, 30.05/30.06/of 3003.10-3003.40) consisting of two/more constituents which have been mixed together for therapeutic/prophylactic uses, not put up in measured doses/in forms/packings for retail sale |
| Bulk Medicines | 300340 | Medicaments containing alkaloids/derivatives thereof but not containing hormones/other products of 29.37/antibiotics, not put up in measured doses/forms/packagings for RS |