News Bulletin

From the Desk of President

Dear Friends,

Welcome to the February 2025 edition of the BDMAI News Bulletin!

We appreciate your engagement with the January edition and look forward to your valuable feedback and suggestions to make this bulletin even more beneficial for our members.

I am pleased to share that last month, we successfully organized two significant seminars. The first was an interactive session with the USP team, where QC, QA, and R&D executives from our member companies discussed challenges in supplying quality APIs to domestic, EU, US, and ROW markets. The second seminar, focused on Pharma SMEs, was conducted in collaboration with FIEO and Pharmexcil. Both events were well-attended and highly informative.

This month, we are planning a seminar on the Implementation of Schedule M, where senior officials from CDSCO, Delhi, and Hyderabad will be invited. More details will be shared by our office

Another important development is BDMAI's collaboration with the Telangana Council of Higher Education through a MoU. This initiative will provide direct access to over 15,000 colleges in Telangana, helping to raise awareness about the pharma industry, promote our training center among students, offer skill-based training, and enhance employability opportunities with our member companies.

Additionally, I would like to draw kind attention of all members that BDMAI is authorized to receive CSR funds for training and Technology Development Center. An appeal was made during last AGM to all member companies for allocating small portion say up to 5% of their CSR budgets to BDMAI. Your support will play a crucial role in imparting life sciences skills to young professionals at our training center which will eventually benefit our Industries.

We look forward to your continued participation and support.
With best regards,

R K Agarwal
National President

In this newsletter you can expect:

Global News in Short

BDMAI Activities

Members Achievements

Technical & Commercial Articles

APIs Imports & Export Data

Merck unveils new cyber-physical trust platform at CES 2025

Merck has launched the beta version of M-Trust, a pioneering cyber-physical trust platform, at CES 2025 to tackle product safety, traceability, and counterfeiting issues. M-Trust is a first-to-market, cyber-physical trust platform that enhances product traceability and authenticity by digitally empowering human capabilities in quality control processes

Pharma Times – 7.1.25

NVIDIA starts 2025 by announcing a trio of partnerships and a research collaboration to boost healthcare sector presence.

US-based Candid Therapeutics has signed another T-cell engager (TCE) partnership, this time with Chinese biotech WuXi Biologics for the global rights to a preclinical asset. Under the deal, Candid will have exclusive global rights to a tri-specific TCE discovered by WuXi using its WuXiBody platform. The Chinese company is set to receive an undisclosed upfront payment, as well as development and sales milestones totalling up to $925m. In moves that continue to strengthen its affiliation with the healthcare industry, NVIDIA has added three new companies to its growing list of AI-based partnerships. The tech company has partnered with clinical research services company IQVIA, genomics specialist Illumina, and Mayo Clinic. Along with a collaboration with research organisation Arc Institute, the collaborations were announced during the JP Morgan Healthcare Conference on 13 January.

Pharmaceutical Technologies 13.1.25

GSK acquires IDRx in $1.15bn deal

IDRx's lead candidate IDRX-42 is being investigated in a Phase I/IIb trial in patients with advanced gastrointestinal stromal tumours. GSK has announced a definitive agreement to acquire IDRx, a US-based biotechnology company specialising in treatments for gastrointestinal cancers, for up to $1.15bn in cash, marking the first deal of the 2025 JP Morgan Healthcare Conference.

Pharmaceutical Technologies 13.1.2025

FDA beats EMA to most approved new drugs in 2024

Key differences occurred in neurological indications courtesy of Kisunla and Cobenfy. On 15 January, the two agencies released respective lists of medicines approved last year. The FDA approved 50 novel drugs that contained an active ingredient not previously approved by the agency,

whilst the EMA authorised 46 new medicines.

Pharma Technologies 15.1.2025

Johnson & Johnson acquires Intra-Cellular Therapies

The deal would be the biggest biotech transaction in more than a year. Johnson & Johnson (J&J) has announced it will acquire Intra-Cellular Therapies, a company specialising in central nervous system disorder treatments.

Pharmaceutical technologies 13.1.2025

UK sees 70% increase in phase I advanced therapy clinical trials in 2024

UK experienced a notable increase in advanced therapy clinical trials in 2024, reaching 187 ongoing trials. This marks a 7% rise from the previous year. Particularly, phase I trials saw an approximate 70% increase, growing from 24 to 41.

Pharma Times 20.1.2025

FDA adds boxed warning to multiple sclerosis drugs after anaphylaxis cases

The FDA reported that six patients died after being injected with Teva's Copaxone or Sandoz's Glatopa. The US Food and Drug Administration (FDA) is adding the risk of anaphylaxis to a new boxed warning of glatiramer acetate, a medicine for multiple sclerosis (MS). The agency issued the warning about the rare but serious risk of allergic reaction to the medicine, known under the brand names Copaxone and Glatopa, via a drug safety communication on 22 January. The products already have warnings of immediate post-injection reaction, chest pain, localised fat loss, and immune response modification, as per the drugs' labels.

Pharma Technologies 21.1.2025

Tris Pharma announces positive results from ALLEVIATE-1 trial of cebranopado

Phase 3 trial shows promising pain relief for acute pain patients

Tris Pharma, Inc. has announced positive results from its ALLEVIATE-1 phase 3 clinical trial evaluating cebranopadol for treating moderate-to-severe acute pain following abdominoplasty surgery. The trial achieved its primary endpoint of significantly reducing pain intensity compared to placebo.

Pharma Times 23.1.2025

Indonesia, India sign MOUs for cooperation in Health, traditional Medicine,
A MOU was signed in the field of Traditional Medicine Quality /assurance between Pharmacopeia Commission for Indian medicine and Homeopathy, which comes under ministry of AYISH and the Indonesia Food and Drug Authority
Health World 26.1.2025

Sonnet BioTherapeutics secures EU patent for FHAB technology

The patent will be effective until February 2038.

The patent, Albumin Binding Domain Fusion Proteins No EP3583125 B1, encompasses therapeutic fusion proteins that utilise F_HAB for the targeting and retention of tumours, and offers extended pharmacokinetics.

Pharma Technology 29.1.2025

Zydus announces USFDA Orphan Drug Designation for Usnoflast in ALS treatment

Orphan drug designation offers development incentives and potential market exclusivity

Zydus has announced that the USFDA has granted Orphan Drug Designation (ODD) to Usnoflast, a novel oral NLRP3 inhibitor, for the treatment of amyotrophic lateral sclerosis (ALS). he designation provides eligibility for development incentives, including tax credits, user fee exemptions, and potential seven-year marketing exclusivity upon FDA approval.

Pharma Times 23.1.2025

Cipla to invest about Rs. 415 crore in South African subsidiary

Pharma major Cipla Ltd on Monday said it will invest about ZAR 900 million (nearly Rs415 crore) in equity share capital of its South African arm Cipla Med pro South Africa Proprietary Ltd. Cipla Med pro South Africa Proprietary Ltd (CMSA), is a wholly-owned subsidiary of Cipla, and is the holding firm for the group operations in South Africa. The group is involved in the manufacturing, marketing, and supply of pharmaceutical products. “The investment will be utilized to reduce inter-group debt and improve the capital structure of CMSA and its subsidiaries,”Cipla said in a regulatory filing.

Business Standard 4.2.2025

Lupin gets USFDA nod for generic HIC drug

Drug maker Lupin on Monday said it has received approval from the US health regulator to market a generic medication for Human Immunodeficiency Virus. The Company has received tentative approval from the US Food and Drug Administration (USFDA) for Darunavir, Cobicistat, Emtricitabine, and Tenofovir Alafenamide tablets, the company said in a statement. The company’s product has been found to be therapeutically equivalent to the reference listed drug Symtuza tablets, 800 mg/150 mg/200 mg/10 mg of Janssen Produtcs, LP, it added. Lupin is the exclusive first-tofile for this Darunavir, Cobicistat, Emtricitabine, and Tenofovir Alafenamide tablets had estimated annual sales of USD 1,374 million in the US. Shares of Lupin were trading 1.29 per cent down at Rs.2,028.70 apiece on BSE.

Pioneer 4.2.2025

Association Activities

Happy to share that Sainor Laboratories Pvt Ltd, Hyderabad on 7th January 2025, donated Rs. 25 lakhs (Rupees Twenty Five lakhs) to BDMAI to undertake training and skill development activities at our Technology and Training Center Sri S Pullaiah Naidu, Sri Ch A P Ramaswara Rao, Sri Tata Rao, Sri Vara Prasad are present in the cheque presentation ceremony. Sri R K Agarwal, National President received the cheque on behalf of Association

On 9th January 2025, BDMAI organized an interactive meeting with USP India team. USP is under the process of reviewing the US Pharmacopiea for 2025-30 cycle . As part of this exercise, USP India team is collaborating with various industry associations to understand the challenges faced by industry in supplying quality APIs. 35 delegates from member industries have attended and interacted with the USP team.

BDMAI, in association with Pharmexcil and FIEO organized a seminar on Role of SMEs in Pharma Industry ‘ on 24th January, 2025. Senior functionaries Director General of Foreign Trade, Drug Control Administration, Telangana BDMAI, Pharmexcil, FIEO, CSB Bank, CRISIL and several industry professionals participated and deliberated issues faced by Pharma SME industries. CRISIL made a detailed presentation on opportunities available for SME sector of Pharma.

Members' Achievements

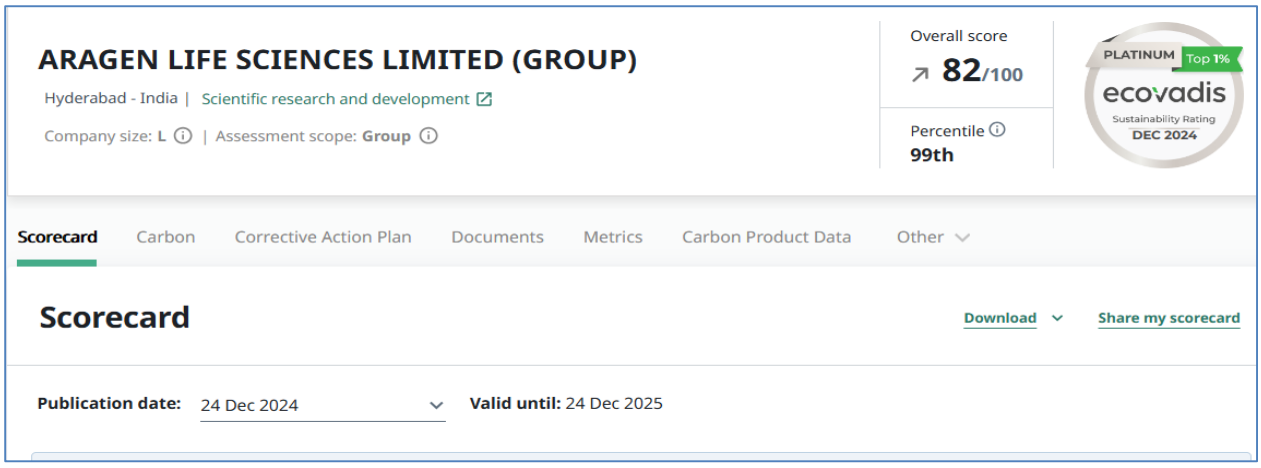
Aragen Achieves Platinum Status in EcoVadis 2024 Sustainability Assessment

Aragen Life Sciences, a global leader in providing end-to-end services for the pharmaceutical and biotech industries, is proud to announce that it has been awarded the prestigious **Platinum rating** in the 2024 EcoVadis Sustainability Assessment. This recognition places Aragen among the top 1% of companies evaluated for their commitment to sustainability and corporate social responsibility (CSR).

Key Highlights of Aragen's Sustainability Achievements:

- **Environmental Stewardship**: Implementation of energy-efficient technologies and resource management systems to minimize environmental impact.
- **Ethical Practices**: Rigorous adherence to ethical business practices and corporate governance standards, ensuring transparency and accountability.
- **Employee Welfare**: Commitment to creating a safe and inclusive work environment, promoting employee wellbeing and career development.
- **Sustainable Supply Chain**: Focus on responsible sourcing and ensuring sustainability across its global supply chain.

Aragen's Platinum rating underscores its leadership in corporate sustainability and reinforces its position as a responsible partner to clients in the life sciences sector. The company remains committed to evolving its practices and making lasting contributions to a more sustainable future.



Pharma Forecast 2025: Industry leaders share their predictions

There are so many sections in the pharma industry that are constantly growing each year, such as AI, sustainability and regulations - how do leaders in pharma see these progressing even further in 2025?

AI

Ana Pedro Jesuíno, associate director of marketed product safety, IQVIA:

In 2025, pharmacovigilance will undergo a bold transformation as AI and Machine Learning (ML) move beyond buzzwords to become the backbone of proactive safety management, reshaping how the pharmaceutical industry engages with real-world data and patient outcomes.

Chris Moore, European president of life sciences firm Veeva:

European biopharmas that prioritise clean, harmonised data will unlock AI's potential in 2025, leveraging regulatory frameworks like the EU AI Act to drive safe and scalable AI adoption.

AI will revolutionise the review process of medical, legal, and regulatory (MLR) content that biopharmas produce, ensuring faster review cycles and better compliance.

Adoption of advanced analytics AI will depend on investment in upskilling teams, and ensuring AI tools enhance decision-making rather than adding unnecessary complexities.

Marcela Miño, global head of lifecycle management and regulatory affairs, IQVIA:

In 2025, AI will reshape pharmacovigilance (PV) and regulatory affairs, transforming compliance into a proactive strategy that drives efficiency, enhances global agility, and redefines resource allocation.

Sustainability

Louise Madden, CEO, H.E.L Group:

2025 marks a pivotal shift in industrial biotechnology as waste byproducts like CO2 and syngas emerge as preferred feedstocks for biomanufacturing. This transition, driven by mounting pressure for decarbonisation, will revolutionise how we produce sustainable aviation fuels (SAF), vaccines, and alternative proteins. High-pressure benchtop bioreactors which maximise substrate availability and volumetric productivity have opened opportunities for large-scale sustainable manufacturing.

Industries integrating advanced bioreactors into their process development will unlock enhanced carbon conversion efficiencies and titres, whilst reducing consumable costs with improved volumetric productivity. The utilisation of automation will play a crucial role in the safety and use of gaseous feedstocks, as smart control systems ensure reproducibility across scales. This technological convergence will significantly reduce production costs, making gaseous carbon-based biomanufacturing comparable and economically competitive with traditional methods

Funding / Cost Saving

Stuart Rose, CEO, OBN:

Predictions from Jefferies of an increase in the public markets should see a several year stagnation of IPOs go into reverse. Probably not dramatic but the sentiment shift should bolster confidence and this, in turn, will create a helpful sentiment for private investment (boosting this also). The latter is critical lifeblood for the smaller companies and the sector needs it badly to leverage the excellent innovation that continues.

Richard J Cuthbert PhD, product manager, flow and antibody business, Bio-Rad Laboratories –

The pharmaceutical and biopharmaceutical industries are undergoing significant restructuring efforts, driven by economic challenges and the need to adapt to evolving market conditions. Cost-saving and restructuring plans have focused on creating leaner, more agile organisations. Automation and outsourcing optimise costs and enhance scalability, allowing companies to adjust capacity with fluctuating demands without fixed costs.
Outsourcing has also become a strategic approach to manage resource-intensive tasks more efficiently, particularly in complex and resource-intensive process such as antibody discovery. By outsourcing, companies can access cutting-edge technologies and expertise without the need for significant in-house investment.

Sabika Rizvi, director of aggregate reporting and benefit risk management services, IQVIA:

In 2025, the pharmacovigilance field will see technology's role expand beyond cost-cutting to redefine operational efficiency and global compliance, but success will hinge on a bold recalibration of the human-machine balance.

Clinical Trials

Jim DiCesare, vice president, financial management solutions at IQVIA Technologies:

To ensure participant satisfaction, retention, diversity and inclusivity is maintained to the highest levels, clinical trials will need to approach their participants with a "white glove" service mentality. To do so, clinical trials will leverage advanced digital technologies to ensure the payment process is done fairly and efficiently.

Clinical trials must evaluate and ensure that their cybersecurity protocols are up-to-date and scalable as they involve more participants for larger and more complex studies.

Dr Brian Burke, chief commercial officer, Tozaro:

The effectiveness of autologous therapies for the treatment of cancer has been shown again and again. However, the number of patients successfully treated with these therapies is generally lower than most people assume - with only 30 to 40 thousand patients treated globally since the inception of CAR-T as a therapy modality. Two significant factors for this low figure are cost and logistics. As a result, allogeneic treatments have been heralded as a more cost-effective option, although progress towards routine use of allogeneic cell platforms has been slow. There is a possibility these therapies may be bypassed altogether by in vivo CAR-T treatments using viruses - with a record number of clinical trials already underway. One recent highlight in this space saw Interius Biotherapeutics announce the first use of durable in vivo CAR therapy in the clinic to treat B-cell malignancies using a lentiviral vector. It's certainly an interesting race in this space!

Patrick Brady, global head of therapeutic innovation and regulatory science, IQVIA:

The regulatory landscape in 2025 will continue to reflect progress made by agencies like the FDA and EMA in fostering clinical trial innovation. Initiatives such as the FDA's Center for Clinical Trial Innovation (C3TI) and the EMA's Accelerating Clinical Trials (ACT EU) program have set the stage for global collaboration, aiming to make clinical research more efficient and attractive.

Drug Discovery

Dr Philip Simister, head of science & entrepreneur advocate, OBN:

The success of GLP-1 receptor agonists for type 2 diabetes and obesity control could see competitor weight-loss drugs being pushed

harder. Microbiome and healthspan/longevity research is expected to grow with more companies entering the space. Neurodegenerative research for major illnesses characterised by dementia (Alzheimer's and Parkinson's diseases) should be boosted by increased early-stage funding.

Shortening of drug discovery pipelines, from early discovery to lead optimisation, will more likely be possible with the implementation of machine learning/deep learning methods in workflows. For comprehensive integration, this will necessitate better data capture and management practices, and a growth in end-to-end lab automation for standardised data acquisition.

Source: European Pharmaceutical Manufacturer

Clinical Formulation and Manufacturing: A Strategic Leap for Indian Bulk Drug Manufacturers

By Ajay Babu Pazhayattil

Venturing into clinical formulation development and manufacturing presents Indian bulk drug manufacturers with an attractive opportunity to diversify and access innovators with value-added services beyond venturing into generic drug formulations. The strategic move aligns with the increasing demand for specialized clinical formulation services. Clinical trials hinge on the reliable production and timely delivery of investigational products. However, contract development and manufacturing organizations (CDMOs) offering clinical formulations often encounter significant challenges, including maintaining confidentiality, navigating ambiguous regulatory/GMP requirements, and addressing logistical delays.

Tackling some hurdles requires defining and adhering to phase-appropriate Good Manufacturing Practices (GMPs) tailored to specific clinical development stages, ensuring compliance and efficiency. Phase-appropriate GMP criteria [Table 1] are essential for positioning manufacturing practices with specific clinical trial phases. Early-stage trials prioritize safety assessments, while later phases emphasize product consistency and quality. The approach should also ensure packaging, labelling, and distribution compliance.

Table 1: An Example of a Phase-Appropriate Strategy

GMP Risk Scale

Category	**1**	**2**	**3**	**4**	**5**
Manufacturing Process	Early phase formulation batches (Stage 1a-QbD)	Clinical, submission, stability, demonstration batches (Stage 1a-QbD)	Full-scale scale-up batches (Stage 1b-QbD)	Process Performance Qualification batches (Stage 2b-PPQ)	Commercial batches (Stage 3a-CPV)
Analytical Method	Non-Validated/ Qualified	Validated/ Qualified (except intermediate precision and robustness)	Fully Validated/ Qualified	Fully Validated/ Qualified	Fully Validated/ Qualified

Internally developed or client-developed API, an efficient onboarding into the clinical trial formulation and manufacturing facility is pivotal. The process begins with a

thorough data assessment and banding, forming the foundation for safety assessments, risk mitigation steps, and determining the need for engineering controls. Once on-boarded, optimal project planning ensures the seamless execution of clinical formulation and batch manufacturing steps. Navigating the complexities of clinical formulation and shipment requires addressing the potential issues such as delays from vendors, the need for formulation optimization, issues associated with shipping them to clinical trial locations, and quality control concerns, all of which may be addressed by implementing proactive measures. Supplier relationships are typically maintained with existing reliable partners alongside maintaining a robust inventory- an area where bulk drug manufacturers excel due to their extensive expertise. The use of dependable carriers and monitoring the shipments to prevent delays is also critical. Using advanced phase-change materials to maintain temperature/RH controls can ensure product integrity during transit is important. With the newer shipping and tracking technologies, bulk drug manufacturers are well-positioned to overcome such product-specific challenges.

Clinical trial regulations demand meticulous attention to labelling, coding, and storage conditions. Blinded trials, in particular, require secure coding systems to maintain blinding while allowing for rapid identification in emergencies. Serialization and traceability infrastructure enhance operational efficiency, ensuring regulatory and logistical standards adherence. By implementing specific labelling and coding procedures and augmenting existing capabilities, more Indian bulk drug manufacturers can start offering innovators competitive and consistent clinical formulation development and manufacturing services alongside their existing API Contract Research and Manufacturing Services (CRAMS).

Incorporating clinical formulation and manufacturing represents a natural and promising growth avenue for bulk drug manufacturers to expand their reach and service offerings. By addressing the nuances of clinical trial formulation requirements, ensuring adherence to phase-appropriate GMP, and leveraging their expertise in supply chain management, Indian bulk drug manufacturers can establish themselves as a formidable player in the global clinical formulation supply landscape. The strategic diversification can position them to meet the growing demand for high-quality clinical formulation services, driving true innovation and growth in the pharmaceutical sector.

References:

1. Ajay Babu Pazhayattil, Michelle Gischewski, Salman Pathan (2023), *Outsourcing and Phase-Appropriate GMP For Clinical Manufacturing Needs,* Outsourced Pharma. https://www.outsourcedpharma.com/doc/outsourcing-and-phase-appropriate-gmp-for-clinical-manufacturing-needs-0001
2. Ajay Babu Pazhayattil, Payal Shah (2023), *Fundamentals of Pharmaceutical and Biologics Regulations: A Global Perspective, Chapter 12: Coordinating Drug Supply for Clinical and Non-Clinical Development,* Regulatory Affairs Professionals Society (RAPS). https://www.raps.org/products/fundamentals-of-pharmaceutical-and-biologics-regulations-a-global-perspective

CUMULATIVE EXPORTS TILL NOVEMBER 2024

BULK DRUGS, DRUG INTERMEDIATES

Rs. In lakhs

S.No.	HSCode	Commodity	Nov 2023 (R	Nov 2024 (F)	%Growth	Apr-Nov 2023 (R)	Apr-Nov 2024 (F)	%Growth
1	29420090	OTHER DILOXANIDE FUROATE, CIMETIDINE, FAMOTIDINE NES	64151	65941	2.79	598419	582598	-2.64
2	29349990	OTHER	33453	43819	30.98	264329	320067	21.09
3	29419090	OTHER ANTIBIOTICS	39588	37099	-6.29	304693	309893	1.71
4	29411030	AMOXYCILLINE AND ITS SALTS	8721	10516	20.59	69108	104265	50.87
5	29333929	Other	10673	13098	22.72	84446	90124	6.72
6	29397900	OTHER	5589	8528	52.58	50809	67098	32.06
7	29372900	OTHR STEROIDAL HORMONS THR DRVTVS AND STRCTL ANLGES	4746	7188	51.44	57961	62572	7.96
8	29415000	ERTHROMYCIN AND ITS DRVTVS SLTS THEREOF	7091	4923	-30.57	63694	56953	-10.58
9	29362920	NCTNC ACID AND NCTNMD(NIACINAMIDE/NIACINE	4481	6159	37.45	49665	50790	2.26
10	29411090	OTHER PENICILLINS AND THR DRVTVS WTH A PENTCILLIANIC ACID STRCTR SLTS THEREOF	5759	7590	31.79	53029	50286	-5.17
11	96020030	GELATIN CAPSULES,EMPTY	6100	5568	-8.71	46795	48245	3.1
12	29420012	IBUPROFANE	4619	3935	-14.8	51395	40910	-20.4
13	29054400	D-GLUCITOL (SORBITOL)	3464	4906	41.64	33383	35259	5.62
14	29393000	CAFFEINE AND ITS SALTS	3697	3194	-13.62	26477	32012	20.91
15	17023010	GLUCOSE LIQUID	3849	4069	5.71	35264	30036	-14.82
16	29389090	OTHER GLYCOSIDES NTRL/RPRDCD BY SYNTHSIS ANDTHR SLTS ETHRS DRVTVS	1857	1330	-28.36	27304	23360	-14.44
17	29369000	OTHER, INCL. NATURAL CONCENTRTS	2527	3941	55.95	21647	23221	7.27
18	29371200	INSULIN AND ITS SALTS	3161	1456	-53.96	22422	23198	3.46
19	29395900	OTHER THEOPHYLLINE AND AMINOPHYLLINE THR DRVTVS, SALTS	2553	2770	8.47	21016	19992	-4.87
20	29372200	HALGNTD DRVTVS OF CORTI COSTEROIDAL	2943	1570	-46.66	18931	19379	2.36
21	29359011	SULPHAMETHOXAZOLE	2522	2217	-12.11	21377	19123	-10.54
22	29371900	OTHER POLYPEPTIDE HORMONES THR DTVTVS AND STRCTL ANLGES	910	1185	30.16	14144	18152	28.34
23	29214600	AMFETAMINE BENZFETAMINE ETC THR SALTS	39	2858	7,296.05	4492	16487	266.98
24	29379090	OTHER	540	1606	197.26	18396	15871	-13.73
25	29411020	AMPICILLINE AND ITS SALTS	383	2380	521.68	12536	14934	19.13
26	29372300	OESTROGENS AND PROGESTOGENS	1591	1497	-5.89	9239	13354	44.54
27	29411040	CLOXACILLINE AND ITS SALTS	1467	2202	50.08	13441	13272	-1.25
28	29224910	AMINO ACETIC ACID (GLYCINE)	1279	1953	52.68	6983	13265	89.97
29	29362100	VITAMINS A AND THEIR DERIVATIVES	1081	1578	45.93	8257	12779	54.77

30	29379020	AMINO-ACID DERIVATIVES	1003	360	-64.11	11744	12425	5.8
31	29362940	VITAMIN D	720	1815	152.22	4591	12402	170.16
32	29362290	OTHER VITAMIN B1I AND ITS DRIVATIVES	414	807	94.82	4837	11966	147.4
33	29419030	CIPROFLOXACINE AND ITS SALTS	1320	1958	48.34	11574	11753	1.55
34	29339100	ALPRA ZOLAM, CAMAZEPAM AND OTHER CMPNDS OF ZEPAM, SALTS THEREOF	1294	1473	13.79	9206	11565	25.62
35	29362800	VITAMIN E AND ITS DERIVATIVES	955	939	-1.65	8750	10756	22.92
36	29420011	CEFADROXIL	1917	262	-86.32	8454	10499	24.19
37	29362990	OTHER VITAMINS AND THR DRVTVS	1763	1519	-13.81	10249	10488	2.32
38	29225021	FRUSEMIDE	1112	535	-51.9	9850	10480	6.4
39	17023031	DEXTROSE,SOLID	1299	928	-28.56	11717	9153	-21.88
40	29398000	OTHER	1359	1688	24.21	13439	8913	-33.68
41	29349920	MORPHOLINE	555	924	66.49	6037	8471	40.32
42	29332920	METRONIDAZOLE METRONIDIAZOLE BENZOATE	972	957	-1.61	10375	8083	-22.09
43	29154010	MONOCHLOROACETIC ACID,THR SALTS AND ESTERS	770	1250	62.45	6564	7992	21.77
44	29332950	ALBENDAZ0LE	503	834	65.75	5758	7064	22.67
45	29420034	FAMOTIDINE	605	694	14.62	7533	7031	-6.66
46	29335920	TRIMETHOPRIM	577	717	24.29	7183	7002	-2.51
47	29051420	SALBUTAMOL SULPHATE	672	907	34.95	5324	6888	29.37
48	29372100	CORTISONE,HYDROCORTISONE,PREDNISONE (DEHY-DROCORTISONE)AND FREDNISOLONE AND PRDNSLN(DEHYDROHYDROCORTISONE)	1021	638	-37.46	6722	6869	2.18
49	17023020	GLUCOSE SOLID	895	959	7.24	6535	6537	0.02
50	29231000	CHOLINE AND ITS SALTS	769	937	21.88	7104	6248	-12.05
51	29215130	P-PHENYLENEDIAMINE	362	407	12.51	7231	6093	-15.74
52	29362210	VITAMIN B1I(THIAMINE, ANEURINE) AND ITS SALT	687	1365	98.71	6271	6082	-3.02
53	29420027	ATENOLOL, PROPRONALOL	1195	624	-47.8	6946	6068	-12.64
54	29362310	VITAMIN B2 (RIBOFLAVIN, LACTOPLAVIN) AND ITS SALTS	284	825	190.18	3486	6051	73.59
55	29419020	CEPHALEXIN AND ITS SALTS	753	283	-62.44	4849	5927	22.25
56	29181520	SODIUM CITRATE	830	969	16.71	9423	5851	-37.91
57	29362700	VITAMIN C (ASCORBIC ACID) AND ITS DRVTVS	398	534	34.14	4422	5807	31.33
58	29420014	RANITIDINE	857	1026	19.77	4174	5708	36.75
59	29072200	HYDROQUINONE (QUINOL) AND ITS SALTS	848	1311	54.63	6010	5663	-5.79
60	29419011	RIFAMPICIN	1505	1397	-7.15	4823	5530	14.67
61	29322010	COUMARIN, METHYLCOUMARINS AND ETHYLCOUMARINS	678	518	-23.62	4883	5494	12.51
62	29331100	PHENAZONE (ANTIPYRIN) AND ITS DERIVATIVES	797	265	-66.82	4430	5414	22.22
63	29181320	METROPROLOL TARTRATE	567	258	-54.41	5424	5206	-4.01

64	29215120	M-PHENYLENEDIAMINE (M-DIAMINOBENZENE)	845	965	14.18	4080	5063	24.12
65	30044990	OTHER	647	551	-14.79	4576	4967	8.54
66	29419019	OTHER RIFAMPICIN AND ITS SALTS	226	171	-24.39	2293	4959	116.22
67	29071930	THYMOL	606	321	-47.07	3158	4812	52.37
68	29171940	FERROUS FUMERATE	492	753	52.97	4547	4762	4.73
69	29225024	D0MPERID0NE	1213	357	-70.52	5561	4437	-20.21
70	29332940	DIMETRIDAZOLE	335	383	14.26	2397	4310	79.81
71	29181610	CALCIUM GLUCONATE	423	755	78.54	3596	4274	18.83
72	29051410	ETHAMBUTOL, ETHAMBUTOL HCL	322	250	-22.47	4676	4232	-9.5
73	29182310	METHYL SALICYLATE	385	529	37.37	3998	4223	5.63
74	29362930	VITAMIN K (MENAPHTHONUM B.P.)	98	1271	1,195.07	315	3935	1,151.28
75	29349100	AMINOREX, BROTIZOLAM AND OTHER LIKE CMPNDS, SALTS THEREOF	47	568	1,118.55	3142	3753	19.44
76	29242960	PYRAZINAMIDE(PYRAZINE CARBOXAMIDE)	358	470	31.29	2847	3362	18.1
77	29420025	AMITRYPTYLINE HCL	322	526	63.13	2532	3359	32.69
78	29420033	OXYCLOZANIDE	415	373	-10.12	2913	3344	14.77
79	29333914	CHLORPHENIRAMINE MALEATE	979	388	-60.36	4593	3190	-30.55
80	29054300	MANNITOL	281	161	-42.75	2417	3149	30.29
81	29163120	BENZYL BENZOATE	279	215	-22.96	1537	3138	104.12
82	30044930	CODEINE AND DERIVATIVES, WITH OR WITHOUT EPHIDRINE HYDROCHLORIDE	108	0	-99.86	288	3104	976.89
83	29362910	FOLIC ACID (VITAMIN B9)	348	391	12.2	2830	3082	8.89
84	29359013	SULPHADIAZINE	288	455	57.74	2772	3071	10.77
85	29332930	MEBENDAZOLE	194	318	64.15	2259	2946	30.38
86	29420021	TIMOLOL MALEATE	86	254	196.48	1030	2800	171.91
87	29335300	ALLOBARBITAL AND OTHR BARBITAL COMPNDS ANDITS SALTS	291	320	9.81	2756	2535	-8.02
88	30044920	CAFFEIN AND SALTS THEREOF	151	196	29.98	1176	2473	110.3
89	29362690	OTHER VITAMIN B12 AND ITS DERIVATIVES	602	329	-45.37	2392	2314	-3.26
90	29241100	MEPROBAMATE (INN)	7	152	2,128.27	123	2186	1,670.73
91	30044910	ATROPIN AND SALTS THEREOF	189	193	1.98	2266	2138	-5.65
92	29333922	Imazethapyr (ISO)		307		2912	2049	-29.64
93	29332910	TINIDAZOLE	90	343	282.11	1435	1902	32.58
94	29309040	L-CYSTINE (ALPHA-AMINO BETA-THIO PROPIONICACID)-SULPHUR CONTAINING AMINO ACID	97	393	304.59	2164	1770	-18.21
95	29181510	POTASSIUM CITRATE	4	195	5,428.49	1444	1694	17.27
96	29335940	1 - AMINO-4METHYL PIPERAZINE	1711			4330	1622	-62.54
97	29182110	SALICYLIC ACID	76	164	116	986	1577	60.01
98	29182120	SODIUM SALICYLATE	220	112	-49.25	1393	1530	9.83
99	29394900	OTHER	117	215	84.28	1138	1383	21.55
100	29414000	CHLORAMPHENICOL AND ITS DRVTVS SLTS THEREOF	299	179	-39.92	1867	1337	-28.41
		India's Total Export of BULK DRUGS, DRUG INTERMEDIATES	**288765**	**305350**	**5.74**	**2517096**	**2550626**	**1.33**

Source: Dept of Commerce website

IMPORTS

BULK DRUGS, DRUG INTERMEDIATES

S.No.	HSCode	Commodity	Nov 2023 (R	Nov 2024 (F)	%Growth	Apr-Nov 2023 (R)	Apr-Nov 2024 (F)	%Growth
1	17023010	GLUCOSE LIQUID	2	0	-95.47	610	35	-94.32
2	17023020	GLUCOSE SOLID	2	35	1,540.45	301	432	43.46
3	17023031	DEXTROSE,SOLID	8	0	-96.57	332	423	27.59
4	17023039	DEXTROSE OTHER THAN SOLID	38	100	161.13	601	542	-9.94
5	17024039	DEXTROSE OTHER THAN SOLID	12	25	101.9	13	95	651.14
6	29051410	ETHAMBUTOL, ETHAMBUTOL HCL	1	357	34,152.97	1	2181	1,46,519.32
7	29051420	SALBUTAMOL SULPHATE	4	43	1,112.12	52	172	228.65
8	29054300	MANNITOL	4072	3420	-16	32286	29211	-9.53
9	29054400	D-GLUCITOL (SORBITOL)	616	720	16.86	5484	6118	11.56
10	29071930	THYMOL	3	6	108.85	43	51	18.96
11	29072200	HYDROQUINONE (QUINOL) AND ITS SALTS	2341	2599	11.02	19538	18367	-5.99
12	29095010	GUAIACOL	293	112	-61.77	2131	790	-62.93
13	29124930	THIACETAZONE		10			10	
14	29124940	3,4,5-TRIMETHOXY-BENZALDEHYEDE		0		746	226	-69.66
15	29154010	MONOCHLOROACETIC ACID,THR SALTS AND ESTERS	106	340	220.43	2565	1562	-39.09
16	29163120	BENZYL BENZOATE	4	50	1,127.76	636	297	-53.31
17	29163150	BENZOCAINE (ETHYLPARA-AMINO BENZOATE)		8		7	16	120.49
18	29163400	PHENYLACETIC ACID AND ITS SALTS	1206	714	-40.75	1713	3574	108.64
19	29171940	FERROUS FUMERATE	9			118	22	-81.13
20	29171970	ETH0XY METHYLENE MAL0NATE,DIETHYL MAL0NATE	1146	997	-12.99	11201	11073	-1.14
21	29181120	CALCIUM LACTATE	339			695	234	-66.33
22	29181320	METROPROLOL TARTRATE	184	181	-1.27	819	459	-43.93
23	29181510	POTASSIUM CITRATE	132	180	36.45	963	1052	9.29
24	29181520	SODIUM CITRATE	293	224	-23.62	2069	1295	-37.42
25	29181550	FERRIC AMMONIUM CITRATE		4		3	4	21.95
26	29181610	CALCIUM GLUCONATE	319	529	65.72	3814	4992	30.89
27	29182110	SALICYLIC ACID	1174	1404	19.56	13217	16079	21.66
28	29182120	SODIUM SALICYLATE	19	1	-94.45	42	33	-21.38
29	29182200	0-ACETYLSALICYLIC ACID ITS SALTS AND ESTRS	25	72	183.22	122	357	192.59
30	29182310	METHYL SALICYLATE	37	1	-96.4	1679	625	-62.79
31	29182320	AMINO SALICYLATE				13		
32	29183030	NALIDIXIC ACID				40	467	1,058.08
33	29199010	GLYCEROPHOSPHATE ACID		1			2	
34	29214236	METHYL DOPA(L-ALPHA METHYL-3, 4-DIHYDROXYPHENYLALANINE)	1052	1126	7.07	7939	7907	-0.41

35	29214600	AMFETAMINE BENZFETAMINE ETC THR SALTS	49	53	9.81	193	252	30.34
36	29215110	O- PHENYLENEDIAMINE	841	907	7.8	6411	9594	49.67
37	29215120	M-PHENYLENEDIAMINE (M-DIAMINOBENZENE)	377	251	-33.32	3190	2206	-30.84
38	29215130	P-PHENYLENEDIAMINE	373	175	-53.04	2439	2723	11.61
39	29222933	PARA ACETYL AMINOPHENOL(PARACETAMOL)	651			3946		
40	29224100	LYSINE AND ITS ESTERS SALTS THEREOF	8776	6650	-24.22	59937	67353	12.37
41	29224210	GLUTAMIC ACID	20	44	115.22	221	432	95.49
42	29224220	MONOSODIUM GLUTAMATE (AZINAMOTO)	3605	3378	-6.29	28868	34403	19.17
43	29224910	AMINO ACETIC ACID (GLYCINE)	1165	1786	53.33	7050	14986	112.56
44	29224920	N-METHYL TAURINE	213	45	-79.13	406	640	57.79
45	29225011	PARA-AMINO-SALICYLIC ACID		1		17	100	479.46
46	29225015	L-TYROSINE(P-HYDROXYPHENYLAMINE)	181	275	52.49	1689	1285	-23.93
47	29225021	FRUSEMIDE		265		3	305	10,410.81
48	29225024	D0MPERID0NE				67		
49	29231000	CHOLINE AND ITS SALTS	15	287	1,771.53	822	1624	97.56
50	29241100	MEPROBAMATE (INN)		185		212	1518	614.38
51	29242910	ACETANILIDE		935		7162	8143	13.7
52	29242960	PYRAZINAMIDE(PYRAZINE CARBOXAMIDE)	72	119	66.56	737	796	8.05
53	29242970	Pretilachlor (ISO)	51	95	86.59	249	1416	467.94
54	29251200	GLUTETHIMIDE (INN)				1		
55	29262000	1-CYANOGUANIDINE(DICYANDIAMIDE)	2349	4984	112.17	47243	43167	-8.63
56	29263000	FENPROPOREX (INN) AND ITS SALTS				1		
57	29264000	ALPHA-PHENYLACETOACETONITRILE	11	24	120.55	65	57	-11.54
58	29280010	ISONIAZID	108	81	-24.46	1578	1440	-8.78
59	29304000	METHIONINE	9782	12588	28.69	70757	96419	36.27
60	29309040	L-CYSTINE (ALPHA-AMINO BETA-THIO PROPIONICACID)-SULPHUR CONTAINING AMINO ACID	395	872	120.96	12614	9970	-20.96
61	29322010	COUMARIN, METHYLCOUMARINS AND ETHYLCOUMARINS	84	130	55.11	291	440	50.81
62	29329300	PIPERAN0L	95	370	288.85	1783	1826	2.42
63	29331100	PHENAZONE (ANTIPYRIN) AND ITS DERIVATIVES	89	80	-9.97	681	742	9.01
64	29331910	3-CARBOXY (PARA SLPHPHNYL)-5 PYRAZOLONE		0		3	118	3,556.15
65	29331920	1(2:5 DCHLR-4-SLPHPHNYL)-3-MTHYL-5-PYRAZLN				1558	61	-96.08
66	29331930	3-MTHYL-1(4-SLPHO-0-TOLUYL-5-PYRAZOLDNE)					2	

67	29331940	PHENYL-METHYL PYRAZOLONE	112	102	-8.88	418	553	32.46
68	29331950	1-PHNYL-5-PYRAZLN-3-CRBOXYLC ACD ETHYLESTR		0			0	
69	29331960	1-(M-SULPHOPHENYL)-3-PYRAZOLONE		57			231	
70	29331970	ANALGIN	230	363	57.38	1444	2248	55.61
71	29331980	0XYPHENBUTAZONE				0	11	15,767.09
72	29332910	TINIDAZOLE				58	38	-33.61
73	29332920	METRONIDAZOLE METRONIDIAZOLE BENZOATE	559	425	-24.01	3940	6534	65.85
74	29332930	MEBENDAZOLE				7	99	1,330.94
75	29332940	DIMETRIDAZOLE					98	
76	29332950	ALBENDAZ0LE	141	0	-99.72	1411	814	-42.31
77	29333914	CHLORPHENIRAMINE MALEATE				69	105	51.5
78	29333917	Chlorantraniliprole (ISO)				134		
79	29333921	Acetamiprid (ISO)				38		
80	29333922	Imazethapyr (ISO)					0	
81	29333929	Other	1570	871	-44.54	10634	11575	8.85
82	29335200	MALONYLUREA (BARBITURIC ACID) AND ITS SALS	195	286	46.4	3074	2710	-11.84
83	29335300	ALLOBARBITAL AND OTHR BARBITAL COMPNDS ANDITS SALTS		4		6	160	2,403.06
84	29335400	OTHER DERIVATIVES OF MALONYLUREA (BARBITURIC ACID), SALTS THEREOF		3		184	6	-96.7
85	29335500	LOPRAZOLAM, MECLOQUALONE, METHAQUALONE , ZIPEROL, SALTS THEREOF		0		7	1	-91.57
86	29335910	AMINOPHYLLINE(CORDOPHYLIN)		5		129	311	140.93
87	29335920	TRIMETHOPRIM				1315	191	-85.46
88	29335930	DIETHYL CARBANAZINE CITRATE				1		
89	29335940	1 - AMINO-4METHYL PIPERAZINE					10	
90	29335950	Bispyribac-sodium (ISO)				17	0	-99.1
91	29339100	ALPRA ZOLAM, CAMAZEPAM AND OTHER CMPNDS OF ZEPAM, SALTS THEREOF	150	327	118.39	1758	1408	-19.9
92	29339200	AZINPHOS-METHYL (ISO)					0	
93	29339920	Carbendazim (ISO)				1	2	112.28
94	29349100	AMINOREX, BROTIZOLAM AND OTHER LIKE CMPNDS, SALTS THEREOF	194			1442	19	-98.69
95	29349200	OTHER FENTANYLS AND THEIT DERIVATIVES				229	442	93.51
96	29349910	CHIARO THIOPHENE-2-CARBOXYL IC ACID	27	31	15.72	4348	310	-92.86
97	29349920	MORPHOLINE	682	301	-55.9	5360	3274	-38.92
98	29349990	OTHER	32583	43295	32.88	353789	369903	4.55

99	29351000	N-METHYLPERFLUOROOCTANE SULPHONAMIDE				101	19	-81.29
100	29353000	N-ETHYL-N-(2-HYDROXYETHYL) PERFLUOROOCTANE SULPHONAMIDE					2	
		India's Total Import of BULK DRUGS, DRUG INTERMEDIATES	**319893**	**320604**	**0.22**	**2482127**	**2542804**	**2.44**

Source: Department of Commerce website

Thank you

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for further improvement