ISSUE 11/2026

BDMAI BULLETIN





From the Desk of President

Dear Friends,

The Indian bulk drug industry is passing through a phase where opportunities for growth are significant, but the challenges confronting domestic manufacturers are equally demanding.

Environmental compliance and common infrastructure have become major concerns for API manufacturers, particularly MSMEs. Improper management and operational inefficiencies in CETPs and hazardous waste treatment facilities, coupled with abnormally high treatment charges imposed by certain operators, are adding significantly to manufacturers' costs. BDMAI has been actively involved in bringing transparency with respect to charges and also requesting for monitoring of these activities by the Regulatory authorities.

Affordable and reliable energy is essential for the competitiveness of the bulk drug industry, as power, steam and fuel constitute significant manufacturing costs. With growing emphasis on renewable energy, access to green power through open access should be extended to industries of all sizes. Small and medium-scale manufacturers should not be deprived of these benefits due to their voltage-level connections. Rationalising open-access policies and ensuring affordable renewable energy will help reduce costs while supporting the industry's sustainability and ESG commitments.

Rationalisation of industrial alcohol regulations is another important issue requiring attention. Industrial alcohol is essential for several pharmaceutical manufacturing processes, but the existing licensing and accounting procedures often impose considerable administrative burdens. State Governments should consider simplified annual licensing, specified quantity allocations and periodic consumption statements without compromising regulatory oversight. Permitting recovery and recycling of spent alcohol through authorised systems would further reduce waste, improve resource efficiency and support sustainable manufacturing.

BDMAI will continue to take up these matters with the concerned Central and State Government authorities and work towards practical solutions in consultation with industry stakeholders.

With warm wishes

Ch A P Rameseswara Rao
National President

In this Bulletin you can expect

Global Pharma Market Intelligence

Analysis of Bulk Drugs Exports & Imports (April-Sep)

Association Activities

Important Trade Notifications

Technical Article

Investments / Joint Ventures / Acquisitions:

Global Pharma Companies:

Company / Country	Development	Financial details / Scope	Industry significance
AstraZeneca / UK	Strategic collaboration with insitro for AI-based drug discovery	No transaction verified for the reporting period; excluded from period-specific investment totals.	AI-based discovery is an emerging pharmaceutical development area.
Esteve / Spain-China	API manufacturing investment in Shaoxing, China	Reported investment exceeds US$80 million; announcement predates the reporting period and is excluded from the period transaction list.	Strengthening of China's API and CDMO manufacturing ecosystem.
GE HealthCare / USA	Acquisition of SOFIE Biosciences	US$945 million; agreement announced on 5 October, before the reporting period.	Expansion in radiopharmaceutical manufacturing and PET imaging supply.

Indian Companies:

Date	Company / Parties	Investment / Transaction	Strategic significance
14 October	Laurus Labs – KRKA Pharma JV (Slovenia)	Laurus invested ₹107.8 crore through a rights issue in KRKA Pharma Pvt. Ltd. Its shareholding remains at 49%.	Supports the development of a finished dosage manufacturing facility in Hyderabad for domestic and international markets.
15 October	Mankind Pharma – Armed Cell Therapeutics, Belgium	Investment of €48 million for acquisition of 70% stake in Armed Cell Therapeutics.	Strategic entry into next-generation CAR-T cancer therapies, including programmes for lymphoma and

			small-cell lung cancer.
16 October	Anuh Pharma – Vanquest Pharma	Asset Transfer Agreement for acquisition of a manufacturing facility at Tarapur, Maharashtra, for ₹72.90 crore.	Expected to add 525 MT per annum capacity for APIs and intermediates.
21 October	Anuh Pharma – Vanquest Pharma	Possession of the acquired manufacturing facility received.	Implementation milestone for the manufacturing expansion announced on 16 October.
29 October	Senores Pharmaceuticals	Proposed capacity expansion involving its subsidiaries in India and the USA, with a total estimated investment of ₹43 crore.	Expansion of pharmaceutical manufacturing and prefilled syringe capacity.
October 2026	Nucelion Therapeutics – Pandorum Technologies	Collaboration for two PRIP-supported ophthalmology development programmes, with a combined planned outlay of ₹16.97 crore.	Development of regenerative medicines using designer exosomes for advanced keratopathy and wet age-related macular degeneration.
4th November 2026	Shilpa CDMO	Propose to invest US$ 50 million in commercial peptide manufacturing	The expansion builds on Shilpa's existing cytotoxic and peptide conjugate product development capabilities, with one line dedicated to cytotoxic peptide manufacturing using solid-phase peptide synthesis.

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GLOBAL PHARMA MARKET INTELLEGENCE

New Drug Approvals & Regulatory Developments:

US FDA:

Date	Drug / Company	Approval or regulatory development	Therapeutic area
14 October	Nogapendekin alfa inbakicept (Anktiva)	Expanded approval in combination with BCG for BCG-unresponsive non-muscle-invasive bladder cancer.	Oncology
16 October	Pembrolizumab (Keytruda) – Merck	Traditional approval for certain patients with unresectable or metastatic TMB-high solid tumours.	Oncology
20 October	Bepirovirsen (Hibsago) – GSK	Novel drug approval for chronic hepatitis B in certain adults, in combination with existing antiviral therapy.	Antiviral
23 October	Insulin icodec (Awiqli)	First once-weekly insulin approved for paediatric patients aged 10 years and above with Type 2 diabetes.	Diabetes
26 October	Talazoparib (Talzenna) + enzalutamide (Xtandi) – Pfizer	Expanded approval for certain patients with HRR gene-mutated metastatic prostate cancer.	Oncology

European Union – EMA

At its meeting held from 12–15 October 2026, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended six new medicines for marketing authorisation.

Medicine	Active ingredient	Therapeutic application	Regulatory status
Rasonque	Daraxonrasib	Metastatic pancreatic cancer	Positive CHMP opinion

Foundayo	Orforglipron	Obesity and Type 2 diabetes	Positive CHMP opinion
Yuviwel	Navepegritide	Achondroplasia in children	Positive CHMP opinion
Fovlussea	Ranibizumab	Retinal disorders	Biosimilar recommendation
Neuzafy	Filgrastim	Neutropenia	Biosimilar recommendation
Kizfizo	Temozolomide	Glioblastoma and malignant glioma	Positive CHMP opinion

United Kingdom – MHRA

Date	Drug	Development	Significance
13 October	Onswik (insulin efsitora alfa)	MHRA authorised once-weekly insulin for adults with Type 2 diabetes.	Long-acting insulin development.
23 October	Icotyde (icotrokinra)	Approved oral treatment for moderate-to-severe plaque psoriasis in eligible adults and adolescents.	Oral immunological therapy.
30 October	Casgevy (exagamglogene autotemcel)	Authorisation extended to children aged five and above with severe sickle-cell disease and transfusion-dependent beta-thalassaemia.	Expansion of gene-editing therapy access.

Australia, Japan

Country / Regulator	Date	Important development
Australia – TGA	3 November	MS-2 Step composite pack (mifepristone and misoprostol) approved for specified pregnancy-related indications.
Japan – PMDA	30 October	Issued a safety alert concerning appropriate use of GLP-1 and GIP/GLP-1 receptor agonists.

Japan – PMDA	2 November	Published early consideration of basic principles for the use of AI in regulatory activities.

Important Drug Approvals for Indian Companies & Regulatory Developments:

Date	Company	Drug / Product	Development
21 October	Sanofi	Fitusiran (Qfitlia)	Received marketing authorisation in India for prophylaxis against bleeding episodes in eligible haemophilia A and B patients.
21 October	Dr. Reddy's Laboratories	Toripalimab (Zytorvi)	Received DCGI approval for an additional indication in advanced oesophageal squamous cell carcinoma.
28 October	Alembic Pharmaceuticals	Valganciclovir oral solution 50 mg/ml	Received final US FDA ANDA approval.
2 November	Lupin	Amifampridine tablets 10 mg	Received US FDA ANDA approval; eligible for shared 180-day generic exclusivity.

Additional CDSCO development – Bulk drug approvals

CDSCO's approval database recorded the following bulk drug approvals on 23 October 2026:

Bulk drug	Manufacturer / supplier	Manufacturing country
Sitagliptin phosphate monohydrate	Symbio Generics / Zhejiang Yongtai Chiral Medicine Technology	China
Iodixanol	Rifa Pharma / Sichuan Renan Pharmaceutical	China
Glutathione	Rifa Pharma / Shandong Jincheng Bio-Pharmaceutical	China

Clinical-trial regulatory developments

CDSCO's clinical-trial approval listing dated 23 October also included:

- Pembrolizumab injection proposed by Kemwell Biopharma.
- Nivolumab and relatlimab combination proposed by Bristol-Myers Squibb India.

The above are only clinical-trial-related permissions

Technology and Drug Development Trends:

The following areas are attracting increasing pharmaceutical R&D and investment interest:

Technology / Segment	**Recent development**	**Potential opportunity for Indian manufacturers**
Peptides and GLP-1 therapies	Increasing development of oral and injectable obesity and diabetes medicines.	Peptide synthesis, amino acid derivatives, protected amino acids and specialised intermediates.
Oligonucleotides and RNA therapeutics	FDA approval of bepirovirsen and continuing RNA-based drug development.	Nucleotide building blocks, phosphoramidites and specialised synthesis capabilities.
CAR-T and cell therapies	Mankind's investment in Armed Cell Therapeutics.	Cell-therapy raw materials, reagents and specialised manufacturing support.
Biosimilars	EMA recommendations for ranibizumab and filgrastim biosimilars.	Biologics manufacturing, analytical standards and specialised formulation inputs.
Regenerative medicines	Nucelion–Pandorum ophthalmology collaboration.	Exosome production, bioprocessing and GMP manufacturing.
Radiopharmaceuticals	International expansion of PET radiopharmaceutical capabilities.	Specialised isotope-related supply chains and radiopharmaceutical manufacturing infrastructure.

ASSOCIATION ACTIVITIES

Representations / Circulars / Inputs

Circulars

Sl. No.	Date	Brief contents and significance
1	23.10.2026	DGTR has issued final findings recommending anti-dumping duty on Ethambutol Hydrochloride originating in or exported from China and Thailand. Inputs/objections were also invited from interested companies in the ongoing investigation concerning Montelukast Sodium imports from China.
2	26.10.2026	Members were informed about initiation of an anti-dumping investigation on Isopropyl Alcohol originating from China. Downstream users were requested to submit economic interest questionnaire responses to DGTR, explaining the likely impact of duty on their operations.
3	29.10.2026	BDMAI, in association with Oren, proposed a free training programme for members in Hyderabad to familiarise them with ESG requirements, EcoVadis ratings and sustainability disclosures expected by global customers.
4	29.10.2026	Department of Pharmaceuticals invited industry suggestions for the forthcoming Union Budget. Members were requested to provide suggestions on customs duty structures, procedures and compliance requirements for submission to the Department of Pharmaceuticals ahead of the pre-budget meeting scheduled for 10 November 2026.
5	03.11.2026	BDMAI circulated details of candidates with 12th standard or lower educational qualifications, available for operator-level positions in manufacturing units. Interested members were invited to contact the HR consultant.

Representations

Date	Subject
19.10.2026	Request for extending simplified regulatory mechanism for industrial alcohol on the lines of methanol and permitting recovery/recycling of spent alcohol

Please visit www.bdmai.org for more details of the above circulars and representations.

Members' Achievements:

Aragen Achieves EDGE Certification for F & G (HPAPI) Blocks at Manufacturing Unit I

Aragen Life Sciences is proud to announce that the **F & G (HPAPI) Blocks** at Manufacturing Unit I have been awarded the prestigious **EDGE (Excellence in Design for Greater Efficiencies) Certification**.

This achievement reflects Aragen's continued commitment to sustainable infrastructure development and environmentally responsible operations. EDGE certification recognizes buildings designed to achieve significant reductions in energy consumption, water usage, and embodied energy in construction materials compared to conventional building practices. Through optimized building design and operational efficiency measures, these facilities contribute to Aragen's broader sustainability and decarbonization





Key Highlights:

- Recognition for excellence in energy, water, and material efficiency
- Supports Aragen's ESG and climate action commitments
- Demonstrates leadership in sustainable infrastructure within the life sciences sector

This accomplishment marks another significant step in Aragen's journey toward building a more sustainable future through responsible innovation and operational excellence.

Export & Import Analysis of Bulk Drugs & Intermediates

Six-month review of India's bulk drugs and intermediates trade | Values in US$ million

Trade performance at a glance

Particulars	Apr–Sep 2025–26	Apr–Sep 2026–27	Change
Exports	2,348.59	2,584.10	+10.0%
Imports	2,228.74	2,115.89	-5.1%
Trade balance (surplus)	119.85	468.20	Surplus widened

India's bulk drugs and intermediates exports increased to US$2,584.10 million in April–September FY 2026–27, from US$2,348.59 million in the corresponding period of the previous year, registering growth of 10.03%. Imports declined by 5.06% to US$2,115.89 million. Consequently, the trade surplus expanded to US$468.20 million, compared with

Leading export destinations:

The United States remained India's largest identified destination for bulk drugs and intermediates exports, at US$299.82 million. Brazil ranked next, followed by the Netherlands, Germany and Bangladesh. Ireland recorded particularly strong growth from a lower base.

Rank	Destination	Exports 2026–27	YoY change
1	USA	299.82	+16.0%
2	Unspecified / not attributed	167.75	+5.1%
3	Brazil	161.41	+27.9%
4	Netherlands	105.71	+18.0%
5	Germany	96.48	+35.9%
6	Bangladesh	90.35	+17.8%
7	Turkey	86.14	+37.3%
8	Ireland	77.46	+129.5%
9	China	74.73	-14.8%
10	Egypt	71.89	+3.2%
11	France	59.81	+1.5%
12	Indonesia	58.53	+11.7%
13	Japan	57.70	-1.9%
14	Spain	55.87	-7.2%
15	South Korea	55.66	+1.8%
16	Russia	53.80	+2.8%
17	Vietnam	46.20	+8.0%
18	UAE	44.35	-14.3%
19	Belgium	41.41	-36.9%
20	Italy	41.28	-18.7%

Leading import sources

China continued to dominate India's import basket. Imports from China stood at US$1,498.68 million, although they were 7.38% lower than in the corresponding period of 2025–26.

Rank	Source country	Imports FY 2026–27	YoY change
1	China	1,498.68	-7.4%
2	Italy	75.59	+33.7%
3	Singapore	56.85	+25.4%
4	Spain	53.24	+24.3%
5	USA	42.98	+11.5%
6	Japan	38.44	+22.0%
7	Germany	37.61	-43.6%
8	Switzerland	28.49	-35.5%
9	Denmark	23.91	+28.4%
10	Netherlands	21.33	-23.1%
11	Malaysia	19.48	+7.6%
12	Hong Kong	18.48	+59.7%
13	United Kingdom	17.91	-15.8%
14	Belgium	17.13	-18.7%
15	France	16.20	-0.3%
16	Austria	14.45	+16.4%
17	Slovenia	14.29	-39.8%
18	Taiwan	14.02	-14.7%
19	Mexico	13.64	-39.8%
20	Czech Republic	13.36	+134.4%

Bilateral trade balance with major partners

The country-wise comparison below combines exports and imports for the 20 largest bilateral trading partners by total trade. A positive balance indicates an export surplus for India; a negative balance indicates a deficit.

Country	Exports	Imports	Balance
China	74.73	1,498.68	-1,423.96
USA	299.82	42.98	256.84
Brazil	161.41	2.24	159.17
Germany	96.48	37.61	58.86
Netherlands	105.71	21.33	84.39
Italy	41.28	75.59	-34.31
Spain	55.87	53.24	2.63

Japan	57.70	38.44	19.27
Singapore	37.30	56.85	-19.54
Bangladesh	90.35	0.21	90.14
Turkey	86.14	0.60	85.54
Ireland	77.46	0.79	76.68
France	59.81	16.20	43.60
Egypt	71.89	0.41	71.48
South Korea	55.66	13.17	42.48
Indonesia	58.53	8.84	49.69
Belgium	41.41	17.13	24.28
Switzerland	27.05	28.49	-1.44
Russia	53.80	1.72	52.08
Vietnam	46.20	8.48	37.72

China represented by far the largest bilateral deficit, at approximately US$1,423.96 million. By contrast, India recorded substantial surpluses with the USA, Brazil, the Netherlands, Bangladesh and Turkey. These figures highlight the contrast between India's export reach and its continuing reliance on China for imported bulk drug inputs.

Top 20 export product groups by HS code

The following table ranks export product groups by their FY 2026–27 value. Descriptions follow the HS-code descriptions supplied in the source workbook.

Rank	HS code	Product description (as classified)	Exports	YoY change
1	29420090	Other diloxanide furoate, cimetidine, famotidine nes	603.67	+12.3%
2	29349990	Other Hetrocyclic compounds	449.57	+22.8%
3	29419090	Other antibiotics	269.70	+26.0%
4	29397900	Other of Vegitable origin	85.28	+4.6%
5	29411030	Amoxycilline and its salts	71.69	-9.5%
6	29372900	Othr steroidal hormons thr drvtvs and strctl anlges	66.02	+14.2%
7	29242980	Paracetamol	56.76	+40.0%
8	29393000	Caffeine and its salts	55.61	+56.4%
9	29362920	Nctnc acid and nctnmd(niacinamide/niacine	52.43	+36.5%
10	29389090	Other glycosides ntrl/rprdcd by synthsis andthr slts ethrs drvtvs	47.19	+27.4%
11	29415000	Erthromycin and its drvtvs slts thereof	44.43	-5.4%
12	29420012	Ibuprofane	41.72	+20.9%
13	96020030	Gelatin capsules,empty	37.62	-12.3%
14	29214600	amfetamine INN and its related apis	37.30	+3.9%
15	29054400	D-glucitol (sorbitol)	32.59	-0.7%

16	17023010	Glucose liquid	30.50	+17.2%
17	29349940	Other Hetrocyclic compounds	27.64	+34.7%
18	29411090	Other penicillins and thr drvtvs wth a pentcillianic acid strctr slts thereof	26.39	-34.8%
19	29371200	Insulin and its salts	24.63	+10.8%
20	29224910	Amino acetic acid (glycine)	22.91	+189.0%

Top 20 import product groups by HS code

Heterocyclic compounds and antibiotic categories were the two largest import groups. Methionine imports rose sharply, while imports classified under 6-APA declined significantly.

Rank	HS code	Product description (as classified)	Imports	YoY change
1	29349990	Other Hetrocyclic compounds	418.13	+28.9%
2	29419090	Other antibiotics	336.62	-13.7%
3	29420090	Other diloxanide furoate, cimetidine, famotidine nes	145.89	-10.1%
4	29304000	Methionine	125.08	+54.0%
5	29415000	Erthromycin and its drvtvs slts thereof	88.92	-6.3%
6	29372900	Othr steroidal hormons thr drvtvs and strctl anlges	75.58	+44.4%
7	29411050	6 - apa	75.17	-56.7%
8	29224100	Lysine and its esters salts thereof	57.72	+0.8%
9	29411090	Other penicillins and thr drvtvs wth a pentcillianic acid strctr slts thereof	42.26	-5.6%
10	29389090	Other glycosides ntrl/rprdcd by synthsis andthr slts ethrs drvtvs	35.72	+9.3%
11	29372300	Oestrogens and progestogens	33.40	+21.1%
12	29262000	1-Cyanoguanidine (dicyandiamide)	30.73	+4.5%
13	29072200	Hydroquinone	28.54	+57.8%
14	29371900	Other polypeptide hormones thr dtvtvs and strctl anlges	27.16	-23.8%
15	29419019	Other rifampicin and its salts	27.04	-13.2%
16	29379090	Other Amino acide Derivatives	26.09	-21.0%
17	29224220	Monosodium glutamate (aginamoto)	23.78	-22.5%
18	29413090	Other tetracyclines and thr drvtvs slts	23.45	+103.4%
19	29393000	Caffeine and its salts	22.65	+23.9%
20	29054300	Mannitol	21.06	-29.8%

Product groups with the largest trade surpluses

The following comparison matches import and export values by HS code. It indicates product groups where recorded exports exceeded imports.

HS code	Product description	Exports	Imports	Surplus
29420090	Other diloxanide furoate, cimetidine, famotidine nes	603.67	145.89	457.78
29397900	Other of Vegitable origin	85.28	5.30	79.98
29411030	Amoxycilline and its salts	71.69	14.82	56.87
29242980	Paracetamol	56.76	2.74	54.02
29362920	Nctnc acid and nctnmd(niacinamide/niacine	52.43	1.25	51.18
29214600	amfetamine INN and its related apis	37.30	0.43	36.88
29420012	Ibuprofane	41.72	4.85	36.87
96020030	Gelatin capsules,empty	37.62	2.11	35.51
29393000	Caffeine and its salts	55.61	22.65	32.95
29349990	Other Hetrocyclic compounds	449.57	418.13	31.44

Product groups with the largest trade deficits

HS code	Product description	Exports	Imports	Deficit
29304000	Methionine	1.92	125.08	-123.16
29411050	6 - apa	0.00	75.17	-75.17
29419090	Other antibiotics	269.70	336.62	-66.92
29224100	Lysine and its esters salts thereof	3.13	57.72	-54.59
29415000	Erthromycin and its drvtvs slts thereof	44.43	88.92	-44.49
29262000	1-Cyanoguanidine (dicyandiamide)	0.06	30.73	-30.67
29419019	Other rifampicin and its salts	3.16	27.04	-23.88
29224220	Monosodium glutamate (aginamoto)	0.27	23.78	-23.51
29413090	Other tetracyclines and thr drvtvs slts	0.19	23.45	-23.26
29072200	Hydroquinone	5.99	28.54	-22.55

Methionine recorded the largest deficit among the product groups listed, followed by 6-APA, other antibiotics, lysine and erythromycin. These categories may merit closer assessment for domestic manufacturing potential, subject to demand, technology, cost competitiveness and environmental considerations.

Important Government Notifications, Circulars, Public Notices and Trade Agreements

CDSCO

Date	Notification / Public Notice	Important details and implications for industry
14 October 2026	Clarification on Export NOC for already-approved r-DNA products	CDSCO issued clarification regarding the requirement of Export NOC for recombinant DNA products already approved by the competent authority. Manufacturers and exporters of r-DNA products should examine the clarification before undertaking exports.
19 October 2026	List of Ethics Committees cancelled by CLA	CDSCO published a list of Ethics Committees whose registrations have been cancelled. Relevant to companies conducting clinical trials and bioavailability/bioequivalence studies.
26 October 2026	WHO alert on falsified DEFITELIO (Defibrotide)	CDSCO issued an alert regarding falsified Defitelio 80 mg/ml, identified in India. The notice identifies the batch number 24GC01A and expiry date April 2027. Importers, distributors and manufacturers should strengthen product authentication and supply-chain checks.
27 October 2026	Strict compliance with Drugs Rules, 1945 – testing of raw materials and finished formulations	CDSCO reiterated the importance of compliance with prescribed testing requirements for both raw materials and finished pharmaceutical formulations. This is important for manufacturers' QC systems, vendor qualification, sampling and release procedures.
27 October 2026	Digital Monitoring System on ONDLS portal for high-risk solvents	CDSCO announced a digital monitoring mechanism on the Online National Drugs Licensing System (ONDLS) portal for monitoring the supply chain of high-risk solvents. Manufacturers and stakeholders handling such solvents should review the applicable reporting and compliance requirements.
28 October 2026	G.S.R. 955(E) – Draft amendment to Drugs Rules, 1945	Proposal to require an authorised person responsible for batch release of products. Manufacturers should examine the proposed responsibilities and submit comments within the prescribed consultation period.
28 October 2026	G.S.R. 951(E) – Rationalisation of shelf life under Rule 31	Notification concerning rationalisation of shelf-life provisions under the Drugs Rules, 1945. Manufacturers should review its applicability to product shelf-life declarations and related labelling requirements.
28 October 2026	G.S.R. 954(E) – Draft amendment to Rule 43A	Proposal to include additional Inland Container Depots (ICDs), ports and Special Economic Zones for import of drugs, medical devices and cosmetics. This may facilitate import logistics and customs clearance.

Important Government Notifications, Circulars, Public Notices and Trade Agreements

Customs and CBIC

Date	Notification / Circular	Details and relevance to pharmaceutical industry
12 October 2026	Customs Tariff (Determination of Origin of Goods under the India–New Zealand FTA) Rules, 2026	Department of Revenue notified the Rules governing determination of country of origin under the India–New Zealand FTA. These rules establish the conditions for claiming preferential customs duty treatment.
16 October 2026	Customs Notification No. 32/2026-Customs	Notification giving effect to the first tranche of tariff concessions under the India–New Zealand FTA. Importers should examine the tariff schedules and eligibility conditions for products covered by the concessions.
19 October 2026	CBIC instruction on acceptance of Electronic Certificate of Origin (e-CoO) under India–New Zealand FTA	CBIC issued instructions for acceptance of electronic Certificates of Origin under the agreement. Exporters and importers should ensure that the prescribed origin documentation is available when claiming preferential treatment.
27 October 2026	CBIC Circular No. 46/2026-Customs	Circular concerning Titanium Dioxide anti-dumping duty and revision of the excluded-use declaration. Relevant to companies using titanium dioxide in applicable manufacturing processes.

DGFT

Date	Notification	Details and implications
1st Oct	RoDTEP Scheme	Continuation of the Remission of Duties and Taxes on Exported Products Scheme up to 31 December 2026
1st Oct	RELIEF Scheme	Extension of timelines under Component II of the Resilience & Logistics Intervention for Export Facilitation up to 31 March 2027
12 October 2026	DGFT Notification – Amendment in Import Policy of Glufosinate and its salts	Minimum Import Price (MIP) condition on imports of Glufosinate and its salts has been extended up to 12 April 2027. The condition applies to specified HS codes 38089193, 38089199, 38089361, 38089391, 38089399, 38089912, 38089991 and 38089999. Although primarily an agrochemical input, this is relevant to chemical manufacturers and importers.
23 October 2026	Public Notice – Amendment under Para 2.92 and	Amendments made to incorporate Tariff Rate Quotas (TRQs) and related provisions under the India–New

	Appendix 2A of Handbook of Procedures, 2023	Zealand FTA. Exporters and importers should refer to the revised procedures for the relevant tariff lines.
22 October 2026	Amendment in import policy of Raw Sugar	Extension of the relevant TRQ timeline for imports of raw sugar. This is not directly related to APIs but is relevant to companies with associated sugar-based supply chains.

Department of Revenue and Department of Commerce

Date	Notification / Development	Details and implications
12 October 2026	Customs Tariff (Determination of Origin of Goods under India–New Zealand FTA) Rules, 2026	Establishes the rules for determining originating goods and eligibility for preferential tariff treatment.
16 October 2026	Notification No. 32/2026-Customs	Implements the first tranche of tariff concessions under the India–New Zealand FTA.
15 October 2026	Third Amendment to SEZ Rules, 2026	Department of Commerce published the third amendment to the Special Economic Zones Rules. SEZ-based manufacturers and exporters should examine its operational implications.
15 October 2026	Fourth Amendment to SEZ Rules, 2026	Further amendments to SEZ Rules, 2026, published by the Department of Commerce. SEZ units should review the revised provisions.
24 October 2026	Anti-dumping duty notification concerning Titanium Dioxide	Department of Revenue issued a notification relating to anti-dumping duty on Titanium Dioxide. Companies using this material should examine its impact on landed input costs.

Department of Pharmaceuticals / NPPA – Drug pricing and policy developments

Date	Notification / Order	Details and industry implications
17 October 2026	Trade Margin Rationalisation (TMR) of 137 non-scheduled anti-cancer drugs	NPPA invoked Paragraph 19 of DPCO, 2013, to rationalise trade margins on 137 identified non-scheduled anti-cancer drugs. The measure is expected to reduce MRPs by up to 70%, depending on the existing price structure.

SOLVENT RECOVERY AND REUSE IN BULK DRUG MANUFACTURING

Technologies, Economic Benefits and Environmental Sustainability

Introduction

Solvents play an indispensable role in the manufacture of Active Pharmaceutical Ingredients (APIs) and pharmaceutical intermediates. They are extensively used in chemical reactions, extraction, crystallisation, purification, washing and drying operations. Commonly used solvents include methanol, ethanol, isopropyl alcohol (IPA), acetone, toluene, ethyl acetate, dichloromethane, acetonitrile and tetrahydrofuran (THF).

In conventional pharmaceutical manufacturing, a substantial quantity of solvents is consumed during various processing operations and subsequently discharged as spent solvent, wastewater containing solvent residues or solvent-bearing waste streams. The American Chemical Society Green Chemistry Institute Pharmaceutical Roundtable notes that solvents can constitute approximately 60–70% of the waste stream in pharmaceutical manufacturing.

With increasing raw material costs, energy expenses, environmental compliance requirements and global expectations for sustainable manufacturing, solvent recovery and reuse have become important opportunities for improving the competitiveness of API manufacturers.

For Indian bulk drug manufacturers, particularly small and medium-scale enterprises (MSMEs), establishing an effective solvent recovery programme can offer considerable economic and environmental advantages.

Why Solvent Recovery is Important

Solvent recovery is the process of separating and purifying solvents from spent solvent streams so that they can be reused in the same manufacturing process or in other suitable applications. The principal benefits include:

- Reduction in manufacturing costs
- Reduction in hazardous wastage generation
- Energy and resource conservation
- Environmental protection
- Improved competitiveness

Solvent recovery should therefore be considered not merely as an environmental compliance activity but as an integral component of manufacturing cost optimisation.

Sources of Recoverable Solvents in API Manufacturing

In bulk drug manufacturing, spent solvents originate from several operations:

- Mother liquors generated during crystallisation.
- Filtrates obtained after filtration of API and intermediates.
- Solvents used for washing and purification.
- Solvents used in extraction and reaction work-up.
- Solvents generated during equipment and plant cleaning.
- Solvent mixtures collected from process condensers and vacuum systems.

However, not all spent solvent streams are suitable for recovery and reuse. Their suitability depends on the type and concentration of impurities, water content, solvent composition, process history and intended application. A systematic assessment of solvent streams should be undertaken to identify those offering the best recovery potential.

Technologies Used for Solvent Recovery

Distillation

Distillation is the most widely established technology for solvent recovery in the pharmaceutical and chemical industries. The process uses differences in boiling points and relative volatility to separate solvents from dissolved impurities and other components. The spent solvent is charged into a distillation vessel and heated. The solvent vapours are condensed in a condenser and collected in a receiver, while higher-boiling impurities and non-volatile residues remain in the distillation vessel. Though this process has its own advantages, may require considerable thermal energy. It may also be unsuitable for certain heat-sensitive materials or solvent mixtures having close boiling points.

Fractional Distillation

Fractional distillation is particularly useful when spent solvent streams contain two or more solvents with different boiling characteristics. A fractionating column improves separation efficiency by providing repeated vapour-liquid contact. For example, mixtures containing solvents such as methanol, ethanol, acetone and other compatible organic solvents may require appropriate fractional distillation arrangements, depending on their composition and relative volatility. The recovered fractions must be tested individually before being considered suitable for reuse.

Vacuum Distillation

Vacuum distillation is used when solvents have high boiling points or when heat-sensitive impurities or products may undergo thermal degradation. By reducing operating pressure, the boiling temperature of the solvent can be lowered. This technology is particularly useful

in pharmaceutical manufacturing where excessive heating may cause degradation of valuable process materials.

Thin Film and Wiped Film Evaporation

Thin film and wiped film evaporators are useful for processing viscous solvent streams containing dissolved or suspended residues. The liquid forms a thin film over a heated surface, allowing rapid evaporation and reducing residence time. These systems may be particularly useful where conventional distillation becomes inefficient due to high viscosity, fouling or thermal sensitivity.

Membrane-Based Solvent Recovery

An emerging technology is Organic Solvent Nanofiltration (OSN). Unlike conventional distillation, which relies on differences in volatility, OSN uses specialised solvent-resistant membranes to separate dissolved compounds from organic solvents. The membrane selectively retains larger molecules and impurities while allowing the solvent to pass through, depending on membrane characteristics and operating conditions.

The technology offers potential advantages in energy efficiency and processing at relatively mild temperatures. However, membrane compatibility, solvent resistance, fouling, selectivity and long-term operational performance need to be established before industrial implementation. OSN is a promising complementary technology rather than a universal replacement for distillation.

Selection of Suitable Solvent Recovery Systems

Before installing a solvent recovery plant, manufacturers should undertake a detailed technical and economic evaluation, considering the factors like solvent composition, quantity, boiling point, impurity profile, water content, thermal stability, purity requirements, energy availability, safety, economics etc.

Quality Control and GMP Requirements

One of the most important considerations in pharmaceutical solvent recovery is ensuring that recovered solvents do not adversely affect the quality of APIs or intermediates. Solvent recovery cannot be treated as a simple distillation activity. It must form part of a controlled and documented GMP system. The US FDA's ICH Q7A Good Manufacturing Practice guidance for APIs specifically recognises the recovery and reuse of solvents, subject to approved procedures and appropriate controls.

The following measures are recommended:

- Segregation of solvent streams
- Defined recovery procedures

- Testing of recovered solvents
- Approval by Quality Assurance
- Batch traceability

Recovered solvents should be used only for applications for which their suitability has been established. A solvent recovered from one process should not automatically be considered suitable for another process. ICH Q3C requirements relating to residual solvents in pharmaceutical substances and products should also be considered wherever applicable. These requirements are distinct from the specifications that need to be established for recovered solvents.

Safety Considerations in Solvent Recovery

Most organic solvents used in API manufacturing are volatile and many are highly flammable. Therefore, solvent recovery installations require appropriate engineering and operational safety measures.

Important precautions include:

- Closed transfer and handling systems.
- Appropriate electrical equipment for hazardous areas.
- Effective earthing and bonding arrangements.
- Adequate ventilation and vapour control.
- Suitable fire detection and firefighting systems.
- Pressure and vacuum protection.
- Appropriate condenser and cooling arrangements.
- Safe storage tanks and transfer pumps.
- Periodic inspection and maintenance.
- Operator training and emergency preparedness.

A systematic hazard identification and risk assessment should be conducted before commissioning the recovery facility. Particular attention should be given to the possibility of flammable vapour accumulation, static electricity, equipment overpressure, incompatible solvent mixtures and exposure to toxic vapours.

This illustration excludes capital investment, financing costs, maintenance beyond the assumed operating expenses, taxes and any difference in the value of recovered versus fresh solvent. Actual savings will depend on solvent prices, recovery efficiency, energy costs, impurity levels and the suitability of recovered solvent for reuse. The example nevertheless demonstrates why solvent recovery deserves serious consideration as a cost-reduction initiative.

Future Developments and Opportunities

Solvent recovery technologies are continuing to evolve. Some important areas of development include:

- Energy-efficient distillation systems.
- Heat integration and vapour recompression.
- Advanced solvent-resistant membrane technologies.
- Automated solvent composition monitoring.
- Digital monitoring of recovery plant performance.
- Improved solvent selection during process development.
- Integration of recovery systems with continuous manufacturing.

Pharmaceutical companies are also increasingly adopting green chemistry principles, with greater emphasis on reducing solvent usage at the process design stage itself. The best approach is therefore not simply to recover solvents after use, but to minimise solvent consumption throughout the manufacturing process.

Efficient solvent management is not merely an environmental responsibility; it is an important component of cost competitiveness and sustainable growth in the Indian bulk drug industry.

References:

- US FDA – ICH Q7A: Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. Particularly Section 14.4 on recovery of materials and solvents. FDA guidance.
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- ICH Q3C – Residual Solvents. Relevant to controlling residual solvents in pharmaceutical substances and products. ICH guideline

EVENTS WHERE BDMAI WILL BE PARTICPATING



