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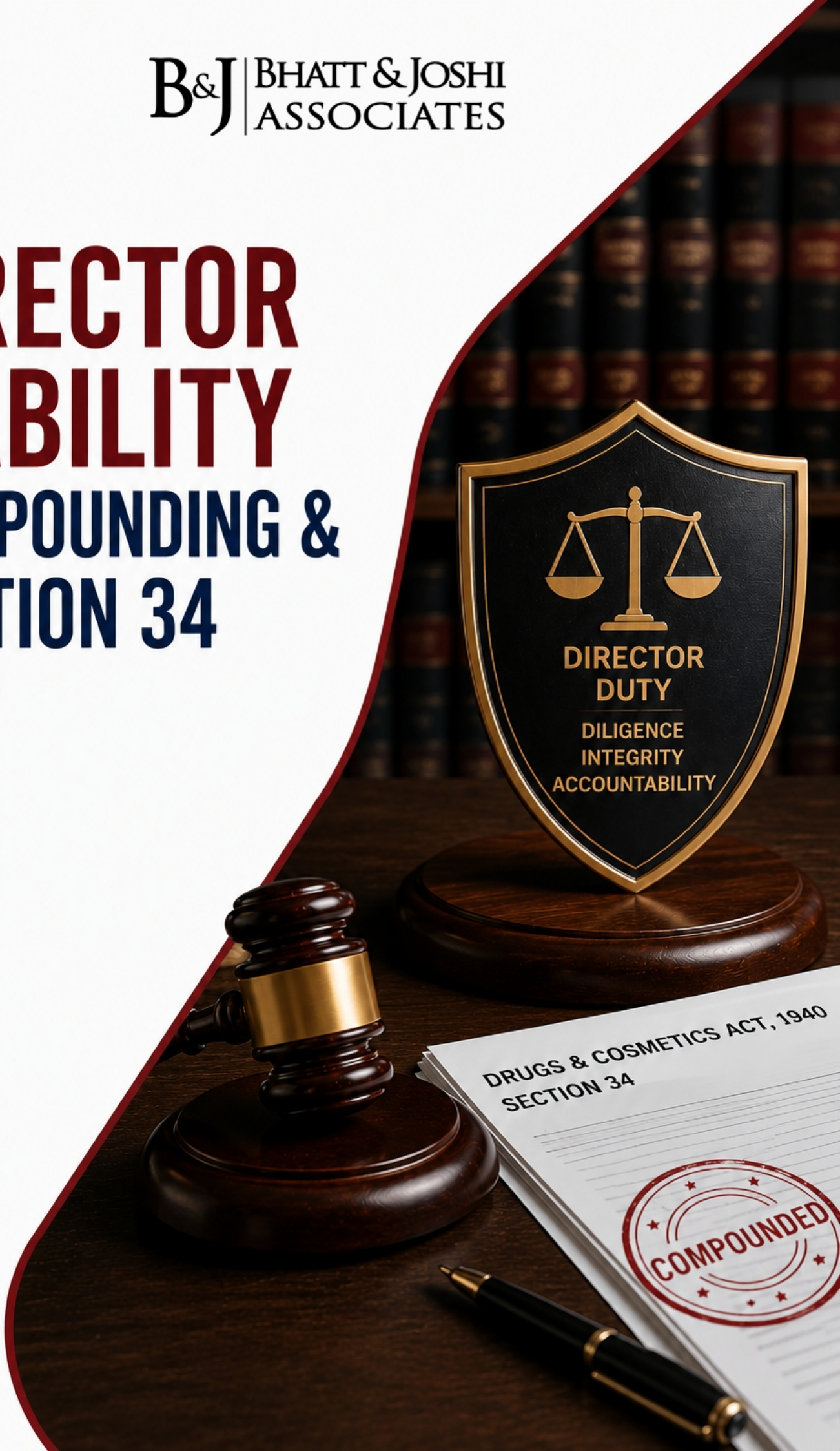
DIRECTOR LIABILITY

COMPOUNDING & SECTION 34



Director Liability, Compounding & Section 34

A Practitioner Handbook on Vicarious Liability, the Foreign-NED Defence, and the 2025 Compounding Regime under the Drugs & Cosmetics Act, 1940

A Practitioner's Handbook for the Pharmaceutical Industry

BHATT & JOSHI ASSOCIATES

Advocates & Legal Consultants

Gujarat High Court, Ahmedabad

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FOREWORD

A Drug Inspector files a complaint. The Government Analyst's report declares a batch "not of standard quality." The complaint names five accused: the company, the managing director, two non-executive directors, and a foreign national who sits on the board as nominee of the overseas parent. The non-executive directors — one a retired bureaucrat, the other a chartered accountant — have never visited the factory floor. The foreign director attends quarterly board meetings by video call from abroad.

Yet all five face criminal prosecution under Section 27(d) of the Drugs and Cosmetics Act, 1940, carrying a mandatory minimum of one year imprisonment.

This handbook addresses the single most important question in pharmaceutical criminal defence: When does a director become personally liable for the company's drug quality failures?

The answer, after Shailyamanyu Singh v. State of Maharashtra (2025 INSC 995), is clearer than it has ever been. This volume synthesises the complete jurisprudence on Section 34 vicarious liability, presents the landmark 2025 Supreme Court decision in full analytical depth, introduces the newly operational Compounding of Offences Rules, 2025 (the first genuine alternative to criminal trial for NSQ cases), and provides a dedicated chapter on the "Foreign-NED Scenario" — the exposure of foreign-national non-executive directors of MNC Indian subsidiaries.

PART I — THE ARCHITECTURE OF SECTION 34

Chapter 1: Section 34 — The Full Text

Section 34 of the Drugs and Cosmetics Act, 1940 provides:

For the purposes of Section 34, "company" includes a firm or other association of individuals, and "director" in relation to a firm means a partner.

Chapter 2: The Two Distinct Routes of Personal Liability

Section 34 creates two independent pathways to personal criminal liability. Understanding the distinction is the foundation of every defence strategy.

2.1 Section 34(1) — "In Charge Of and Responsible To"

The proviso to Section 34(1) — the "due diligence" defence — provides an escape route even after the prosecution establishes the "in charge" threshold:

Defence A — "Without knowledge": The specific batch that was found NSQ was manufactured without the personal knowledge of the officer. Documentation: Board resolution delegating manufacturing authority to the Rule 76 competent technical person; the named QC head's batch release records; the officer's other documented activities during the relevant period.

Defence B — "Due diligence exercised": The officer implemented all required GMP systems and procedures. Documentation: GMP compliance records; Schedule M audit reports; Annual Product Quality Review; training records; SOP registers; inspection book entries; third-party audit reports. The standard quality control systems were in place and functioning.

Critical practical point: Due diligence is not proved by saying "I relied on the QC department." Due diligence means implementing a properly structured pharmaceutical quality management system, ensuring qualified people are in charge, reviewing periodic quality reports, and taking action on deviations. The documents created during normal GMP compliance (BMRs, SOPs, training records, Annual PQR, audit reports) are the evidence of due diligence.

2.2 Section 34(2) — "Consent, Connivance or Neglect"

Section 34(2) begins with a non-obstante clause ("Notwithstanding anything contained in sub-section (1)"), meaning it operates independently of Section 34(1). A director can be prosecuted under Section 34(2) even if they were not "in charge of" the company's business — but only if the prosecution proves consent, connivance, or neglect with specific factual averments.

This is the provision most frequently misused by Drug Inspectors who add directors' names to complaints by designation alone, without any factual basis for alleging consent, connivance, or neglect.

PART II — THE LANDMARK DECISIONS

Chapter 3: State of Haryana v. Brij Lal Mittal, (1998) 5 SCC 343

This Supreme Court decision remains the foundational authority on Section 34(1):

Key holdings:

Directorship per se does not establish "in charge of and responsible to"

The complaint must contain specific averments — not mere designations

Where the complaint fails to state the specific role of each accused in the company's pharmaceutical operations, proceedings against individual directors are liable to be quashed

Chapter 4: Sunil Bharti Mittal v. CBI, (2015) 4 SCC 609

Although arising in the telecom context, this Constitution Bench decision is regularly applied in D&C; cases:

Application to D&C; cases: Where a complaint merely states that "A is a director of the company and is therefore liable," without particularising A's role in manufacturing, quality control, or distribution, the Sunil Bharti Mittal standard is not met.

Chapter 5: Shailyamanyu Singh v. State of Maharashtra (2025 INSC 995) — The Game-Changer

Decided: 22 July 2025 | Bench: Justices Vikram Nath and Sandeep Mehta | Reportable

This is now the leading Supreme Court authority on Section 34(2) NED liability and the single most important decision for every pharmaceutical company with non-executive directors on its board.

5.1 Facts

The appellant was a Director of Procter & Gamble Hygiene & Health Care Ltd. He was summoned under Sections 18B, 28A, 18(a)(vi), 27(d), and 22(1)(cca) of the D&C; Act for alleged distribution of

expired Vicks Multi Pain Relief Gel through an unlicensed entity. The complaint named him as an accused solely by virtue of his directorship.

5.2 Supreme Court Holdings

Holding 1 — Section 34(2) requires positive proof, not mere designation:

The Court held that Section 34(2), despite its non-obstante clause, requires proof of "consent, connivance or neglect". Mere directorship is insufficient. The complaint must contain specific averments showing how the director was responsible for the conduct of the business at the relevant time.

Holding 2 — Distinction between Section 34(1) and Section 34(2):

The Court systematically distinguished the two sub-sections:

Holding 3 — Cases cited and applied:

The Court relied on Brij Lal Mittal (1998), Lalankumar Singh (2022 SCC OnLine SC 1383), Sunita Palita (2022) 10 SCC 135, Siby Thomas v. Somay Ceramics (2024) 1 SCC 348, Dayle De'Souza, and Sunil Bharti Mittal (2015).

Holding 4 — The summoning order was quashed:

The Court quashed the summoning order against the director, holding that the complaint did not disclose any specific act of consent, connivance, or neglect attributable to him.

5.3 The Five-Stage Section 34 Analysis (Post-Shailyamanyu Singh)

Based on the synthesis of Brij Lal Mittal, Sunil Bharti Mittal, Shailyamanyu Singh, and the Rajasthan HC 2025 dissolution-test ruling, the following five-stage framework now governs every Section 34 analysis:

Stage 1 — Statutory hook: Section 34(1) deems guilty any person who, at the time of the offence, was "in charge of, and was responsible to, the company for the conduct of the business" — this is conjunctive.

Stage 2 — Proviso defence: Such person can prove the offence was committed "without his knowledge" or "that he had exercised all due diligence." The proviso is conditional and arises only after Stage 1 is established.

Stage 3 — Section 34(2) extension: Where the offence is committed with the consent, connivance, or attributable neglect of any director/manager/secretary/officer, that person is also deemed guilty. Shailyamanyu Singh requires the complaint to plead and prove this with specific averments — a "bald statement" is fatal.

Stage 4 — Quashing under Section 528 BNSS / Article 226: Failure of pleading on Stage 1 or Stage 3 is a ground for quashing on the Bhajan Lal (1992) line, reinforced by the four-step test.

Stage 5 — Procedural overlays: Cognizance must be by Drug Inspector (Section 32; Rakesh Kumar v. State of Bihar, SC 2024); shelf-life expiry vitiates Section 25(3) right (Laborate Pharmaceuticals); Section 23(4)(iii) violation vitiates the chain (Laborate); CDL report under Section 25(4) is conclusive (Amery Pharmaceuticals; Hetero Labs, HP HC 2024).

PART III — THE FOREIGN-NED SCENARIO: MNC SUBSIDIARY EXPOSURE

Chapter 6: The Pattern — MNC Subsidiary, Foreign Parent, Indian Prosecution

6.1 The Typical Fact Pattern

A foreign pharmaceutical company operates in India through a wholly-owned Indian subsidiary. The Indian subsidiary holds a manufacturing licence in Form 28 with a named Rule 76 competent technical person who is an Indian resident. The board of the Indian subsidiary includes:

An Indian managing director (executive, resident)

Two or three Indian independent directors (non-executive, resident)

One or two foreign nominee directors appointed by the parent company (non-executive, non-resident, attend quarterly board meetings by video call)

A Drug Inspector draws a sample from a chemist's shelf. The Government Analyst declares it NSQ. The complaint names the company, the managing director, the Rule 76 person, and — critically — the foreign nominee director as Accused No. 3.

The foreign NED has never visited the manufacturing facility, has no operational role in production or quality control, does not sign batch release records, and was not present in India when the batch

was manufactured or sold. The complaint contains no specific averment of consent, connivance, or neglect attributable to this director.

6.2 Why This Matters — Beyond Criminal Liability

For the foreign NED, the consequences extend far beyond Indian criminal law:

Personal criminal liability carrying a mandatory minimum of one year imprisonment under Section 27(d)

Inability to obtain bail remotely — the NED must appear before an Indian Magistrate

Passport and immigration complications — a pending criminal case in India affects visa applications worldwide

Corporate governance liability in Japan — under the Companies Act of Japan (Kaisha-h■), a director of a foreign parent may face shareholder derivative suits if their nominee director is prosecuted abroad

Reputational damage — a criminal summons against a named individual director of a multinational pharmaceutical company generates adverse publicity disproportionate to the underlying offence

Insurance coverage gaps — standard D&O; policies may exclude criminal prosecution under foreign drug safety statutes

6.3 The Defence Strategy — Shailyamanyu Singh Applied

The foreign-national NED has the following defence architecture, now firmly established:

Ground 1 — No "in charge of" status under Section 34(1):

The foreign NED was not "in charge of and responsible to" the Indian subsidiary for the conduct of its business. Evidence: Board resolution showing the managing director as the person in charge of day-to-day operations; Form 28 manufacturing licence naming the Rule 76 competent person (not the NED); the NED's non-resident status, quarterly attendance, and limited board-level oversight role.

Ground 2 — No consent, connivance, or neglect under Section 34(2):

Per Shailyamanyu Singh (2025 INSC 995), the complaint must contain specific averments of the NED's consent, connivance, or neglect. A complaint that merely states "Accused No. 3 is a director of the company" without particularising any act or omission attributable to the NED is fatally defective. The Supreme Court in Shailyamanyu Singh quashed the summoning order on precisely this ground.

Ground 3 — DCC Section 33-P Guidelines — Category C Minor Defect:

If the NSQ finding is a Category C minor defect (e.g., dissolution test failure with API within limits), the DCC Guidelines issued under Section 33-P mandate administrative action, not criminal prosecution. The Rajasthan High Court (March 2025) quashed complaints on this ground.

Ground 4 — Section 25(3)/(4) Retesting Right Denied:

If the manufacturer's portion under Section 23(4)(iii) was not sent, or if the shelf life has expired before CDL retesting, the prosecution is a "lame prosecution" (Laborate Pharmaceuticals, (2018) 15 SCC 93).

Ground 5 — The CBDT Circular Analogy (Novel but Principled):

Section 33-P empowers the Central Government to issue directions to State Governments on matters of policy. The DCC Guidelines were issued under this power. By analogy to CBDT circulars being binding on Assessing Officers (UCO Bank v. CIT; Catholic Syrian Bank Ltd. v. CIT; CCE v. Dhiren Chemical), Section 33-P directions should bind State Drug Controllers. This argument is doctrinally available but not yet judicially endorsed in a D&C; case — it is a frontier advocacy position available to any pharmaceutical company defending foreign NEDs in Indian NSQ prosecutions.

6.4 Practical Checklist for MNC Subsidiaries

Every multinational pharmaceutical company operating in India through a subsidiary should immediately:

■ Review all board compositions — identify which directors are non-executive and non-resident

■ Ensure the Form 28 manufacturing licence names only the Rule 76 competent person and the managing director — not NEDs

■ Pass a Board resolution clearly delineating manufacturing authority, quality control responsibility, and day-to-day operational control — vest these exclusively in the resident executive director and the Rule 76 person

■ Maintain contemporaneous records of NED attendance (dates, mode, agenda items) — to demonstrate limited oversight role

■ Ensure D&O; insurance covers Indian criminal proceedings under the D&C; Act — check policy exclusions

■ Establish a protocol for immediate legal response upon receipt of any Drug Inspector complaint naming a foreign NED

■ Brief foreign-national directors annually on their exposure under Indian pharmaceutical law and the defences available

PART IV — THE 2025 COMPOUNDING REGIME

Chapter 7: Section 32B — Finally Operational After 17 Years

Section 32B of the D&C; Act was inserted by the Drugs and Cosmetics (Amendment) Act, 2008 to permit compounding (settlement) of certain offences. For seventeen years, it remained a dead letter — no rules were framed to operationalise it.

On 24 April 2025, the Central Government notified the Drugs and Cosmetics (Compounding of Offences) Rules, 2025 (GSR 259(E)), bringing Section 32B to life. This is the single most important procedural development in pharmaceutical prosecution since the 2008 Amendment Act.

7.1 What Can Be Compounded

7.2 The Compounding Procedure

Step 1 — Application: The accused (company or individual) files an application in the prescribed Form before the compounding authority. This can be filed before or after institution of prosecution.

Step 2 — Reporting authority report: The designated reporting authority must submit a report within one month (extendable) assessing the application.

Step 3 — Opportunity of hearing: The applicant is entitled to be heard.

Step 4 — Order: The compounding authority allows or rejects the application with reasons.

Step 5 — Payment: Compounding sum must be paid within 30 days of the order. Non-refundable.

Step 6 — Immunity: Upon payment, the applicant receives immunity from prosecution for the compounded offence.

Step 7 — Withdrawal safeguard: Immunity can be withdrawn if the applicant concealed material facts, provided false evidence, or failed to comply with conditions.

7.3 Compounding Authority

The compounding authority is not below the rank of:

Central: Licensing Authority / Central Licensing Authority / Central Licence Approving Authority

State: State Licensing Authority of equivalent rank

7.4 Strategic Implications

For Category C minor defects (dissolution failure, minor assay variation, labelling defect): Compounding is now the preferred resolution pathway. It avoids: criminal trial with mandatory minimum imprisonment; adverse publicity; the stigma of a criminal record for directors; and the 3-5 year trial timeline. The compounding sum is a known, quantifiable cost that can be budgeted.

For directors: Compounding resolves the prosecution against all accused in the complaint. A company that compounds the offence effectively protects its directors from personal criminal liability for that specific batch.

For foreign-national NEDs: Compounding eliminates the need for the NED to appear before an Indian Magistrate, obtain bail, or engage in protracted criminal proceedings. It is the fastest route to closure.

Limitation: The accused cannot claim compounding as of right — it is discretionary. But the 2025 Rules create a structured, form-based process that significantly increases predictability.

PART V — THE QUASHING PETITION: SECTION 528 BNSS

Chapter 8: Grounds for Quashing in Director Liability Cases

A petition under Section 528 of the Bharatiya Nagarik Suraksha Sanhita, 2023 (replacing Section 482 CrPC for petitions filed on or after 1 July 2024) is the primary remedy for individual directors wrongly named in NSQ complaints.

Chapter 9: BNSS Migration — What Changes and What Doesn't

The Bharatiya Nagarik Suraksha Sanhita, 2023 came into force on 1 July 2024, replacing the Code of Criminal Procedure, 1973. For pharmaceutical prosecution practitioners, the key mapping is:

Transitional rule: Proceedings pending before 1 July 2024 continue under CrPC. Petitions filed on or after 1 July 2024 must invoke BNSS sections, even if the underlying complaint pre-dates BNSS. Multiple High Courts (Punjab & Haryana, Delhi, Rajasthan, Sikkim) have confirmed this.

Substantive continuity: The Bhajan Lal (1992) line of quashing jurisprudence remains fully applicable under Section 528 BNSS. The Sikkim HC in Deepam Pradhan v. Krishna Kumari Bhandari (June 2025) expressly held that Section 528 BNSS is identical in scope to Section 482 CrPC.

APPENDIX A — SECTION 34 DEFENCE DOCUMENTATION CHECKLIST

Use this checklist whenever a director or officer is named in an NSQ complaint:

Immediate (Day 1-3):

■ Obtain certified copy of the complaint — read for specific averments against each named individual

■ Verify: Is each director's role particularised, or merely stated by designation?

■ Check Form 28 manufacturing licence — who is named as the Rule 76 competent person?

■ Check: Was the named director serving at the date of manufacture of the batch?

Assessment (Day 3-7):

■ Prepare Section 34(1) factual matrix — for each named person, document whether they were "in charge of and responsible for" manufacturing operations

■ Prepare Section 34(2) factual matrix — identify any evidence of consent, connivance, or neglect attributable to each person

■ Collect Board resolutions showing delegation of manufacturing authority

■ Collect NED attendance records, meeting minutes, agenda items

■ For foreign-national NEDs — collect passport, visa records, physical presence/absence during the relevant period

Legal Response (Day 7-28):

■ File Section 25(3) notice within 28 days

■ Evaluate whether to file Section 528 BNSS quashing petition immediately (parallel track)

■ Evaluate whether to apply for compounding under the 2025 Rules (alternative track)

■ For foreign-national NEDs — engage counsel at the relevant High Court for urgent anticipatory bail / quashing

APPENDIX B — PENALTY SCHEDULE AND COMPOUNDING ELIGIBILITY

REFERENCES

Drugs and Cosmetics Act, 1940 (India Code consolidated text)

Drugs and Cosmetics Rules, 1945 (CDSCO consolidated 2024)

Drugs and Cosmetics (Compounding of Offences) Rules, 2025, GSR 259(E) dt 24.04.2025

Shailyamanyu Singh v. State of Maharashtra, 2025 INSC 995 (SC, 22 July 2025)

State of Haryana v. Brij Lal Mittal, (1998) 5 SCC 343

Sunil Bharti Mittal v. CBI, (2015) 4 SCC 609

Laborate Pharmaceuticals India Ltd. v. State of Tamil Nadu, (2018) 15 SCC 93

M/s Medicamen Biotech Ltd. v. Rubina Bose, (2008) 7 SCC 196

Amery Pharmaceuticals v. State of Rajasthan, (2001) 4 SCC 382

Rakesh Kumar v. State of Bihar (SC, 2024)

Rajasthan HC dissolution-test-as-minor-defect ruling (March 2025)

Hetero Labs Ltd. v. Union of India, Cr. MMO No. 810/2023, HP HC (8 January 2024)

DCC Guidelines under Section 33-P (40th DCC Meeting)

Bharatiya Nagarik Suraksha Sanhita, 2023 (Sections 514, 528, 531)

BHATT & JOSHI ASSOCIATES

Advocates & Legal Consultants

Gujarat High Court | Ahmedabad, Gujarat, India

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For enquiries and legal assistance, contact the firm at Gujarat High Court, Ahmedabad.