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ASSOCIATES

# NSQ DEFENCE AND PROSECUTION LAW

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# Pharmaceutical Enforcement Response Handbook

What to Do When Your Drug is Found Not of Standard Quality

*A Practitioner's Handbook for the Pharmaceutical Industry*

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**BHATT & JOSHI ASSOCIATES**

Advocates & Legal Consultants

Gujarat High Court, Ahmedabad

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Volume I | Pharmaceutical Law Series

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## FOREWORD

*A Drug Inspector collects a sample from a chemist's shelf. A Government Analyst declares it "not of standard quality." A complaint is filed before a Magistrate. Suddenly, the manufacturer — whose directors may never have seen the specific batch, whose quality control records are impeccable, and whose product may have failed for a single minor parameter — faces criminal prosecution carrying mandatory minimum imprisonment.*

**This handbook is written for exactly this situation. It is a reactive, crisis-response guide — a step-by-step manual for what pharmaceutical companies, their directors, and their legal teams must do, from the moment a sample is drawn by a Drug Inspector to the final disposal of the matter in court.**

The framework presented here draws on the literal text of the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945, the DCC prosecution guidelines issued under Section 33-P, and the leading Supreme Court and High Court decisions on NSQ prosecution, retesting rights, vicarious liability, and quashing.

## PART I — THE LEGAL ANATOMY OF AN NSQ PROSECUTION

### Chapter 1: Understanding What "Not of Standard Quality" Actually Means in Law

#### 1.1 The Statutory Standard — Section 16 and the Indian Pharmacopoeia

The Act's framework for drug quality rests on a single, objective standard: conformity with the Indian Pharmacopoeia (IP) (or other applicable pharmacopoeia notified in the Second Schedule to the Act). Under Section 16, the Central Government prescribes standards of quality by reference to the IP, and a drug that fails to conform to those standards is, by statutory definition, "not of standard quality" (NSQ).

This standard is absolute and objective — ignorance of the failure, good faith, or absence of criminal intent is not a defence to the basic charge of manufacturing/selling an NSQ drug under Section 18(a)(i). Section 19(1) expressly

provides:

The Act, therefore, creates a strict liability offence for NSQ manufacture/sale — but this strict liability operates only at the threshold of whether the offence is committed. The Act separately provides multiple procedural, categorical, and substantive defences which are the central focus of this handbook.

## 1.2 Three Tiers of Drug Quality Violations

The D&C; Act creates three distinct categories of offence, each with very different consequences:

The classification of the offence determines the entire penal exposure. Every NSQ complaint must be scrutinised at the outset: is the case truly framed as NSQ (Section 18(a)(i)/Section 27(d)), or has the Drug Inspector elevated it to adulteration (Section 17A) or spurious (Section 17B)?

## 1.3 The Full Definitions — Know Your Enemy

"Adulterated Drug" — Section 17A (verbatim):

A drug shall be deemed to be adulterated if:

(a) it consists in whole or in part of any filthy, putrid or decomposed substance; or

(b) it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health; or

(c) its container is composed in whole or in part of any poisonous or deleterious substance which may render contents injurious; or

(d) it bears or contains, for colouring purposes only, a colour other than prescribed; or

(e) it contains any harmful or toxic substance which may render it injurious to health; or

(f) any substance has been mixed therewith so as to reduce its quality or strength

**"Spurious Drug" — Section 17B (verbatim):**

A drug shall be deemed to be spurious if:

(a) it is manufactured under a name belonging to another drug; or

(b) it is an imitation of, or substitute for, another drug or resembles another drug in a manner likely to deceive; or

(c) the label/container bears the name of an individual or company that is fictitious or does not exist; or

(d) it has been substituted wholly or in part by another drug or substance; or

(e) it purports to be the product of a manufacturer of whom it is not truly a product

**Key practical point:** Particulate matter in an injectable, even if characterised loosely as "foreign substance" by a Drug Inspector, does not automatically satisfy any element of Section 17A. The presence of the drug's own crystals (ciprofloxacin sedimentation) is none of: filthy/putrid/decomposed; insanitary contamination; harmful/toxic substance; or strength reduction. Similarly, it does not satisfy any element of Section 17B (spurious). The correct charge — if any — is NSQ under Section 16/18(a)(i).

## Chapter 2: The Full Penalty Schedule — What Is Actually at Stake

Under Section 27, the penalties are:

Repeat offenders under Section 30:

- Repeat under S.27(b): 7–10 years + fine ≥ ₹2 lakh
- Repeat under S.27(c): 10 years to life + fine ≥ ₹3 lakh
- Repeat under S.27(d): 2–4 years + fine ≥ ₹50,000

**The most critical practical point:** A straightforward NSQ prosecution (under Section 27(d)) carries a mandatory minimum of one year imprisonment. This is not a minor fine — this is criminal imprisonment with a statutory mandatory minimum. Every NSQ complaint must be taken with the utmost seriousness from day one.

## **PART II — THE DRUG INSPECTOR'S SAMPLING PROCEDURE: YOUR FIRST LINE OF DEFENCE**

### **Chapter 3: Section 23 — The Mandatory Sampling Protocol**

Every NSQ prosecution begins with a sample drawn by a Drug Inspector. Understanding — and immediately verifying — whether the statutory sampling protocol was followed correctly is the first and most immediately actionable step after receiving notice of an NSQ finding.

#### **3.1 The Step-by-Step Mandatory Procedure under Section 23**

##### **Step 1 — Tender of price:**

The Inspector must tender the fair price of the sample and may require a written acknowledgment. If price is refused, a receipt in the prescribed form must be issued.

##### **Step 2 — Written intimation of purpose — Form 17 (MANDATORY):**

Before taking the sample, the Inspector must intimate in writing in the prescribed form (Form 17) to the person from whom the sample is taken that the sample is being taken for the purpose of test or analysis. Failure to issue Form 17 is a fatal procedural defect — it is not a mere irregularity.

##### **Step 3 — Division of sample in the presence of the person:**

In the presence of the person (unless the person wilfully absents), the sample must be divided into four portions (or three portions if taken from the manufacturing premises) and effectively sealed and marked. The person must be permitted to add their own seal and mark to all or any portions.

##### **Step 4 — Restoration of one portion to the manufacturer/dealer:**

One portion must be restored to the person from whom it is taken. This is not optional — it is mandatory. The manufacturer's right to independent testing depends

on receiving this portion.

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**Step 5 — Disposal of remaining portions:**

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**One portion: forthwith sent to the Government Analyst for test/analysis**

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**One portion: produced before the Court in any proceedings**

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**One portion (where taken): sent to the manufacturer under Section 23(4)(iii) if the dealer has disclosed the manufacturer's name under Section 18A**

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### **3.2 Immediate Checks for the Manufacturer — Checklist**

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**Upon learning that a sample has been drawn from a batch of your product, immediately verify:**

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- Was Form 17 (written purpose intimation) issued by the Inspector?
- Was the sample divided in the presence of your representative?
- Were all portions properly sealed and marked?
- Were the seals intact and not tampered with?
- Was one portion restored to your dealer/representative at the time of sampling?
- Has the manufacturer received their portion under Section 23(4)(iii)?
- What was the storage condition of the sample at the retailer/distributor from whom it was drawn?
- What was the temperature and storage history at the point of sampling?
- What is the remaining shelf life of the product at the time of sampling?
- What is the remaining shelf life today?

**Why every item on this checklist matters: Defects in any of these steps are judicially recognised as grounds for challenging the probative value of the Government Analyst's report, and — if they prejudice the manufacturer's right to retesting — grounds for quashing the entire prosecution.**

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## **Chapter 4: Government Analyst's Report — Section 25**

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### **4.1 What the Government Analyst Reports**

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**The Government Analyst (GA) delivers a signed report in triplicate in the prescribed form stating:**

- Name and description of the sample
- Tests conducted and results
- Whether the drug conforms to or fails to conform to the prescribed standard
- The specific parameter(s) failed (e.g., dissolution test, assay, sterility, particulate matter)

**The Inspector then distributes copies:**

- One copy to the person from whom the sample was taken (dealer/stockist)
- One copy to the manufacturer (if disclosed under Section 18A)
- Third copy retained for use in prosecution

#### **4.2 The Critical Legal Status of the GA Report**

**The GA's report is evidence of the facts stated therein — but this evidence is not conclusive by default.**

Under Section 25(3):

**This 28-day window is the most important single deadline in pharmaceutical NSQ proceedings. Missing it forfeits the right to controvert the GA report. Meeting it preserves the manufacturer's most powerful defence — the right to retesting at the Central Drugs Laboratory.**

**CRITICAL: The 28-day clock starts from the date the manufacturer actually receives the copy of the GA report. If the manufacturer's copy under Section 23(4)(iii) was never sent, the clock has not started running.**

#### **4.3 The Difference between "Standard Quality Failure" and "Analytical Limitations"**

The GA report's scientific value depends heavily on:

- Whether the correct IP test method was followed
- Whether the equipment was properly calibrated
- Whether the sample was stored properly between sampling and analysis
- Whether the sample was transported under controlled conditions
- Whether the test was conducted before the drug's shelf life expired

**In particulate matter cases (injectable products): The IP test for visible particles (IP 2.15.1) requires visual inspection under controlled conditions. The IP for sub-visible particles (2.9.19) uses light obscuration or microscopy. The GA's report must**

identify: (a) the number and size of particles; (b) the nature of the particles (intrinsic/extrinsic); and (c) the test method used. Without particle identification, the GA report does not establish that the particles are "foreign" — an essential element of the NSQ finding under the particulate matter monograph.

## **PART III — THE 28-DAY RESPONSE PROTOCOL: WHAT TO DO IMMEDIATELY**

### **Chapter 5: The First 28 Days — Non-Negotiable Actions**

The receipt of a Government Analyst's report declaring your product NSQ triggers a strict 28-day countdown. The following actions must be completed within this window:

#### **Day 1-3: Assessment and Legal Consultation**

**Preserve all documentation relating to the batch: Batch Manufacturing Record (BMR), all analytical records, raw material testing records, environmental monitoring records, stability data, distribution records**

**Retrieve the manufacturer's sample portion (if not already in possession)**

**Engage legal counsel immediately — do not wait to "see what happens"**

**Read the Government Analyst report carefully — identify: the specific parameter that failed; the test method used; whether the IP method was followed; whether the GA report specifies the nature of the failure (e.g., "presence of foreign particles" or "ciprofloxacin sedimentation" — these are legally different)**

**Check the batch's remaining shelf life — this determines the urgency of retesting**

#### **Day 3-7: Internal Technical Assessment**

**Conduct an internal investigation using your retained reference sample — test the retained reference sample against the specific failing parameter at your QC**

**laboratory or a NABL-accredited third-party laboratory**

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**Obtain a certificate of analysis from a private NABL-accredited laboratory testing the retained/manufacture's sample — while this is not legally conclusive, it builds the evidentiary foundation for disputing the GA report**

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**Prepare a Root Cause Analysis (RCA) — identify all possible reasons why the batch might have shown the failing parameter (storage conditions at retailer, temperature excursion during transport, inherent physicochemical properties of the molecule, etc.)**

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**Check storage compliance at the point of sampling — obtain records or affidavits from the distributor/retailer regarding temperature logs and storage conditions**

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**Day 7-14: Dispute the GA Report — Section 25(3) Notice**

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**Draft and dispatch the Section 25(3) notice by RPAD/Speed Post to:**

- The Drug Inspector who took the sample (at the address given in Form 17)
- The Court before which any proceedings in respect of the sample are pending (if a complaint has been filed)

The notice must unambiguously state:

**Retain proof of dispatch and delivery — the 28-day deadline is jurisdictional; delay cannot be condoned**

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**File a formal application before the Magistrate (if a complaint has been taken cognizance of) under Section 25(4) requesting the court sample to be sent to the CDL**

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**Day 14-28: Pre-Cognizance Actions (if complaint not yet filed)**

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**Write to the Drug Inspector requesting delay in filing the complaint until the CDL retesting is completed — while there is no legal obligation on the Inspector to delay, this creates a documented record of your demand**

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**Write to the State Drug Controller alerting them to the disputed GA report and requesting administrative review before prosecution is initiated**

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Check whether DCC Category C guidelines apply (see Chapter 6 below) — if so, write formally to the licensing authority and State Drug Controller invoking Section 33-P guidelines

## PART IV — THE DCC PROSECUTION GUIDELINES: YOUR FIRST SUBSTANTIVE DEFENCE

### Chapter 6: Section 33-P and the DCC Guidelines — Category A, B, C

Section 33-P of the Act empowers the Central Government to give directions to State Governments regarding the exercise of their powers and discharge of their functions under Chapter IV. Under this power, the Central Government has issued prosecution guidelines through the Drugs Consultative Committee (DCC) that classify NSQ drug defects into categories and prescribe the appropriate response.

These guidelines, though their legal validity is contested (see Chapter 7), have been judicially applied to quash prosecutions in multiple cases including the Rajasthan HC judgment of 2025.

#### 6.1 The Three-Category Classification

**Critical: Ciprofloxacin injection with visible sedimentation (where all other parameters including assay, sterility, endotoxin, pH are within IP limits) squarely falls within Category C. The DCC guidelines expressly list "clear liquid preparations showing sedimentation" as a Category C minor defect.**

#### 6.2 How to Use the DCC Guidelines in Defence

The invocation of DCC Category C guidelines should appear at three stages:

##### Stage 1 — Pre-Prosecution (Administrative):

Write to the State Drug Controller invoking the Section 33-P guidelines and asserting that the defect is a minor defect under Category C that warrants only administrative action, not prosecution. Request that no complaint be filed and that only administrative measures (advisory, voluntary recall if warranted) be taken.

## **Stage 2 — Pre-Cognizance (Magistrate Stage):**

If a complaint is filed despite Category C classification, file a detailed objection before the Magistrate under Section 245 CrPC (or Section 265G BNSS) at the time of first appearance, placing the DCC guidelines on record.

## **Stage 3 — Section 482/528 CrPC/BNSS Quashing Petition:**

### **The DCC guidelines argument was the primary basis of quashing in:**

- *Laborate Pharmaceuticals India Ltd. v. State of Tamil Nadu*, (2018) 15 SCC 93 (Supreme Court) — cough syrup declared NSQ for minor defect; prosecution quashed as DCC guidelines mandated only administrative action
- 2025:RJ-JD:15744, Rajasthan HC — dissolution test failure with API within limits; Category C minor defect; prosecution quashed

The standard argument is:

## **6.3 The Legal Controversy Around the DCC Guidelines**

**It is important for legal counsel to be aware of the ultra vires challenge to DCC guidelines:**

### **Arguments against the DCC guidelines' validity:**

- Section 33 of the Act does not authorise the DCC to modify or dilute the Act's strict liability scheme for NSQ drugs
- The guidelines impermissibly import a mens rea requirement (criminal intent/gross negligence for Category B) into what is a strict liability offence
- The 70% label claim threshold in Category B creates a standard lower than the IP standard prescribed under Section 16 — which only the legislature can modify
- Under *Commissioner of Central Excise, Bolpur v. Ratan Melting and Wire Industries*, (2008) 13 SCC 1, a circular contrary to statute has no existence in law

### **Arguments for the guidelines' applicability:**

- They have been judicially applied by the Supreme Court in *Laborate Pharmaceuticals*
- They represent a legitimate exercise of Section 33-P policy power
- They are consistent with the principle that prosecution is a discretionary exercise of power and administrative remedies should be exhausted first
- Prosecuting minor, non-harmful defects wastes judicial resources and disproportionately affects manufacturers

**Practical guidance:** Use the DCC guidelines as a supplementary argument, not as the sole ground. Courts have been receptive to them but the ultra vires controversy means they should always be combined with the substantive statutory defences (Section 19, Section 25(3)/(4), vicarious liability).

## PART V — THE STATUTORY DEFENCES

### Chapter 7: Section 19 — The Complete Defence Provisions

Section 19 of the Act provides three distinct defences, each applicable to different scenarios.

#### 7.1 Section 19(1) — What Does NOT Work as a Defence

Section 19(1) specifically bars the following as sole defences:

- Ignorance of the nature, substance, or quality of the drug
- Ignorance of the circumstances of its manufacture or import
- The fact that a purchaser buying only for testing purposes was not prejudiced

**Practical implication:** Do not present a defence based solely on "we didn't know the batch was NSQ." This is explicitly excluded. The defences must be structural, scientific, or procedural.

#### 7.2 Section 19(2)(a) — The Innocuous Addition Defence

A drug shall not be deemed to be misbranded, adulterated, spurious, or below standard quality only by reason of the fact that:

**Applicability:** This applies where a manufacturing excipient (stabiliser, preservative, solubilising agent) is identified by the Government Analyst as an "added substance" or where a formulation additive is characterised as adulterant. Common examples: lactic acid in ciprofloxacin injection (added to maintain solubility), benzalkonium chloride in ophthalmic drops.

#### 7.3 Section 19(2)(b) — The Unavoidable Intermixture Defence (MOST POWERFUL FOR INJECTABLE/PARTICULATE CASES)

This is the primary substantive defence for injectable particulate matter cases. The defence requires establishing:

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The particles are "extraneous substance" — but if the particles are the drug itself (ciprofloxacin crystals from pH-dependent precipitation), they are not extraneous at all. The Government Analyst must first prove the particles are extraneous. Absence of particle composition analysis in the GA report means this essential element is not established.

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The intermixture was unavoidable — given the physicochemical properties of ciprofloxacin (fluoroquinolone, pH-sensitive solubility, lactic acid-dependent solubilisation), precipitation of ciprofloxacin crystals under temperature excursion or pH shift is an inherent and scientifically documented phenomenon, not a manufacturing defect.

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The vendor was not aware — if the batch passed all QC checks at the manufacturing stage (as evidenced by the BMR analytical release records), the manufacturer had no knowledge of the intermixture when the drug was sold/distributed.

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#### Key cases directly on point:

- Prem Pharmaceuticals v. State of MP, 1989 Cri LJ 2028 (MP HC, Indore): NaCl injection with foreign particles — prosecution quashed on the ground that absence of chemical analysis of particles means the prosecution cannot establish they are "extraneous"; Section 19(2)(b) applicable
- Narendrakumar Mangilal Dani v. State of Maharashtra, 2001 ALL MR (Cri) 2261 (Bombay HC): IV injections with visible suspended matter — particles are a natural phenomenon of storage; IP itself acknowledges separation of small solid particles "on keeping"; prosecution quashed
- Anandkumar Satyanarayan Loya v. State of Maharashtra (Bombay HC, Aurangabad): Same ratio — development of particles due to faulty preservation cannot be ruled out; manufacturer not responsible for post-despatch storage failures

#### 7.4 Section 19(3) — The Chain-of-Custody Defence (For Distributors and Retailers)

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A person other than the manufacturer shall not be liable for an NSQ offence if they prove:

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(a) The drug was acquired from a duly licensed manufacturer, distributor, or dealer

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(b) They did not know and could not with reasonable diligence have ascertained that the drug in any way contravened Section 18

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**(c) While in their possession, the drug was properly stored and remained in the same state as when acquired**

**Critical practical point: This defence is available to distributors and retailers — not to manufacturers. However, it creates a mirror obligation on the manufacturer — to establish that the drug was in standard condition when it left the factory. BMRs, analytical release records, and dispatch records serve this purpose.**

## **PART VI — THE RIGHT TO RETESTING: SECTION 25(3) AND 25(4)**

### **Chapter 8: The Central Drugs Laboratory — Your Single Most Powerful Weapon**

**The Central Drugs Laboratory (CDL) report is the apex scientific authority in Indian pharmaceutical prosecution. Its legal effect is completely different from the Government Analyst's report:**

The Supreme Court in *Medicamen Biotech Ltd. v. Rubina Bose*, (2008) 7 SCC 196 held:

The Himachal Pradesh High Court (2024) reaffirmed:

#### **8.1 Triggering the CDL Process — Step by Step**

**File Section 25(3) notice within 28 days (see Chapter 5) — this is the trigger**

**File a formal application under Section 25(4) before the Magistrate requesting the court-deposited sample be sent to the CDL. The application should be:**

- In writing, under the CrPC/BNSS
- Addressed to the Magistrate seized of the matter
- Citing Sections 25(3) and 25(4) of the D&C; Act
- Requesting that the portion deposited with the Court (Section 23(4)(ii)) be sent to the CDL for retesting
- Accompanied by the Section 25(3) notice (to establish that the 28-day condition is met)

**The Court may send the sample on its own motion or at the request of either side — if the Magistrate is reluctant, an urgent application before the High Court under**

## **Section 482 CrPC/528 BNSS can be filed seeking a direction to the Magistrate**

The CDL's report is conclusive — if the CDL finds the drug conforming to standard, the prosecution must be quashed on the basis of the conclusive evidence. The Supreme Court in *Amery Pharmaceuticals v. State of Rajasthan*, (2001) 4 SCC 382 and the HP HC 2024 judgment squarely held this.

### **8.2 The Shelf Life Problem — Section 25(4) Right Frustrated**

If the shelf life of the drug expires before the CDL retesting can be completed, the manufacturer's right to retesting under Section 25(4) is effectively frustrated. The consequences are penal to the prosecution, not the manufacturer.

#### **State of Haryana v. Brij Lal Mittal, (1998) 5 SCC 343 (Supreme Court):**

The respondents/manufacturers were directors of a pharmaceutical company. The prosecution delayed filing the complaint. By the time the petitioners were summoned, the shelf life had expired. The Court (while upholding quashing on vicarious liability grounds) confirmed that deprivation of the retesting right due to prosecution-caused delay is a ground for quashing.

#### **Laborate Pharmaceuticals India Ltd. v. State of Tamil Nadu, (2018) 15 SCC 93 (Supreme Court):**

#### **Identification of this ground requires checking:**

- Date of manufacture of the batch
- Shelf life (expiry date on label)
- Date of sampling
- Date of GA report
- Date of filing of complaint
- Date of cognizance
- Current date (May 2026)

If the expiry date has passed AND the CDL retesting has not yet been done, a Section 482/528 petition with this as the primary ground has a very high probability of success.

### **8.3 When the CDL Sample Has Already Been Tested**

If the CDL has already tested the sample (on the prosecution's initiative), the CDL report is conclusive. However, the HP High Court (2024) held that if the manufacturer

was not provided a copy of the CDL report or had no opportunity to request further retesting, the conclusiveness cannot work against the manufacturer. The CDL report would then be admissible without examination of its author, but the manufacturer retains the right to adduce independent evidence.

## PART VII — VICARIOUS LIABILITY: PROTECTING DIRECTORS AND OFFICERS

### Chapter 9: Section 34 — The Full Text and Its Implications

Section 34 of the Drugs and Cosmetics Act, 1940 (verbatim):

For purposes of Section 34:

"Company" includes a firm or other association of individuals

"Director" in relation to a firm means a partner

#### 9.1 The Two Distinct Routes of Personal Liability under Section 34

The key judicial interpretation of Section 34(1) — *State of Haryana v. Brij Lal Mittal*, (1998) 5 SCC 343 (Supreme Court):

The Supreme Court upheld quashing of proceedings against the directors because the complaint did not contain specific averments establishing their personal role in the company's pharmaceutical operations at the time of the offence.

#### 9.2 The Complaint Must Contain Specific Averments — Not Mere Designations

Every NSQ complaint must be scrutinised for:

Does it merely state that "A, B, C are directors/partners of the company"? — Insufficient for Section 34(1) liability

Does it specifically state each named individual was "in charge of and responsible to the company for the conduct of the manufacturing/quality control operations at

**the time of the specific batch's manufacture and sale"? — Required but often absent**

**Does it identify which specific officer had operational control over the batch that was found NSQ? — Necessary for Section 34(2)**

**If the complaint lacks these specific averments, a Section 482/528 petition for quashing of the proceedings against individual officers/directors is maintainable and should be filed promptly.**

The position is reinforced by the following Supreme Court cases applied mutatis mutandis:

- Sunil Bharti Mittal v. CBI, (2015) 4 SCC 609: A director cannot be impleaded merely by virtue of his office; vicarious liability requires specific factual averments
- Gunmala Sales (P) Ltd. v. Anu Mehta, (2015) 1 SCC 103: Same principle; unimpeachable documentary evidence (e.g., Form 28 naming a different person as competent technical staff) can be used at the quashing stage

### **9.3 The "Without Knowledge / Due Diligence" Defences**

**Under the Section 34(1) proviso, a person who is established to have been "in charge" can still avoid personal liability by proving either:**

#### **Defence A: "Without my 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 period of manufacture

#### **Defence B: "Due diligence exercised":**

- The officer implemented all required GMP systems and procedures
- Documentation: GMP compliance records; Schedule M compliance audit reports; the Annual Product Quality Review; training records; SOP registers; inspection book entries; third-party audit reports
- The officer had no reason to believe a particular batch would be NSQ
- 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 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.

## PART VIII — THE COMPLAINT STAGE AND CRIMINAL COURT PROCEDURE

### Chapter 10: Section 32 — Cognizance of Offences

#### Under Section 32 of the Act:

This creates a threshold check:

- Was the complaint filed by a Drug Inspector?
- If filed by a Drug Inspector — was the Inspector authorised for the specific category of drugs?
- Was the sanction of the appropriate authority obtained before filing?

Failure of the complainant to establish their locus standi under Section 32 is a preliminary objection that should be taken at the very first hearing.

#### 10.1 Section 32A — Power of Court to Implead the Manufacturer

Under Section 32A, where a complaint is filed against a retailer or distributor (not the manufacturer), the Court has the power to implead the manufacturer if it considers it necessary to the just decision of the case. This cuts both ways — the Court can add the manufacturer to proceedings, and manufacturers should monitor proceedings against retailers who sold their products.

#### 10.2 Section 32B — Compounding of Certain Offences

Section 32B allows compounding (settlement) of certain offences — but not offences under Section 27(a) (likely to cause death/grievous hurt) or repeat offences under Section 30. For straightforward NSQ cases under Section 27(d), compounding with payment of the prescribed sum is a faster resolution route than trial. The sum for compounding must be prescribed by the Central Government under Rule 68A of the Rules.

## PART IX — THE QUASHING PETITION: A COMPLETE STRATEGY GUIDE

### Chapter 11: Section 482/528 — Grounds for Quashing

A petition under Section 482 CrPC (now Section 528 BNSS) for quashing of a complaint/summoning order in a drug NSQ case is the most powerful and efficient remedy. It is heard by the High Court and, if successful, quashes the complaint at the threshold — before any trial.

The Supreme Court in *State of Haryana v. Bhajan Lal*, 1992 Supp (1) SCC 335 laid down the circumstances where quashing is appropriate. For pharmaceutical NSQ cases, the most commonly invoked grounds are:

#### Ground 1 — Government Analyst's Report Vitiating by Procedural Defect

Any of the following procedural defects in the sampling procedure vitiates the GA report and renders the prosecution unsustainable:

- Form 17 not issued
- Sample not divided in the presence of the manufacturer/dealer
- Seals tampered or not properly applied
- Manufacturer's portion not restored under Section 23(4)(i)
- Manufacturer's portion not sent under Section 23(4)(iii)
- Sample transported in conditions that could cause deterioration/change

Authority: *Laborate Pharmaceuticals* (2018) 15 SCC 93; multiple High Court decisions.

#### Ground 2 — Section 25(3)/(4) Right to Retesting Denied

The most commonly successful ground in modern pharmaceutical quashing jurisprudence:

##### Sub-ground 2(a): Manufacturer's portion never sent under Section 23(4)(iii):

The manufacturer was never able to conduct independent testing because their mandatory sample was not provided.

##### Sub-ground 2(b): 28-day notice was given but CDL testing never done:

The manufacturer timely disputed the GA report, but the prosecution did not cause the court sample to be sent to the CDL.

### **Sub-ground 2(c): Shelf life expired before CDL testing could be done:**

Even if the sample is now in court custody, the shelf life of the drug has expired, making CDL retesting impossible. The manufacturer's right under Section 25(4) has been permanently destroyed by the prosecution's delay.

Authority: Medicamen Biotech (2008) 7 SCC 196; Laborate Pharmaceuticals (2018) 15 SCC 93; Brij Lal Mittal (1998) 5 SCC 343.

### **Ground 3 — DCC Category C Minor Defect (Section 33-P)**

The defect is a Category C minor defect under the DCC guidelines; the prosecution has not first resorted to administrative measures; prosecution for a minor defect that does not pose patient safety risk is an abuse of process.

Authority: Laborate Pharmaceuticals (2018) 15 SCC 93; 2025:RJ-JD:15744 (Rajasthan HC).

### **Ground 4 — Section 19(2)(b) Unavoidable Intermixture**

The particles/substance found are not "extraneous" — they are the drug substance itself; even if extraneous, the intermixture was unavoidable; the Government Analyst has not conducted particle composition analysis to establish the particles are foreign matter.

Authority: Prem Pharmaceuticals (1989 Cri LJ 2028); Narendrakumar Dani (2001 ALL MR Cri 2261); Anandkumar Loya (Bombay HC, 2016).

### **Ground 5 — Absence of Specific Averments — Section 34**

The complaint does not contain specific averments establishing that the individually named directors/officers were "in charge of and responsible to the company for the conduct of business" in relation to manufacturing operations at the time of the offence. Mere designation as director is insufficient.

Authority: Brij Lal Mittal (1998) 5 SCC 343; Sunil Bharti Mittal (2015) 4 SCC 609; Gunmala Sales (2015) 1 SCC 103.

### **Ground 6 — CDL Report Clears the Drug (If Already Obtained)**

If the CDL has already tested the sample and found it conforming to standard, the CDL report is conclusive evidence superseding the GA report, and continued prosecution is an abuse of process.

Authority: Amery Pharmaceuticals v. State of Rajasthan (2001) 4 SCC 382; HP HC 2024.

### **Ground 7 — Limitation Period Expired**

**Under Section 468 CrPC, no court can take cognizance of an offence after the expiry of the period of limitation. For an offence under Section 27(d) (punishable with up to**

2 years), the limitation period is 3 years from the date of the offence (the date of sale/manufacture/sampling). If cognizance is taken after this period without condonation, the prosecution is barred by limitation.

Authority: 2025:RJ-JD:15744 (Rajasthan HC — this precise ground was upheld).

## PART X — COMPREHENSIVE CASE LAW MATRIX

### Chapter 12: Decided Cases by Ground of Quashing

## PART XI — STEP-BY-STEP RESPONSE PROTOCOL — MASTER FLOWCHART

### Chapter 13: The Complete Response Protocol from Sample to Disposal

DRUG INSPECTOR DRAWS SAMPLE ■■■ IMMEDIATE: Verify Section 23 sampling procedure compliance ■■■ Form 17 issued? [Y/N] ■■■ Sample divided in presence? [Y/N] ■■■ Portions sealed/marked? [Y/N] ■■■ Manufacturer portion restored? [Y/N] ■ GOVERNMENT ANALYST REPORT RECEIVED ■■■ WITHIN 28 DAYS: File Section 25(3) notice disputing GA report ■■■ Send by RPAD to Drug Inspector ■■■ Send to Court (if complaint filed) ■■■ File Section 25(4) application before Magistrate for CDL retesting ■■■ SIMULTANEOUSLY: Internal investigation ■■■ Test retained reference sample at NABL lab ■■■ Root Cause Analysis ■■■ Check: Is defect Category C under DCC guidelines? ■■■ Check: Shelf life remaining? ■■■ IF Category C (minor defect): ■■■ Write to State Drug Controller invoking Section 33-P ■■■ Request administrative action only (no prosecution) ■ COMPLAINT FILED BEFORE MAGISTRATE ■■■ FIRST DATE: File preliminary objections ■■■ Section 32 — locus of complainant ■■■ Section 25(3)/(4) — retesting application ■■■ Section 34 — insufficient averments (individual officers) ■■■ PARALLEL: File Section 482/528 quashing petition in High Court ■ with all available grounds (in order of strength): ■ 1. CDL retesting right denied / shelf life expired ■ 2. Section 23 procedure violated ■ 3. DCC Category C guidelines violated ■ 4. Section 19(2)(b) unavoidable intermixture ■ 5. Section 34 no specific averments for individual officers ■ 6. Limitation expired (if applicable) ■ CDL TESTING DONE: ■■■ CDL PASSES DRUG → Apply to quash based on conclusive CDL report ■■■ CDL FAILS DRUG → Defend on trial; use Section 19 defences; challenge adulteration/spurious characterisation; consider Section 32B compounding

## PART XII — DOCUMENTATION CHECKLIST FOR REACTIVE COMPLIANCE

### Chapter 14: What Documents to Preserve Immediately Upon NSQ Notice

When an NSQ complaint is filed against your company or you receive notice of an adverse GA report, immediately secure and preserve the following documents:

#### Batch-Specific Documents:

- Batch Manufacturing Record (BMR) for the specific batch number
- Analytical Release Record (Certificate of Analysis issued at time of manufacture)
- Raw Material Test Reports for all raw materials used in the batch
- In-process Control Records for the batch
- Environmental Monitoring Records for the manufacturing date
- Sterilisation Records (for injectable batches — autoclave charts, sterilisation cycles)
- Reference sample — locate and preserve in appropriate storage conditions
- Packaging Records and label samples for the batch
- Dispatch Records — where was the batch distributed? To which distributors? On what dates?
- Cold Chain Records (for temperature-sensitive products) — temperature logs during transport

#### Personnel Records:

- Form 28 licence (naming the Rule 76 competent technical person at the time of manufacture)
- Employment records and qualifications of the Rule 76 competent person at time of manufacture
- Training records for production and QC staff
- Name of the person who actually signed off the BMR (batch release signature — Rule 78 obligation)

#### GMP Compliance Records:

- Most recent GMP self-inspection/audit report for the manufacturing site
- Annual Product Quality Review for the product for the relevant year
- SOPs for the manufacturing process and QC testing of the specific product
- Stability data for the batch/product
- Any deviation reports, CAPA records relating to the batch or product

### Section 34 Defence Records:

- Board resolutions/minutes showing delegation of manufacturing authority
- Organisational chart showing the manufacturing chain of command
- List of directors/officers with their actual roles — distinguish between executive and non-executive directors
- Employment contracts of the Rule 76 competent person
- Evidence that individual directors named in the complaint had no operational role in manufacturing

### Market/Distribution Records:

- Storage conditions at the distributor/retailer from whom the sample was drawn — obtain affidavits or records
- Temperature excursion reports (if any) during transport or storage
- Any customer complaints about the batch prior to the sampling

## PART XIII — ADMINISTRATIVE REMEDIES AND LICENCE PROTECTION

### Chapter 15: Protecting the Manufacturing Licence During a Prosecution

NSQ prosecution proceedings are separate from licence suspension/cancellation proceedings. However, they often trigger parallel administrative action. Here is how to manage both tracks:

#### 15.1 Responding to Show Cause Notice for Licence Suspension

If the licensing authority issues a show-cause notice for licence suspension following an NSQ finding:

**Do not ignore or file a brief reply — file a detailed, documented reply establishing:**

- All IP parameters other than the failing parameter were within limits
- GMP compliance — BMRs, SOPs, audit records attached
- Root cause analysis establishing the failure was due to post-despatch storage, inherent molecular behaviour, or isolated batch deviation (not systemic)
- Actions already taken: voluntary recall, CAPA, process improvement

**Request a personal hearing — you are entitled to an opportunity of hearing before any adverse order; insist on it**

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**Invoke the DCC guidelines — if the defect is Category C, the guidelines provide that only administrative warning or advisory is warranted; suspension/cancellation is disproportionate**

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**File a writ petition under Article 226 if the licensing authority acts against the weight of evidence — courts have consistently held that suspension/cancellation must be preceded by proper inquiry and opportunity**

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## **15.2 Voluntary Recall vs. Forced Recall**

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**A voluntary recall, initiated by the manufacturer before being directed by authorities, demonstrates:**

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- Bona fide concern for patient safety
- Proactive compliance
- Absence of criminal intent (relevant to Section 34 proceedings)
- GMP compliance (Schedule M requires a functional recall SOP)

**Always initiate a voluntary recall of the specific batch when a credible NSQ finding is made, even if contested. Document every step. This record of voluntary action is the strongest evidence of the "due diligence" defence under Section 34(1).**

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## **APPENDIX A — COMPLETE QUASHING PETITION GROUNDS — READY RECKONER**

For a petition under Section 528 BNSS/482 CrPC in a pharmaceutical NSQ matter, the following grounds should be assessed and included as applicable:

## **APPENDIX B — 28-DAY ACTION CHECKLIST (TEAR-OUT READY)**

## APPENDIX C — QUICK REFERENCE: PENALTIES AT A GLANCE

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