



Medicines & Healthcare products Regulatory Agency

Defective Medicines Online Reporting Form – Reference Guide

Licence holders, or nominated representatives, should report defective medicine reports directly via the online reporting form, accessed via <https://icsrsubmissions.mhra.gov.uk/login>.

This site is already used by many organisations to submit Individual Case Safety Reports (ICSRs) and Suspected Unexpected Serious Adverse Reaction reports (SUSARs) to the MHRA. As such, your organisation may already have an organisation account for these purposes. **Before attempting to register a new account please check whether this is the case so that the correct registration process below can be followed.**

The reporting process via the portal has been designed to replicate the current process for defective medicines case reporting, removing the need to email information to the DMRC directly and provide you with access to what has been submitted. Verbal reports can be made by contacting the DMRC Helpline, and should always be made, if the report concerns a critical or major defect, or is outside of office-hours.

The data collected in the online reporting form is based on our internal processes centred around the E2B R3 Individual Case Safety Report (ICSR) Specification and Related Files, however, tailored to reporting of defective medicines.

1. Accessing the Form for the First Time/ Registration

As above, this portal is already used by many organisations for other purposes. All existing users will automatically be granted the ability to report using this form; it is not something that manually needs to be added to existing users' accounts.

If you are not an existing user using the portal for other purposes, you should first **determine whether your organisation is already registered, to allow you to determine the correct approach for gaining access, as below:**

- i. Scenario 1: Organisation already registered on ICSR submissions portal to submit ICSRs: **not using a CRO**

There is no need for any further action from the MHRA as this can be handled internally by your organisation.



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Your organisation should have existing organisation lead(s) who can set up accounts for any new users as per the standard process for new ICSR submissions portal users.

All organisation leads will be able to view both ICSR and defective medicine transmissions.

ii. Scenario 2: Organisation currently registered on ICSR submissions portal using a CRO to submit ICSRs

This can be handled by asking the CRO to set up users. Any CRO user(s) with the organisation lead account(s) can set up any new users for the organisation.

Please note: if an organisation lead creates a defective medicines user and your organisation has CRO users with organisation lead permissions, those CRO leads will be able to view all defective medicines reports submitted via the portal, and vice versa.

If this presents a data protection concern/ issue, please do not request that the CRO organisation lead(s) set(s) you up, but instead please email: dmrc@mhra.gov.uk explaining this; you will be able to continue to submit via email in the meantime.

iii. Scenario 3: Organisation not currently registered on ICSR submissions portal

Organisations should register by selecting “**Request company account**” on the portal login page: [Sign in | MHRA](#). This will set up the organisation, and an organisation lead, who can subsequently create any further new users.

*Please note: if your organisation currently submits ICSRs via MHRA gateway, please enter the full company name followed by “**Defective Medicines Only**” in the Company Name field. This is to ensure that the team does not switch your route of ICSR transmissions to the portal.*

In future enhancements we will look to include “defective medicines” in the submission type drop-down.

2. Defective Medicines Reporting Form Specific Data Entry Guidance

Access to the Defective Medicines Reporting Form can be configured by selecting:

- a) Report Submission
- b) New Report



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- c) Select 'Defective Medicines Reporting Form' from the drop-down menu
- d) Previously submitted reports can be access via the 'Report Management' option, with further options to export the report as a PDF or XML for use in local systems once an individual report is selected.

The guidance below provides further specific information on how to ensure that data is accurately entered into the form.

1. Organisation Case Information

Organisation Unique Identifier	UI specific to this individual case report. Must be in correct format: (Country Code)-(Company)-(text) e.g. GB-COMPANY1-2394. It may be helpful for the reporting organisation use their own reference number/digits for ease of identification.
Date of Creation	Auto-generated date, specific to the date the report was created/submitted
Date company first made aware of suspected defect	Optional date field
Date of receipt of the most recent information for this report	Optional date field
Worldwide Unique Case Identification	Auto-generated unique identifier for the case, to match the process for Yellow Card reports
Identification Number of the Report Which Is Linked to This Report	Optional field, include the MHRA reference number to which this report relates to if a previous Yellow Card report was received. i.e. in the event a Yellow Card report was received, however the issue transpired to be a quality issue, this YC report reference



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	should be provided so the DMRC can link the case and any associated signals
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2. Reporter

Source of information	Identify how this was first notified to the company, via own internal mechanism and testing or via external reporters
If 'Customer / Patient / HCP Complaint' selected, optional fields to complete	Provide details, where consent has been provided, to share the reporter details for any specific DMRC follow up

3. Product Information

Medicinal Product Information	Data to be provided relating to the impacted medicinal product(s). Multiple products can be added to one online reporting form by using the 'Add' option following completion of one suspected defective product
Product Licence Information	Free text field
Medicinal Product Name	Select via drop-down list or free text available
Active Pharmaceutical Ingredient	Free text field. Products with multiple APIs should follow the protocol below:



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	e.g. metformin / vildagliptan
Strength (number) (Optional)	Free text field
Strength (unit) (Optional)	Select via drop-down list
Formulation (Optional)	Free text field, route of administration of the product
Product Container Type Size (Optional)	Free text field. Specific to the pack size, e.g. 28
Quantities Impacted (Optional)	Free text field. If there are multiple batches impacted, use Case Details and Further Information to capture further data
Product Licensed In The UK	Select via drop-down list
Product Legal Status	Select via drop-down list
Batch/Lot number (Optional)	Free text field. Where multiple batches are impacted, each product/batch should be added as an individual product by using the 'Add' option following completion of one suspected defective product
Expiry Date	Date field
Contract Manufacturing Organisation / Company Manufacturing Site Information	Free text field, specific to where the suspected defective product has been manufactured. Only company name is required here. If this is unavailable, please use name of company reporting suspected defect
Proposed Market Action(Optional)	Select via drop-down list



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4. Event

Defect classification	The DMRC have proposed to utilise MedDRA (Medical Dictionary for Regulatory Activities) terminology for capturing quality defect reports. This field is a search as you type field, e.g. 'out of specification' will bring up a list to choose from. The DMRC assessment team will always check the correct MedDRA term has been selected. See Appendix 8 for more information.
Defect as reported by the primary source	Free text field to completion of the defect, for reports that do not originate from a complaint, a short description of the defect can be provided, however the Case Details and Further Information is preferred for a full case narrative
Defect resulted in death?	Select via drop-down list
Defect was life threatening?	Select via drop-down list
Defect caused / prolonged hospitalisation?	Select via drop-down list
Defect was disabling / incapacitating?	Select via drop-down list
Defect resulted in congenital anomaly / birth defect?	Select via drop-down list
Defect caused any other medically important condition?	Select via drop-down list



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5. Case Details and Further Information

Defect description	<p>Defect description</p> <p>Please provide as much information as possible, including, but not limited to, the following:</p> <p>(a) initial defect impact assessment and immediate action undertaken</p> <p>(b) health hazard evaluation/risk assessment</p> <p>(c) description of the root cause or ongoing hypothesis</p> <p>(d) proposed market action and supply impact to the UK market and other markets</p> <p>(e) corrective and preventative actions (CAPA) and full deviation report</p>
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6. Attachments

Attachments	<p>Maximum individual file size 5mb. Maximum combined file size 10mb.</p> <p>If further files are required, please indicate this in Section 5 above and the DMRC will confirm when considering the initial assessment.</p>
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MedDRA Terms

The following MedDRA Terms provide an overview of the terms to be used for defect classification. The terms below all belong to the System Organ Class (SOC) Name: Product Issues and High Level Group Term (HLGT) Name: Product quality, supply, distribution, manufacturing and quality system issues. Industry stakeholders should select the most appropriate Preferred Term (PT) Name or Lowest Level Term (LLT) Name from the list below. Please note that this list is not exhaustive and other terms can be selected if more appropriate.

High Level Term (HLT) Name	Preferred Term (PT) Name	Lowest Level Term (LLT) Name
Product quality issues NEC	Adulterated product	Adulterated product
Manufacturing production issues	Device misassembly during manufacturing	Device misassembly during manufacturing
Product quality issues NEC	Drug delivery system issue	Drug delivery system issue
Product quality issues NEC	Drug delivery system malfunction	Drug delivery system malfunction
Product quality issues NEC	Failure of additional condition for nonprescription use	Failure of additional condition for nonprescription use
Product packaging issues	Failure of child resistant product closure	Failure of child resistant product closure
Product packaging issues	Failure of child resistant product closure	Failure of child resistant mechanism for pharmaceutical product
Quality system issues	Improper management of out of specification result	Out of specification result not investigated
Quality system issues	Improper management of out of specification result	Improper management of out of specification result
Quality system issues	Improper management of out of specification result	Out of specification result invalidated without investigation
Quality system issues	Improper management of out of specification result	Out of specification result invalidated without appropriate rationale
Manufacturing production issues	Inadequate aseptic technique in manufacturing of product	Inadequate aseptic technique in manufacturing of product
Quality system issues	Inappropriate batch production records	Missing batch production record
Quality system issues	Inappropriate batch production records	Incomplete batch production record
Quality system issues	Inappropriate batch production records	Inappropriate batch production records



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Product distribution and storage issues	Inappropriate release of product for distribution	Product distribution prior to required testing
Product distribution and storage issues	Inappropriate release of product for distribution	Inappropriate release of product for distribution
Product distribution and storage issues	Inappropriate release of product for distribution	Product distribution prior to validation of process
Product distribution and storage issues	Inappropriate release of product for distribution	Product distribution prior to quality control unit release
Product quality issues NEC	Issue with additional condition for nonprescription use	Issue with additional condition for nonprescription use
Product physical issues	Liquid product physical issue	Product foaming
Product physical issues	Liquid product physical issue	Liquid phase separation
Product physical issues	Liquid product physical issue	Product appearance cloudy
Product physical issues	Liquid product physical issue	Product viscosity variable
Product physical issues	Liquid product physical issue	Liquid product flow abnormal
Product physical issues	Liquid product physical issue	Liquid product physical issue
Product physical issues	Liquid product physical issue	Liquid product consistency issue
Product physical issues	Liquid product physical issue	Abnormal liquid product viscosity
Product physical issues	Liquid product physical issue	Bubbles present in liquid product
Product physical issues	Liquid product physical issue	Increased liquid product viscosity
Product physical issues	Liquid product physical issue	Decreased liquid product viscosity
Product physical issues	Liquid product physical issue	Particle present in liquid product
Manufacturing facilities and equipment issues	Manufacturing equipment cleaning issue	Manufacturing equipment cleaning issue
Manufacturing facilities and equipment issues	Manufacturing equipment cleaning issue	Use of inappropriate cleaning agent in manufacturing
Manufacturing facilities and equipment issues	Manufacturing equipment issue	Manufacturing equipment issue
Manufacturing facilities and equipment issues	Manufacturing equipment issue	Manufacturing equipment filter issue
Manufacturing facilities and equipment issues	Manufacturing equipment issue	Manufacturing equipment high efficiency air filter issue
Manufacturing facilities and equipment issues	Manufacturing equipment sanitisation issue	Manufacturing equipment sanitization issue



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Manufacturing facilities and equipment issues	Manufacturing equipment sanitisation issue	Manufacturing equipment sanitisation issue
Manufacturing facilities and equipment issues	Manufacturing equipment sterilisation issue	Manufacturing equipment sterilization issue
Manufacturing facilities and equipment issues	Manufacturing equipment sterilisation issue	Manufacturing equipment sterilisation issue
Manufacturing facilities and equipment issues	Manufacturing facilities issue	Manufacturing facilities issue
Manufacturing facilities and equipment issues	Manufacturing facilities issue	Manufacturing facility pressure differential issue
Manufacturing facilities and equipment issues	Manufacturing facilities issue	Manufacturing facility high efficiency air filter issue
Manufacturing issues NEC	Manufacturing issue	Manufacturing issue
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing not reported
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing not performed due to pandemic
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing not documented due to pandemic
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing not investigated due to pandemic
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, safety incorrectly performed
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, purity incorrectly performed
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, potency incorrectly performed
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, identity incorrectly performed
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, stability incorrectly performed
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, sterility incorrectly performed
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, safety not performed or documented
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue due to pandemic manpower disruption



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Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, purity not performed or documented
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, potency not performed or documented
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, identity not performed or documented
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, sterility not performed or documented
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing issue	Manufacturing laboratory analytical testing issue, stability not performed or documented
Manufacturing laboratory controls issues	Manufacturing laboratory analytical testing method management issue	Manufacturing laboratory analytical testing method management issue
Manufacturing laboratory controls issues	Manufacturing laboratory controls calibration issue	Manufacturing laboratory controls calibration issue
Manufacturing laboratory controls issues	Manufacturing laboratory controls issue	Manufacturing laboratory controls issue
Manufacturing laboratory controls issues	Manufacturing laboratory controls issue	Manufacturing laboratory data control issue
Manufacturing materials issues	Manufacturing material testing deviation	Manufacturing material testing deviation
Manufacturing materials issues	Manufacturing materials contamination	Manufacturing materials contamination
Manufacturing materials issues	Manufacturing materials contamination	Manufacturing excipient contamination
Manufacturing materials issues	Manufacturing materials contamination	Manufacturing raw material contamination
Manufacturing materials issues	Manufacturing materials contamination	Manufacturing inactive ingredient contamination
Manufacturing materials issues	Manufacturing materials contamination	Manufacturing active pharmaceutical ingredient contamination
Manufacturing materials issues	Manufacturing materials issue	Product raw material issue
Manufacturing materials issues	Manufacturing materials issue	Manufacturing materials issue
Manufacturing materials issues	Manufacturing materials issue	Manufacturing excipient issue
Manufacturing materials issues	Manufacturing materials issue	Manufacturing component issue
Manufacturing materials issues	Manufacturing materials issue	Manufacturing raw material issue
Manufacturing materials issues	Manufacturing materials issue	Manufacturing material impurities
Manufacturing materials issues	Manufacturing materials issue	Incoming material container defective
Manufacturing materials issues	Manufacturing materials issue	Manufacturing inactive ingredient issue



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Manufacturing materials issues	Manufacturing materials issue	Lack of manufacturing materials due to pandemic
Manufacturing materials issues	Manufacturing materials issue	Shortage of inactive ingredient due to pandemic
Manufacturing materials issues	Manufacturing materials issue	Incoming material container out of specification
Manufacturing materials issues	Manufacturing materials issue	Shortage of manufacturing component due to pandemic
Manufacturing materials issues	Manufacturing materials issue	Shortage of manufacturing materials due to pandemic
Manufacturing materials issues	Manufacturing materials issue	Manufacturing active pharmaceutical ingredient issue
Manufacturing materials issues	Manufacturing materials issue	Incoming material container closure out of specification
Manufacturing materials issues	Manufacturing materials issue	Shortage of active pharmaceutical ingredient due to pandemic
Manufacturing production issues	Manufacturing process control procedure incorrectly performed	Manufacturing process control procedure incorrectly performed
Manufacturing production issues	Manufacturing process control procedure issue	Manufacturing process control procedure issue
Manufacturing production issues	Manufacturing process control procedure issue	Manufacturing process control bulk material issue
Manufacturing production issues	Manufacturing process control procedure issue	Manufacturing process control procedure filling issue
Manufacturing production issues	Manufacturing process control procedure issue	Manufacturing process control procedure media fill issue
Manufacturing production issues	Manufacturing process control procedure issue	Manufacturing process control procedure temperature issue
Manufacturing production issues	Manufacturing process control procedure issue	Manufacturing process control procedure aseptic processing issue
Manufacturing production issues	Manufacturing process control procedure issue	Manufacturing process control, process water out of specifications
Manufacturing production issues	Manufacturing process control procedure issue	Manufacturing process control procedure equipment calibration issue
Manufacturing production issues	Manufacturing process control procedure issue	Manufacturing process control procedure environmental monitoring issue
Manufacturing production issues	Manufacturing process control procedure not performed	Manufacturing process control procedure not performed
Product distribution and storage issues	Manufacturing product shipping issue	Manufacturing product shipping issue
Product distribution and storage issues	Manufacturing product storage issue	Manufacturing product storage issue
Manufacturing production issues	Manufacturing production issue	Manufacturing production issue
Manufacturing production issues	Manufacturing production issue	Manufacturing facility shutdown due to pandemic
Manufacturing production issues	Manufacturing production issue	Manufacturing production disrupted due to pandemic
Manufacturing production issues	Manufacturing production issue	Manufacturing production temporarily discontinued due to pandemic



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Manufacturing production issues	Manufacturing production issue	Manufacturing production permanently discontinued due to pandemic
Manufacturing laboratory controls issues	Manufacturing stability testing issue	Manufacturing stability testing issue
Manufacturing laboratory controls issues	Manufacturing stability testing issue	Manufacturing stability testing pH issue
Manufacturing laboratory controls issues	Manufacturing stability testing issue	Stability protocol deviation not documented
Manufacturing laboratory controls issues	Manufacturing stability testing issue	Manufacturing stability testing potency issue
Manufacturing laboratory controls issues	Manufacturing stability testing issue	Manufacturing stability testing moisture issue
Manufacturing laboratory controls issues	Manufacturing stability testing issue	Manufacturing stability testing preservative issue
Manufacturing laboratory controls issues	Manufacturing stability testing issue	Manufacturing stability testing container closure issue
Manufacturing laboratory controls issues	Manufacturing stability testing issue	Manufacturing stability testing content uniformity issue
Manufacturing laboratory controls issues	Manufacturing stability testing issue	Manufacturing stability testing chemical analysis purity issue
Manufacturing materials issues	Material from non-qualified supplier used	Material from non-qualified supplier used
Manufacturing laboratory controls issues	Out of specification product testing issue	Out of specification product testing issue
Manufacturing laboratory controls issues	Out of specification product testing issue	Out of specification testing issue, not reported due to pandemic
Manufacturing laboratory controls issues	Out of specification product testing issue	Out of specification testing issue, not performed due to pandemic
Manufacturing laboratory controls issues	Out of specification product testing issue	Out of specification testing issue, not documented due to pandemic
Manufacturing laboratory controls issues	Out of specification product testing issue	Out of specification testing issue, not investigated due to pandemic
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results pH
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results assay
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results density



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Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results potency
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results moisture
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results impurity
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results stability
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results cold flow
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results viscosity
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results friability
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results appearance
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results osmolality
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results fill volume
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results dissolution
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results shear stress
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results precipitates
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results peel adhesion
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results contamination
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results melting point
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results particle size
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results tack property
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results residual solvent



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Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results blend uniformity
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results specific gravity
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results container closure
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results residual monomers
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results weight uniformity
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results elemental impurity
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results disintegration time
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results preservative content
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results content of uniformity
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results delivered dose uniformity
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results for component packaged with final product
Manufacturing laboratory controls issues	Out of specification test results	Out of specification test results active pharmaceutical ingredient impurity
Manufacturing laboratory controls issues	Out of trend test result	Out of trend test result
Manufacturing laboratory controls issues	Out of trend test result	Out of trend test result assay
Manufacturing laboratory controls issues	Out of trend test result	Out of trend test result stability
Manufacturing laboratory controls issues	Out of trend test result	Out of trend test result dissolution
Product packaging issues	Packaging design issue	Packaging design issue
Product label issues	Physical product label issue	Product label loose
Product label issues	Physical product label issue	Product label missing
Product label issues	Physical product label issue	Product label damaged
Product label issues	Physical product label issue	Product label missing text



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Product label issues	Physical product label issue	Physical product label issue
Product label issues	Physical product label issue	Product label placement issue
Product quality issues NEC	Product adhesion issue	Product adhesion issue
Product quality issues NEC	Product adhesion issue	Product adhesion excessive
Product quality issues NEC	Product adhesion issue	Product adhesion increased
Product quality issues NEC	Product adhesion issue	Product adhesion decreased
Product quality issues NEC	Product adhesion issue	Product adhesion insufficient
Product quality issues NEC	Product adhesion issue	Medicinal patch adhesion issue
Product quality issues NEC	Product adhesion issue	Medicinal patch adhesion increased
Product quality issues NEC	Product adhesion issue	Medicinal patch adhesion excessive
Product quality issues NEC	Product adhesion issue	Medicinal patch adhesion decreased
Product quality issues NEC	Product adhesion issue	Medicinal patch adhesion insufficient
Product physical issues	Product after taste	Product after taste
Product physical issues	Product after taste	Medication after taste
Product supply and availability issues	Product availability issue	Drug shortage
Product supply and availability issues	Product availability issue	Product availability issue
Product supply and availability issues	Product availability issue	Drug shortage due to pandemic
Product supply and availability issues	Product availability issue	Drug delivery device unavailable
Product supply and availability issues	Product availability issue	Product unavailable due to pandemic
Product label issues	Product barcode issue	Product barcode issue
Product label issues	Product barcode issue	Product barcode missing
Product label issues	Product barcode issue	Product barcode on wrong product
Product label issues	Product barcode issue	Product barcode readability issue
Product packaging issues	Product blister packaging issue	Unit-dose blister pack issue
Product packaging issues	Product blister packaging issue	Product blister packaging issue
Product packaging issues	Product blister packaging issue	Product blister packaging separated
Product physical issues	Product caught fire	Product caught fire



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Product physical issues	Product caught fire	Inflammable product caught fire
Product contamination and sterility issues	Product cleaning inadequate	Product cleaning inadequate
Product packaging issues	Product closure issue	Vial stopper damage
Product packaging issues	Product closure issue	Product closure leak
Product packaging issues	Product closure issue	Product closure issue
Product packaging issues	Product closure issue	Product stopper coring
Product packaging issues	Product closure issue	Product closure missing
Product packaging issues	Product closure issue	Product closure deterioration
Product packaging issues	Product closure removal difficult	Product closure removal difficult
Product physical issues	Product coating issue	Product coating issue
Product physical issues	Product coating issue	Product coating cracked
Product physical issues	Product coating issue	Product coating incomplete
Product physical issues	Product colour issue	Product color issue
Product physical issues	Product colour issue	Product colour issue
Product physical issues	Product colour issue	Product discoloration
Product physical issues	Product colour issue	Product color leaching
Product physical issues	Product colour issue	Product discolouration
Product physical issues	Product colour issue	Product colour leaching
Product physical issues	Product colour issue	Product color variation
Product physical issues	Product colour issue	Product colour variation
Product packaging issues	Product commingling	Product commingling
Product packaging issues	Product commingling	Wrong product and correct product in same container
Product packaging issues	Product commingling	Wrong and correct product strengths in same container
Product quality issues NEC	Product complaint	Product complaint
Product quality issues NEC	Product complaint	Pharmaceutical product complaint
Product quality issues NEC	Product compounding quality issue	Product compounding quality issue



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Product packaging issues	Product container issue	Product vial breakage
Product packaging issues	Product container issue	Product container leak
Product packaging issues	Product container issue	Product container issue
Product packaging issues	Product container issue	Product container damaged
Product packaging issues	Product container issue	Product container discoloration
Product packaging issues	Product container issue	Product container type incorrect
Product packaging issues	Product container issue	Product container discolouration
Product packaging issues	Product container issue	Product container size incorrect
Product packaging issues	Product container seal issue	Product container seal issue
Product contamination and sterility issues	Product contamination	Product contamination
Product contamination and sterility issues	Product contamination	Device contamination during use
Product contamination and sterility issues	Product contamination	Preservation media contamination
Product contamination and sterility issues	Product contamination	Device contamination prior to use
Product contamination and sterility issues	Product contamination	Therapeutic product contamination
Product contamination and sterility issues	Product contamination	Pharmaceutical product contamination
Product contamination and sterility issues	Product contamination chemical	Product contamination chemical
Product contamination and sterility issues	Product contamination microbial	Device colonisation
Product contamination and sterility issues	Product contamination microbial	Device colonization
Product contamination and sterility issues	Product contamination microbial	Product biofilm coating
Product contamination and sterility issues	Product contamination microbial	Product contamination mold
Product contamination and sterility issues	Product contamination microbial	Product contamination mould
Product contamination and sterility issues	Product contamination microbial	Product contamination viral



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Product contamination and sterility issues	Product contamination microbial	Product contamination fungal
Product contamination and sterility issues	Product contamination microbial	Product contamination exotoxin
Product contamination and sterility issues	Product contamination microbial	Product contamination bacterial
Product contamination and sterility issues	Product contamination microbial	Product contamination microbial
Product contamination and sterility issues	Product contamination microbial	Product contamination endotoxin
Product contamination and sterility issues	Product contamination microbial	Product contamination endospores
Product contamination and sterility issues	Product contamination physical	Product contamination soil
Product contamination and sterility issues	Product contamination physical	Product contamination hair
Product contamination and sterility issues	Product contamination physical	Product contamination metal
Product contamination and sterility issues	Product contamination physical	Product contamination glass
Product contamination and sterility issues	Product contamination physical	Product contamination insect
Product contamination and sterility issues	Product contamination physical	Product contamination plastic
Product contamination and sterility issues	Product contamination physical	Product contamination physical
Product contamination and sterility issues	Product contamination physical	Product contamination plant matter
Product contamination and sterility issues	Product contamination physical	Product contamination animal matter
Product contamination and sterility issues	Product contamination physical	Product contamination inorganic matter
Product contamination and sterility issues	Product contamination physical	Product contamination foreign material
Product contamination and sterility issues	Product contamination physical	Product contamination particulate matter
Product contamination and sterility issues	Product contamination with body fluid	Product contamination with blood



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Product contamination and sterility issues	Product contamination with body fluid	Product contamination with body fluid
Product contamination and sterility issues	Product contamination with body fluid	Product contamination with blood derivative
Counterfeit, falsified and substandard products	Product counterfeit	Spurious product
Counterfeit, falsified and substandard products	Product counterfeit	Falsified product
Counterfeit, falsified and substandard products	Product counterfeit	Product counterfeit
Counterfeit, falsified and substandard products	Product counterfeit	Pharmaceutical product counterfeit
Product quality issues NEC	Product delivery mechanism issue	Product dropper issue
Product quality issues NEC	Product delivery mechanism issue	Product dropper missing
Product quality issues NEC	Product delivery mechanism issue	Product dropper tip issue
Product quality issues NEC	Product delivery mechanism issue	Product dosing cup missing
Product quality issues NEC	Product delivery mechanism issue	Product dropper tip missing
Product quality issues NEC	Product delivery mechanism issue	Product spray mechanism issue
Product quality issues NEC	Product delivery mechanism issue	Product delivery mechanism issue
Product quality issues NEC	Product delivery mechanism issue	Product dropper improperly calibrated
Product quality issues NEC	Product delivery mechanism issue	Product dropper calibration unreadable
Product quality issues NEC	Product delivery mechanism issue	Product dosing cup markings unreadable
Product physical issues	Product deposit	Product deposit
Product physical issues	Product deposit	Product crystals present
Product physical issues	Product deposit	Product precipitate present
Product physical issues	Product deposit	Product sedimentation present
Product packaging issues	Product desiccant issue	Product desiccant issue
Product packaging issues	Product desiccant issue	Product desiccant damaged
Product packaging issues	Product desiccant issue	Product desiccant missing



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Product quality issues NEC	Product design issue	Product design issue
Product distribution and storage issues	Product distribution issue	Product shipment delay
Product distribution and storage issues	Product distribution issue	Product distribution issue
Product distribution and storage issues	Product distribution issue	Product shipment delay due to pandemic
Product distribution and storage issues	Product distribution issue	Product distribution delay due to pandemic
Product physical issues	Product dosage form issue	Product dosage form issue
Product physical issues	Product dosage form issue	Product dosage form imprint incorrect
Product physical issues	Product dosage form issue	Product dosage form identification issue
Product label issues	Product expiration date issue	Product expiration date issue
Product label issues	Product expiration date issue	Product expiration date missing
Product label issues	Product expiration date issue	Product expiration date incorrect
Product label issues	Product expiration date issue	Product expiration date illegible
Product label issues	Product expiration date issue	Product label expiration date extended
Product quality issues NEC	Product formulation issue	Product ingredient issue
Product quality issues NEC	Product formulation issue	Product formulation issue
Product quality issues NEC	Product formulation issue	Wrong active ingredient in product
Product physical issues	Product gel formation	Product gel formation
Product label issues	Product identification number issue	Product identification number issue
Product label issues	Product identification number issue	Product identification number missing
Product label issues	Product identification number issue	Product identification number incorrect
Product label issues	Product identification number issue	Product identification number illegible
Product quality issues NEC	Product impurity	Product impurity
Product quality issues NEC	Product impurity	Product impurities found
Counterfeit, falsified and substandard products	Product label counterfeit	Product label counterfeit
Product label issues	Product label issue	Misbranded product



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Product label issues	Product label issue	Carton label issue
Product label issues	Product label issue	Product label issue
Product label issues	Product label issue	Carton label missing
Product label issues	Product label issue	Product leaflet issue
Product label issues	Product label issue	Product leaflet missing
Product label issues	Product label issue	Product leaflet text wrong
Product label issues	Product label issue	Product package insert issue
Product label issues	Product label issue	Product label text illegible
Product label issues	Product label issue	Product package insert missing
Product label issues	Product label issue	Product label strength missing
Product label issues	Product label issue	Product package insert incorrect
Product label issues	Product label issue	Product label strength incorrect
Product label issues	Product label issue	Product package insert text wrong
Product label issues	Product label on wrong product	Wrong product leaflet
Product label issues	Product label on wrong product	Product label on wrong product
Product physical issues	Product leakage	Product leakage
Product label issues	Product lot number issue	Product lot number issue
Product label issues	Product lot number issue	Product lot number missing
Product label issues	Product lot number issue	Product charge number issue
Product label issues	Product lot number issue	Product lot number incorrect
Product label issues	Product lot number issue	Product lot number illegible
Product quality issues NEC	Product measured potency issue	Product measured subpotent
Product quality issues NEC	Product measured potency issue	Product measured superpotent
Product quality issues NEC	Product measured potency issue	Product measured potency issue
Product quality issues NEC	Product measured potency issue	Product measured potency decrease over time
Product physical issues	Product odour abnormal	Product odor abnormal
Product physical issues	Product odour abnormal	Product odour abnormal



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Product physical issues	Product odour abnormal	Product smell abnormal
Product quality issues NEC	Product origin unknown	Product origin unknown
Product quality issues NEC	Product origin unknown	Product manufacturer unknown
Product packaging issues	Product outer packaging issue	Product outer packaging issue
Counterfeit, falsified and substandard products	Product packaging counterfeit	Product packaging counterfeit
Product packaging issues	Product packaging difficult to open	Product packaging difficult to open
Product packaging issues	Product packaging issue	Bag port defect
Product packaging issues	Product packaging issue	Product packaging issue
Product packaging issues	Product packaging quantity issue	Package empty units
Product packaging issues	Product packaging quantity issue	Package volume overfill
Product packaging issues	Product packaging quantity issue	Package volume underfill
Product packaging issues	Product packaging quantity issue	Package quantity incorrect
Product packaging issues	Product packaging quantity issue	Package dosage units missing
Product packaging issues	Product packaging quantity issue	Product packaging quantity issue
Product packaging issues	Product packaging quantity issue	Unit-dose blister packaging partial fill
Product physical issues	Product physical consistency issue	Product physical consistency issue
Product physical issues	Product physical issue	Tablet issue
Product physical issues	Product physical issue	Capsule open
Product physical issues	Product physical issue	Product burst
Product physical issues	Product physical issue	Capsule issue
Product physical issues	Product physical issue	Tablet cracked
Product physical issues	Product physical issue	Tablet damaged
Product physical issues	Product physical issue	Tablet chipped
Product physical issues	Product physical issue	Product friable
Product physical issues	Product physical issue	Tablet clumping
Product physical issues	Product physical issue	Cracked product



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Product physical issues	Product physical issue	Product damaged
Product physical issues	Product physical issue	Product clumping
Product physical issues	Product physical issue	Product crumbling
Product physical issues	Product physical issue	Product explosion
Product physical issues	Product physical issue	Capsule separation
Product physical issues	Product physical issue	Product overheating
Product physical issues	Product physical issue	Capsule extra shell
Product physical issues	Product physical issue	Capsule fill abnormal
Product physical issues	Product physical issue	Tablet physical issue
Product physical issues	Product physical issue	Capsule physical issue
Product physical issues	Product physical issue	Product physical issue
Product physical issues	Product physical issue	Soft gelatin capsule burst
Product physical issues	Product physical issue	Scored tablet splitting issue
Product physical issues	Product physical issue	Tablet does not break into pre-defined pieces
Product packaging issues	Product primary packaging issue	Product primary packaging issue
Product packaging issues	Product primary packaging issue	Medicinal product interaction with primary packaging
Manufacturing production issues	Product process control issue	Product process control issue
Manufacturing production issues	Product quality control issue	Product quality control issue
Product quality issues NEC	Product quality issue	Product quality issue
Product quality issues NEC	Product quality issue	Product quality complaint
Product quality issues NEC	Product quality issue	Product lot specific issue
Product quality issues NEC	Product quality issue	Topical product difficult to remove from application site
Product physical issues	Product reconstitution quality issue	Product reconstitution quality issue
Product physical issues	Product shape issue	Product shape issue
Product physical issues	Product size issue	Product size issue
Product physical issues	Product solubility abnormal	Product solubility abnormal
Product physical issues	Product solubility abnormal	Product solubility increased



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Product physical issues	Product solubility abnormal	Product solubility decreased
Product physical issues	Product solubility abnormal	Product dissolution abnormal
Product physical issues	Product solubility abnormal	Product dissolution decreased
Product physical issues	Product solubility abnormal	Product dissolution increased
Product contamination and sterility issues	Product sterility issue	Device sterility issue
Product contamination and sterility issues	Product sterility issue	Product sterility issue
Product contamination and sterility issues	Product sterility issue	Product sterility lacking
Product contamination and sterility issues	Product sterility issue	Product sterile packaging missing
Product contamination and sterility issues	Product sterility issue	Product sterile packaging disrupted
Product quality issues NEC	Product substitution issue	Product substitution issue
Product quality issues NEC	Product substitution issue	Biosimilar product substitution issue
Product quality issues NEC	Product substitution issue	Product substitution issue brand to brand
Product quality issues NEC	Product substitution issue	Product substitution issue brand to generic
Product quality issues NEC	Product substitution issue	Product substitution issue generic to brand
Product quality issues NEC	Product substitution issue	Product substitution issue generic to generic
Product quality issues NEC	Product substitution issue	Product substitution issue reference biologic product to biosimilar
Product supply and availability issues	Product supply issue	Supply shortage
Product supply and availability issues	Product supply issue	Product supply issue
Product supply and availability issues	Product supply issue	Product delay due to pandemic
Product supply and availability issues	Product supply issue	Drug supply chain interruption
Product supply and availability issues	Product supply issue	Drug supply chain interruption due to pandemic
Product supply and availability issues	Product supply issue	Drug import channel interruption due to pandemic
Product supply and availability issues	Product supply issue	Product supply chain interruption due to pandemic
Product quality issues NEC	Product tampering	Product tampering
Product quality issues NEC	Product tampering	Medication tampering



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Product quality issues NEC	Product tampering	Tampering with medication
Product physical issues	Product taste abnormal	Product taste abnormal
Product physical issues	Product taste abnormal	Peculiar taste of pharmaceutical product
Product distribution and storage issues	Product temperature excursion issue	Product temperature excursion issue
Product supply and availability issues	Recalled product	Recalled product
Counterfeit, falsified and substandard products	Suspected counterfeit product	Suspected falsified product
Counterfeit, falsified and substandard products	Suspected counterfeit product	Suspected counterfeit product
Product contamination and sterility issues	Suspected product contamination	Suspected product contamination
Product quality issues NEC	Suspected product quality issue	Suspected product quality issue
Product quality issues NEC	Suspected product tampering	Suspected product tampering