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Professional paper

Complaints management in the pharmaceutical industry: A Case Study

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Abstract

Effective complaints management in the pharmaceutical industry is one of the cornerstones for ensuring product quality, regulatory compliance, and customer safety and satisfaction. Adequate handling of complaints ensures not only compliance with regulatory standards, but also maintenance of public confidence, the company's reputation, and a continuous improvement of product quality. To ensure proper complaint management we must understand the importance of providing an effective complaint management system, the regulatory obligations framing it, and the processes of handling complaints, focusing on involving best practices and the potential challenges pharmaceutical companies face.

This paper describes the process of handling a complaint that a pharmaceutical company has received from a foreign regulatory agency. The complaint referred to a burning sensation in the eyes after applying an eye ointment containing 1% chloramphenicol and a change in the smell of the ointment. After conducting an extensive investigation, the quality of the product was confirmed and it was demonstrated that there is no risk to patient health.

Key words: complaint, quality system management (QMS), product quality, patient safety, adverse event, CA/IA (Corrective Action/Improvement Action), chloramphenicol, eye ointment.

Introduction

In the pharmaceutical industry, a complaint can be considered any expression of dissatisfaction with a drug or medical product, originating from consumers, healthcare professionals, or other entities involved in the distribution and use of the product. The pharmaceutical industry is controlled by strict regulatory standards to ensure safety, efficacy, and quality of the products. Effective complaint management is essential for maintaining these standards, but it also allows companies to identify, investigate, and resolve issues promptly. Complaints management is crucial in many aspects. It has a role of a feedback mechanism, enabling pharmaceutical companies to identify and rectify issues related to product quality and safety (IPA Sub-Group 5, 2020). It helps in monitoring the effectiveness of the quality management system (QMS), ensuring continuous improvement and compliance with Good Manufacturing Practices (GMP). Establishing a robust complaints management process, as part of the overall QMS, mitigates risks associated with adverse events, which can have severe consequences to patients' health and the company's reputation (EMA, ICH guideline Q10, 2015).

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Regulatory agencies such as the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and other national authorities mandate strict guidelines for complaint management in the pharmaceutical sector. The EMA's guidelines emphasize the importance of a comprehensive pharmaceutical quality system that integrates complaint handling with other quality management processes (EU GMP, Volume 4, Chapter 8, 2014; **EMA, ICH guideline Q10, 2015**). Similarly, according to FDA regulations, manufacturers must establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit (FDA *Title 21, Volume 4, sec.211.198, 2012*). These procedures must ensure that complaints are promptly evaluated and investigated, and necessary corrective and improvement actions (CA/IA) are taken to mitigate any risks to public health. These regulatory frameworks ensure that pharmaceutical companies adhere to high standards of quality and safety, fostering a culture of continuous improvement.

Despite the structured processes, pharmaceutical companies face several challenges in effective complaint management, such as analyzing large volumes of data, complex investigations, compliance with evolving regulatory requirements, timeliness, etc.

To overcome the challenges mentioned above and to ensure effective complaints management, pharmaceutical companies should adopt some practices, such as continuous staff training, robust documentation, advanced data analytic tools (Rajendran et al., 2023), multidisciplinary teams, effective CA/IA implementation (Braga, 2007; Santosh et al., 2015), and continuous improvement of management processes (Keen, 2021).

By adhering to regulatory guidelines, employing best practices, and addressing challenges proactively, pharmaceutical companies can ensure product safety, enhance customer satisfaction, and maintain regulatory compliance. Continuous improvement in complaints management processes is essential for advancing pharmaceutical quality systems and overall trust in pharmaceutical products.

The complaint management processes in a pharmaceutical company must be strictly defined and described in a Standard Operating Procedure (SOP) or other type of written document, to ensure an efficient complaint management system (Choudhary, 2011). This document should provide a detailed explanation of all the steps that should be followed once a complaint is received, including the roles and responsibilities of personnel involved, timelines, and the documentation format. The SOP must be regularly updated to reflect any changes in regulatory requirements or internal processes (FDA Title 21, Volume 4, sec.211.198, 2012; WHO Technical Report Series 986, Annex 2, 2014).

This paper demonstrates how a specific complaint was resolved by adhering to regulatory standards and following the principles outlined in the relevant guidelines. Additionally, it provides the steps taken to address the issue, ensuring that all actions were carried out in alignment with established legal and procedural frameworks.

Case study

The Quality Assurance unit in a pharmaceutical company has received information from the Global Pharmacovigilance unit, that an adverse event and quality defect of a medicinal product eye ointment, containing 1% chloramphenicol, has been reported to the foreign representatives of the company, by the Regulatory Agency in the same foreign country. The data from the reported event has been submitted to the pharmacovigilance database of the World Health Organization, www.who-umc.org, by the agency.

The defect refers to a reported adverse event, burning sensation in the eye, and abnormal smell of the ointment. It concerns a 40-year-old male patient who experienced a burning sensation in the eye after application, in the area where the ointment was applied. The patient also noticed an abnormal smell of rancidity of the product.

Material and methods

Reagents and Standards

Chloramphenicol Reference Standard, Chloramphenicol Impurity B (4-nitrobenzaldehyde R, for synthesis), Sodium heptane sulphonate ($C_7H_{15}O_3SNa$, for ion pair chromatography), Potassium dihydrogen phosphate (KH_2PO_4, p.a.), Petroleum spirit (boiling range, 40 to 60 °C, p.a.; Synonyms: Petroleum spirit, Petroleum ether), Triethylamine ($C_6H_{15}N$, p.a.), Methanol (CH_4O, HPLC grade), Water (H_2O, Purified water).

Method

The analytical procedure used for determination of related and degradation products in the eye ointment retention samples is a gradient HPLC method that has been adopted by the European Pharmacopoeia, the monograph of chloramphenicol (04/2019:0071), and further developed and validated as an "in house" method. It is the same method that is in routine use for the analysis of related and degradation products of commercial batches at release. The procedure is performed in conditions that provide protection from light, due to the photosensitivity of the API.

Chromatographic conditions

The analysis was conducted on Dionex UltiMate 3000 Series UHPLC equipped with LPG-3400SD pump, WPS-3000TSL autosampler, column compartment TCC-3000SD, and VWD-3400RS detector. Hypersil BDS C18

250 x 4.6 mm i.d; 5 □m chromatographic column was used, with 1 mL/min gradient flow of the mobile phase consisting of Mobile phase A (Solution A: Methanol (68:32 V/V)) and Mobile phase B (Methanol). Solution A was prepared by dissolving 2.0 g of sodium heptane sulphonate, 6.8 g of potassium dihydrogen phosphate, and 5 mL of triethylamine in 900 mL of water. This solution was adjusted to pH 2.5 with phosphoric acid, diluted to 1000 mL with water, and filtered through a 0.45 µm RC membrane filter.

Preparation of solutions

Two different standard solutions were prepared:

- Standard solution for system suitability that contains 0.002 mg/mL Chloramphenicol Impurity B and 1 mg/mL Chloramphenicol Reference Standard, dissolved in methanol and finally diluted with Mobile Phase A.
- Standard solution S that contains 0.002 mg/mL Chloramphenicol Reference Standard dissolved in methanol and finally diluted with Mobile Phase A (0.2%).

Two Sample solutions were prepared. Each Sample solution was prepared with API extraction from a measured quantity of ointment containing 25 mg Chloramphenicol, by heating (45 °C) and vigorously mixing the ointment with petroleum. The final dilution contains 1 mg/mL Chloramphenicol dissolved in methanol.

Before injecting, all solutions were filtered through a 0.45 µm Nylon membrane filter.

Results and discussion

Once the complaint was submitted, it was addressed following the procedures presented in the company's standard operating procedure. The processes of an efficient complaint management system include several key steps, which are described in greater detail in the following flowchart (Fig. 1).

Following the standard operating procedure, after receiving the information, the responsible person for complaint management from QA filled out the complaint registration form in the electronic data management system, where a unique identification code was automatically generated. All the information provided by the complainant, including the batch number, details of the incident leading to the complaint, and the patient's data, was thoroughly documented in the report.

The initial evaluation of the complaint, conducted by the responsible Quality Assurance (QA) personnel, addressing the quality issue, revealed that this was an isolated incident with no previous reports of similar occurrences for the batch or the product in general. Similarly, the Pharmacovigilance unit's evaluation of the adverse event confirmed that the patient's reaction was classified as a non-serious adverse effect, consistent with those outlined in the product's patient information leaflet.

After the initial evaluation and classification of the complaint, all concerned departments were notified and requested to appoint delegates for the investigation team. Each delegate of the formed multidisciplinary investigation team was asked to conduct a thorough inspection of the records in their own departments.

Regarding the matter, all the batch records from the manufacturing site, the packaging site, and the quality control unit were inspected, including the master production protocol, the APIs and excipients certificates for analysis (CoA), the analytical dossiers for the semi-finished, and the finished product, the master protocol for packaging, as well as the records from the distribution chain. All the records showed appropriately executed operating procedures.

The same batch of the eye ointment bulk product was divided into four different batches of finished products, intended for four different markets. No complaints were received for none of the three other batches. The records for the other mentioned batches were also inspected and no deviations or any other no-conformities were reported. Complete analysis, according to the approved product specifications, has been performed on all four batches, before and after sterilization. No out-of-specification (OOS) nor out-of-trend/expectation (OOT/OOE) results were reported for none of the batches. All the results from the in-process control are also within the specification limits, all arrangements regarding prevention of contamination were appropriately applied, and there are no reports of any service interventions of the manufacturing or the packaging equipment.

During the investigation of the quality control reports, the data from the stability-in-use study was also inspected. As presented in the report, the product has been tested under the following conditions:

- Ambient conditions: Temperature in the interval 15-25 °C and approximately 60% relative humidity.
- Storage time: 28 days.
- Frequency: Samples were tested on the 14^{th} and the 28^{th} day.
- Test parameters: Stability testing includes analysis for those parameters, which are critical and can discover product changes.
- Test method: The test was carried out according to the method for control of the finished product.

Quality requirements: From opening until the complete usage, the product should be in accordance with the shelf-life specification.

All samples were opened at the same time, five times a day, and an amount of one therapeutic dose of each sample was taken.

During the time in which the product has been tested, no complications from chemical aspect nor visual defects have been observed. All results presented in the report show that the product, stored at constant ambient conditions, is stabile for one month after the first opening (Table 1).

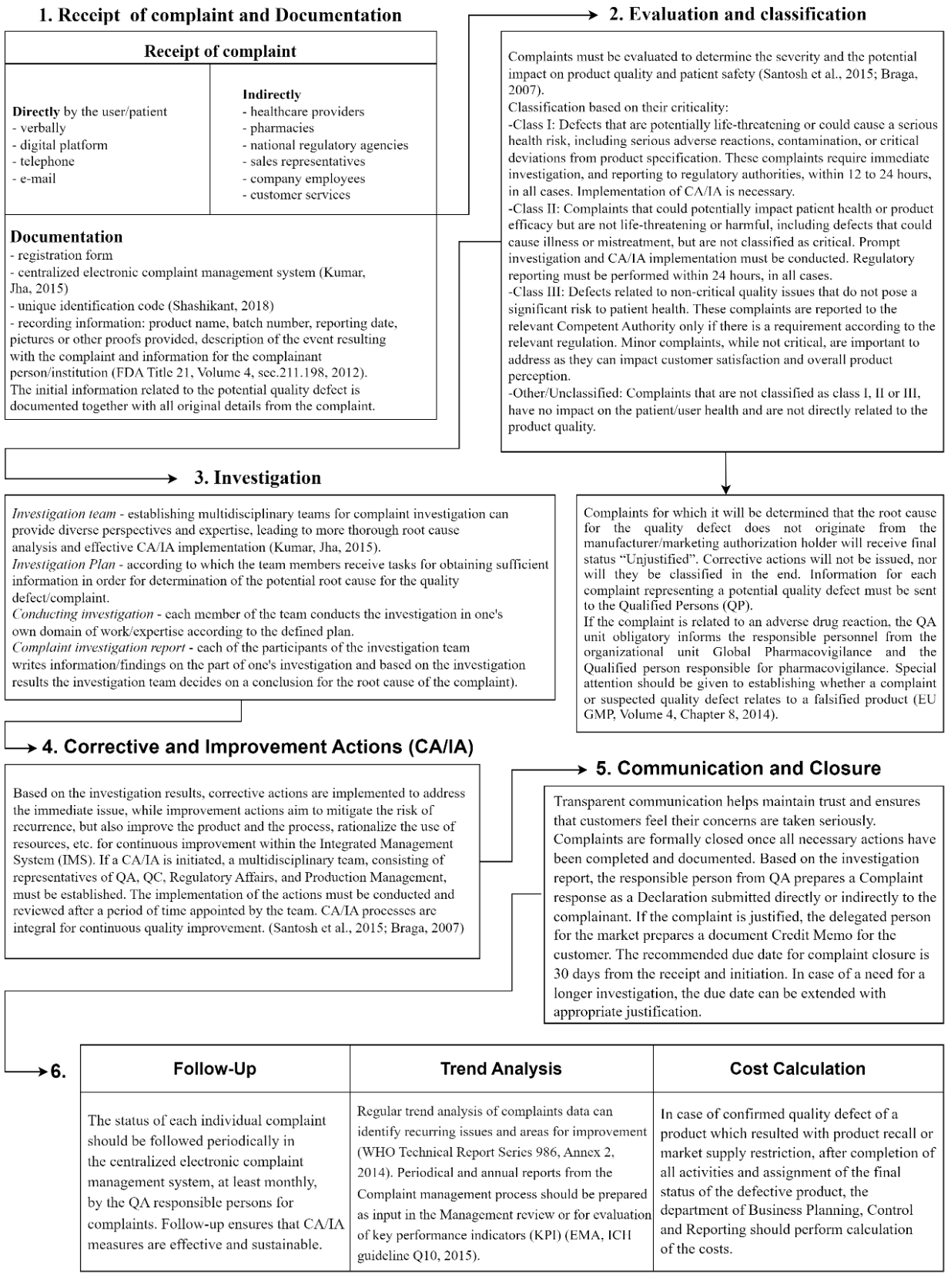


Fig. 1. Flowchart of the key steps for an efficient complaint management system.

Table 1 Tested parameters and obtained results from the stability-in -use study for Chloramphenicol eye ointment 1%, 5g.

Tested parameters	Quality specification during the shelf-life	Initial analysis	14 days	28 days
Appearance	Homogenous ointment	Confirms	Confirms	Confirms
Color	Transparent white	Confirms	Confirms	Confirms
Assay:				
- Chloramphenicol	90.0-105.0% of label claimed	99.14%	98.88%	98.63%
Related and degradation products:				
- Individual impurities	Not more than 1.0%	Not detected	Not detected	Not detected
- Total impurities	Not more than 2.0%	Not detected	Not detected	Not detected
Sterility	Sterile	Sterile	/	/

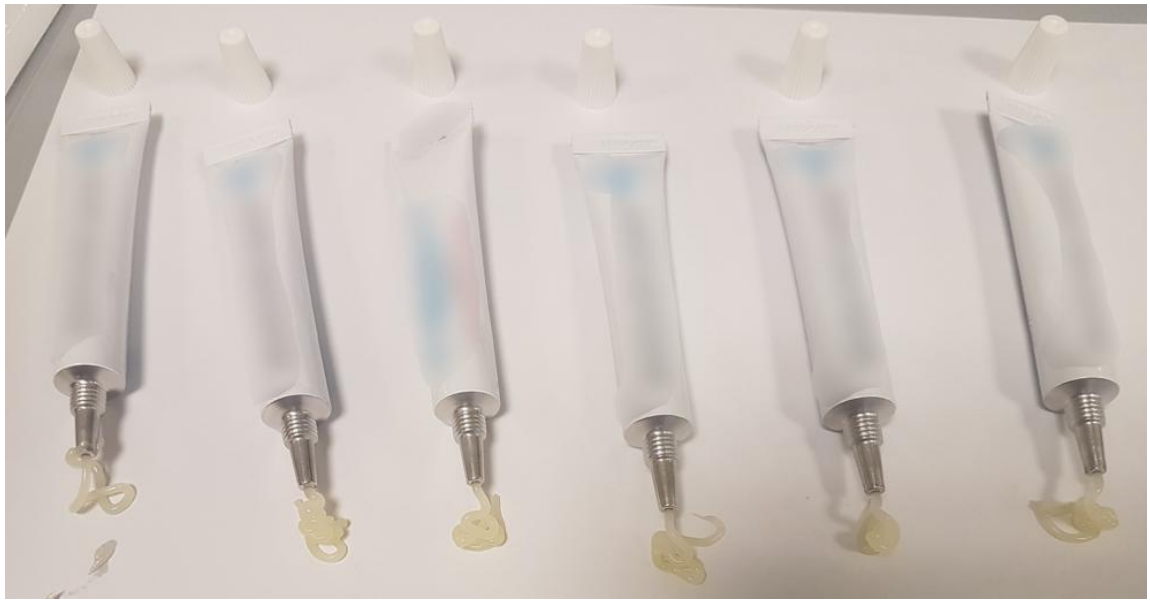


Fig. 2. Retention samples in primary packaging, showing the color and consistency of the ointment.

Results from testing of the retained samples

Since the complaint sample was not provided, at the request of the QA unit, an organoleptic examination on six retention samples of the concerned batch was performed, by the QC unit (Fig. 2). No visual defects were noticed, and it was confirmed that the ointment smelled of lanolin, which is part of the ointment composition. No smell of rancidity was noted.

Furthermore, to confirm that no additional degradation of the product has happened during the storage period, the multidisciplinary team decided that the QC unit should retest the parameter Related and degradation products and compare the obtained results with the results from the initial analysis for batch release. The initial analysis was conducted on the 13th of December 2023 and the reanalysis of the retention samples was conducted on the 11th of March 2024.

As prescribed in the analytical procedure any peak less than 0.25 times the area of the principal peak in the chromatogram obtained with Standard Solution S (0.05%), as well as peaks due to diluent and placebo were discarded. Relative retention times and correction factors of the specified impurities are shown in Table 2.

Table 2. Relative retention times and correction factor of the specified impurities

Peak name	RRT (Relative Retention Time) with reference to Chloramphenicol	Correction Factor
Impurity A	about 0.7	Multiply the peak area of impurity A by 0.7
Impurity B	about 0.9	Multiply the peak area of impurity B by 0.4
4-nitrobenzoic acid	about 1.2	Multiply the peak area of 4-nitrobenzoic acid by 0.5

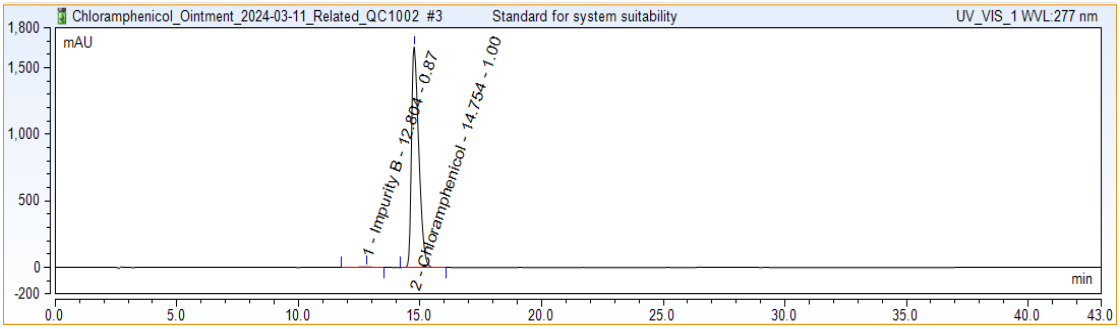


Fig. 3. Chromatogram obtained from Standard solution for system suitability.

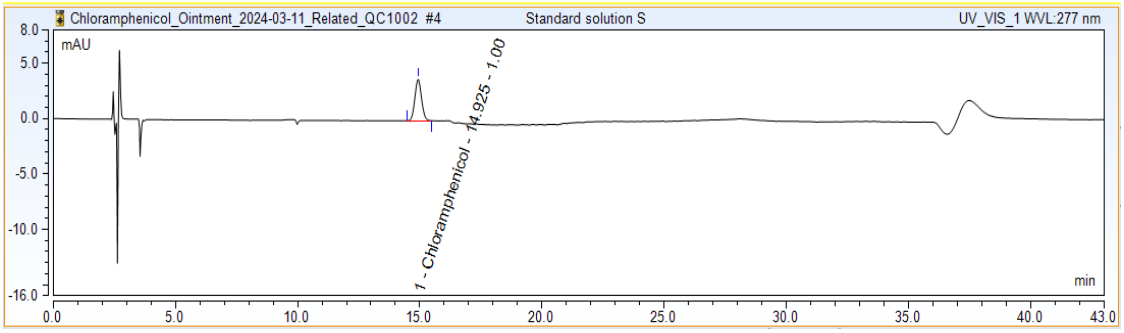


Fig. 4. Chromatogram obtained from Standard solution S.

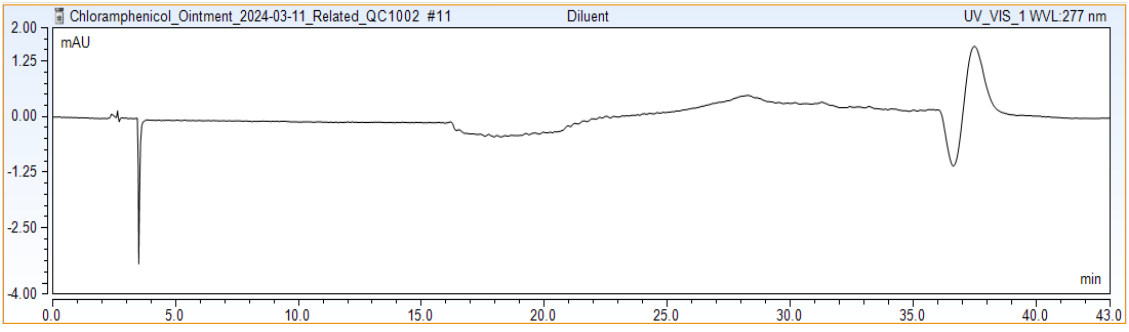


Fig. 5. Chromatogram obtained from Diluent.

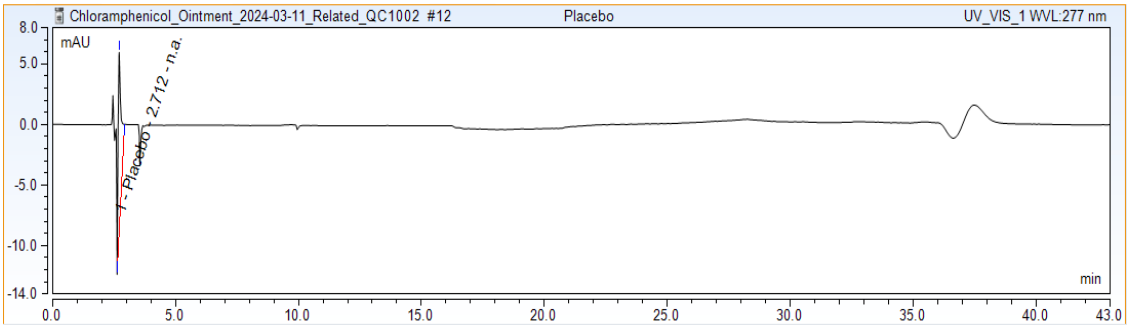


Fig. 6. Chromatogram obtained from Placebo.

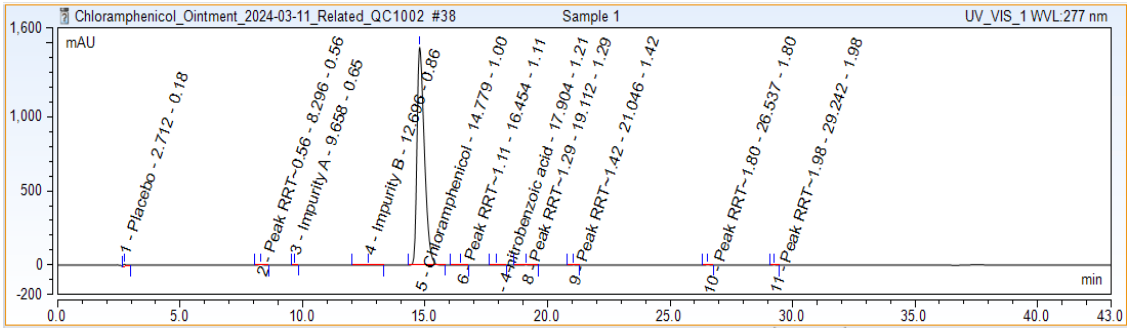


Fig. 7. Chromatogram obtained from Sample solution 1.

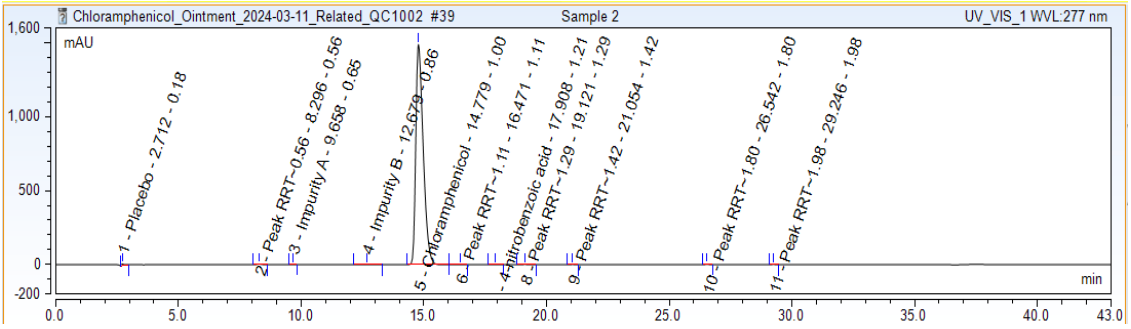


Fig. 8. Chromatogram obtained from Sample solution 2.

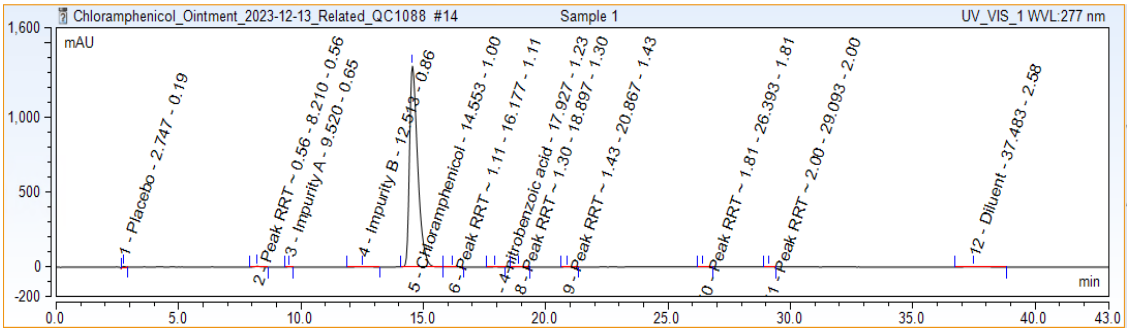


Fig. 9. Chromatogram obtained from Sample solution 1 in the initial analysis for comparison.

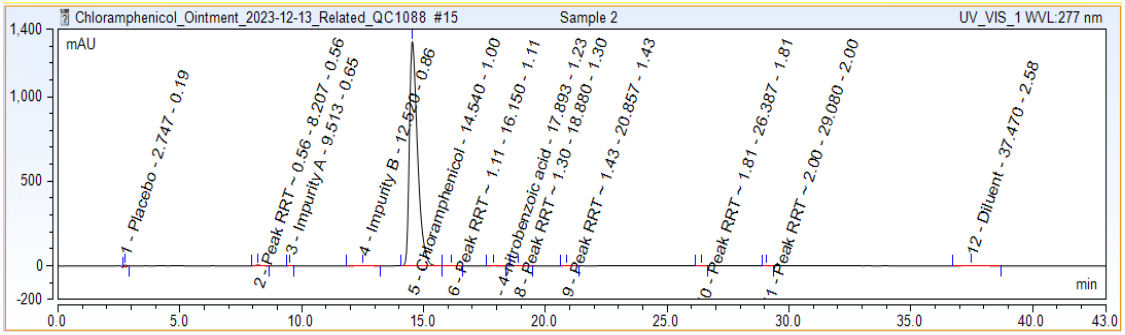


Fig. 10. Chromatogram obtained from Sample solution 2 in the initial analysis for comparison.

The chromatograms obtained after testing the retention samples for the parameter Related and degradation products, according to the method described earlier are given in Figures 3-10.

The system suitability of the method was confirmed and the results for the detected related and degradation products were automatically calculated in the electronic software (Fig. 11). The obtained results meet the release specification limits for the parameter: Impurity A – Not more than 1.0%; Any unspecified impurity – Not more than 0.50%; Total impurities – Not more than 2.0%.

As presented in Table 3, the results from the reanalysis confirm the characteristic impurity profile of the product. No additional impurities or degradation products were detected, and the amount of the detected impurities corresponds to the initial analysis.

Closure of the case

Regarding the reported adverse event, the Global Pharmacovigilance unit performed appropriate investigation and evaluation and provided a CIOMS (Council for International Organizations of Medical Sciences) report, generated and evaluated in specific software, where a unique code was automatically assigned for the case. According to the statement in the CIOMS report, the adverse event from the complaint is assessed as a non-serious spontaneous case report. Similar experiences, as the one reported in the complaint, are described in the section "Possible side effects" of the product's PIL (Patient Information Leaflet).

The following is stated in the PIL: "Like all medicines, this eye ointment can cause side effects, although not everybody gets them. Stop using the product and contact your doctor immediately if any skin problems occur, such as rashes or itching around the eyes or if there is a stronger redness, you bruise more easily than usual, or if you get an infection more easily or more often than usual. You may also feel more tired or weak. Serious side effects include hypersensitivity reactions that can manifest as angioneurotic edema (swelling), anaphylaxis, hives, fever, and vesicular or maculopapular dermatitis (skin changes). In such cases, the treatment should be stopped immediately.

In case of any adverse reactions after administration of the drug, it is necessary to inform the doctor or the pharmacist. This includes all possible side effects that are not listed in this patient guide, as well as those that are listed."

The conducted investigation did not determine any quality issue of the product regarding the reported abnormal smell. Fats and oils oxidize when they stay in the open air for a long time, which changes their smell and taste. This process is known as rancidity. The abnormal smell and the rancidity of the product are probably a result of improper storage after the first opening or damaged primary packaging. The batch was manufactured and tested according to the requirements of cGMP. The performed investigation showed that the quality of the medicinal product was not affected during the manufacturing and packaging process, nor the storage period.

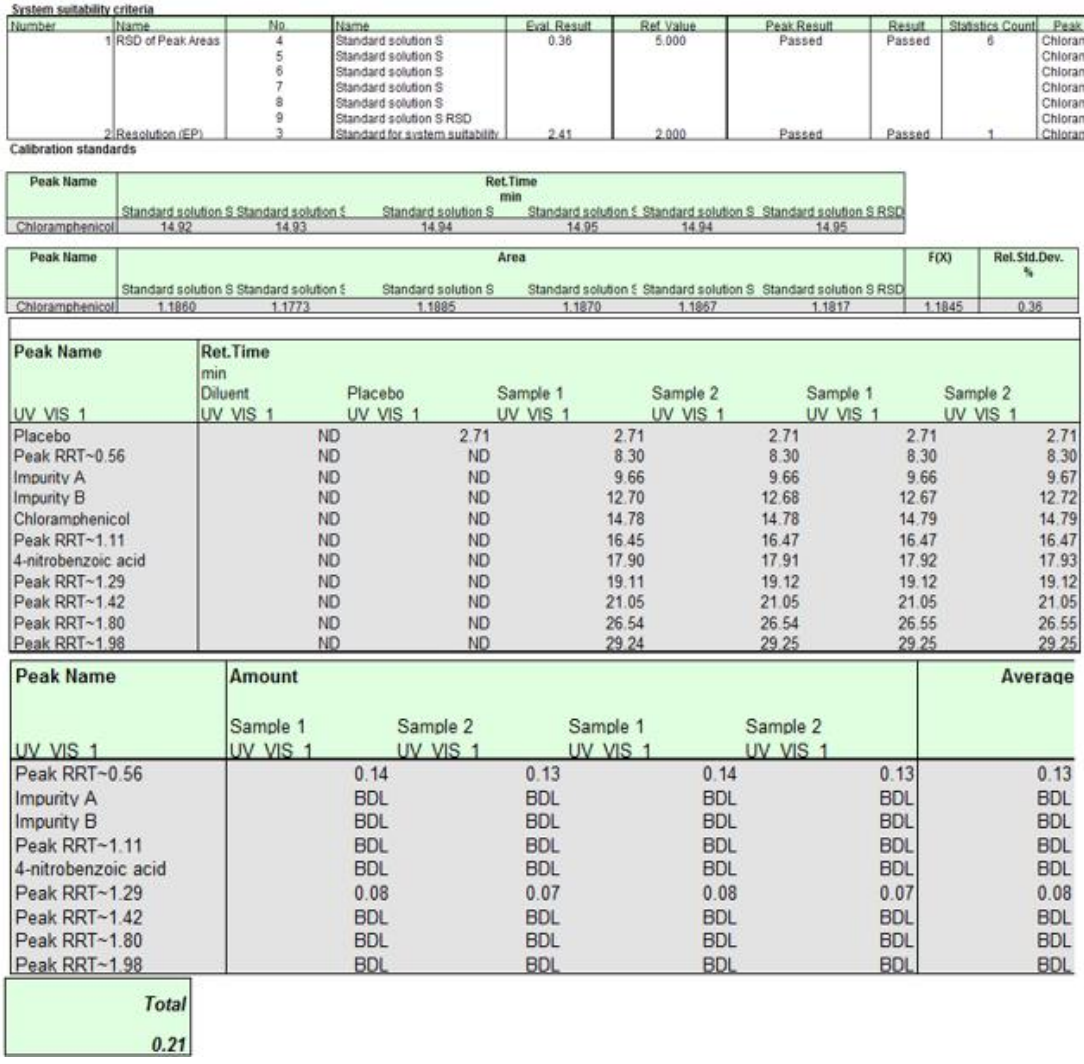
Since no quality issue of the product batch was identified, there is no risk to the patient's health emerging from the product quality. Therefore, according to the conclusion from the QA investigation, regarding the reported abnormal smell, the complaint received the status "Unjustified claim".

The conclusion of the QA investigation was incorporated into the CIOMS report, which was forwarded to the foreign representatives, to be further sent as an official answer to the Regulatory Agency which filed the complaint.

The reported adverse event was classified as a non-serious side effect of the medicinal product, and since it occurred in a foreign country, according to the domestic regulations it was not reported to the Macedonian Agency for Medicines and Medical Equipment (MALMED).

Conclusion

The complaint described in the case study was resolved by following all the necessary steps taken to address the issue, according to the well-defined standard



System suitability criteria

Number	Name	No	Name	Eval. Result	Ref. Value	Peak Result	Result	Statistics Count	Peak Name
1	RSD of Peak Areas	4	Standard solution S	0.36	5.000	Passed	Passed	6	Chloramphenico
		5	Standard solution S						Chloramphenico
		6	Standard solution S						Chloramphenico
		7	Standard solution S						Chloramphenico
		8	Standard solution S						Chloramphenico
		9	Standard solution S RSD						Chloramphenico
2	Resolution (EP)	3	Standard for system suitability	2.41	2.000	Passed	Passed	1	Chloramphenico

Calibration standards

Peak Name	Ret.Time min					
	Standard solution S	Standard solution S	Standard solution S	Standard solution S	Standard solution S	Standard solution S RSD
Chloramphenicol	14.92	14.93	14.94	14.95	14.94	14.95

Peak Name	Area						F(X)	Rel.Std.Dev. %
	Standard solution S	Standard solution S	Standard solution S	Standard solution S	Standard solution S	Standard solution S RSD		
Chloramphenicol	1.1860	1.1773	1.1885	1.1870	1.1867	1.1817	1.1845	0.36

Peak Name	Ret.Time min					
UV_VIS_1	Diluent UV_VIS_1	Placebo UV_VIS_1	Sample 1 UV_VIS_1	Sample 2 UV_VIS_1	Sample 1 UV_VIS_1	Sample 2 UV_VIS_1
Placebo	ND	2.71	2.71	2.71	2.71	2.71
Peak RRT~0.56	ND	ND	8.30	8.30	8.30	8.30
Impurity A	ND	ND	9.66	9.66	9.66	9.67
Impurity B	ND	ND	12.70	12.68	12.67	12.72
Chloramphenicol	ND	ND	14.78	14.78	14.79	14.79
Peak RRT~1.11	ND	ND	16.45	16.47	16.47	16.47
4-nitrobenzoic acid	ND	ND	17.90	17.91	17.92	17.93
Peak RRT~1.29	ND	ND	19.11	19.12	19.12	19.12
Peak RRT~1.42	ND	ND	21.05	21.05	21.05	21.05
Peak RRT~1.80	ND	ND	26.54	26.54	26.55	26.55
Peak RRT~1.98	ND	ND	29.24	29.25	29.25	29.25

Peak Name	Amount				Average
UV_VIS_1	Sample 1 UV_VIS_1	Sample 2 UV_VIS_1	Sample 1 UV_VIS_1	Sample 2 UV_VIS_1	
Peak RRT~0.56	0.14	0.13	0.14	0.13	0.13
Impurity A	BDL	BDL	BDL	BDL	BDL
Impurity B	BDL	BDL	BDL	BDL	BDL
Peak RRT~1.11	BDL	BDL	BDL	BDL	BDL
4-nitrobenzoic acid	BDL	BDL	BDL	BDL	BDL
Peak RRT~1.29	0.08	0.07	0.08	0.07	0.08
Peak RRT~1.42	BDL	BDL	BDL	BDL	BDL
Peak RRT~1.80	BDL	BDL	BDL	BDL	BDL
Peak RRT~1.98	BDL	BDL	BDL	BDL	BDL

Total
0.21

Fig. 11. Results from the related and degradation products analysis of the retention samples.

Table 3. Comparison of the results from the HPLC analysis for determination of related and degradation products content, obtained in the initial analysis and the reanalysis of the retention samples.

Peak name	Initial analysis (%)	Reanalysis (%)
Peak RRT~0.56	0.185	0.131
Impurity A	0.012 (BDL)	0.015 (BDL)
Impurity B	0.029 (BDL)	0.016 (BDL)
Peak RRT~1.11	0.053	0.019 (BDL)
4-nitrobenzoic acid	0.018 (BDL)	0.013 (BDL)
Peak RRT~1.30/1.29	0.097	0.076
Peak RRT~1.43/1.42	0.059	0.040 (BDL)
Peak RRT~1.81/1.80	0.046 (BDL)	0.046 (BDL)
Peak RRT~2.00/1.98	0.032 (BDL)	0.022 (BDL)

operating procedures, in accordance with the regulatory standards, and following the principles outlined in the relevant guidelines. The extensive investigation that was carried out resulted in confirmation of the product's quality and demonstrated that there is no risk to patient health.

References

Braga, G.K., 2007. Complaint Handling in Pharmaceutical Companies. https://onlinelibrary.wiley.com/doi/pdf/10.1002/qaj.398

Choudhary, A., 2011. SOP for Handling of Market Complaints in Pharmaceuticals: Pharmaguideline. Available at: https://www.pharmaguideline.com/2011/08/sop-for-handling-of-market-complaints.html

EMA, 2015. ICH guideline Q10 on Pharmaceutical Quality System. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-guideline-q10-pharmaceutical-quality-system-step-5_en.pdf

EU GMP, 2014. Volume 4, Part I - A Guide to Good Manufacturing Practice: "The rules governing medicinal products in the European Union", Chapter 8 - Complaints, Quality Defects and Product Recalls Available at: https://health.ec.europa.eu/document/download/b1eb2292-cb0d-4e3f-aea9-e3fe79faf6e3_en?filename=2014-08_gmp_chap8.pdf%20(2&7)

IPA Sub-Group 5, 2020. Handling of Market Complaints, Best Practice Document. Available at: https://www.ipa-india.org/wp-content/uploads/2023/03/forum-2020a.pdf

Keen, R., 2021. ISO 9001 Checklist - 10.3 - Continual Improvement [with Procedure]. Available at: https://www.iso-9001-checklist.co.uk/10.3-continual-improvement-eur.htm

Kumar, N., Jha, A., 2015. A Model of Pharmaceutical Customer Complaints and Redressal System. Global journal for research analysis 4(12), ISSN No 2277-8160

Rajendran, P., Dsouza, K., Rodriguez, P., Aboshiha, A., 2023. Complaint Management Is a Powerful Source of Value in Health Care. Available at: https://www.bcg.com/publications/2023/managing-complaints-in-healthcare

Santosh, J., Audumbar, M., Ritesh, B., Ashpak, T., Jyotiram, S., 2015. Systematic Approach for Complaint Handling in Pharmaceutical Industries. PharmaTutor Magazine 3(3), 24-30.

Shashikant, G.S., Chabbra, C., Nayan, G., 2018. Handling of Market Complaints and Recalls, Review of Fda-483 Form. Asian Journal of Pharmaceutical Research and Development 6 (3), 55-59. https://doi.org/10.22270/ajprd.v6i3.369

U.S. Food and Drug Administration (FDA), 2012. PART 211 CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS “Code of Federal Regulations, Title 21, Volume 4, sec.211.198 “Complaint files”.

Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=211.198

WHO, 2014. Good Manufacturing Practices for Pharmaceutical Products: Main Principles, Annex 2, WHO Technical Report Series 986. Available at: https://www.gmp-compliance.org/files/guidemgr/TRS986annex2.pdf

Резиме

Управување со жалби во фармацевтската индустрија: Студија на случај

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Клучни зборови: жалба, управување со системот за квалитет (QMS), квалитет на производот, безбедност на пациентот, несакан настан, CA/IA (Корективна мерка/Мерка за подобрување), хлорамфеникол, маст за очи.

Ефективното управување со жалби во фармацевтската индустрија е еден од темелите за обезбедување квалитет на производот, усогласеност со регулативата, како и безбедност и задоволство на клиентите. Соодветното постапување по добиена жалба обезбедува не само усогласеност со регулаторните стандарди, туку и одржување на довербата на јавноста, угледот на компанијата и континуирано подобрување на квалитетот на производот. За да обезбедиме правилно управување со жалби, мора да ја разбереме важноста од обезбедување на ефективен систем за управување со жалби, регулаторните обврски кои го обликуваат тој систем, како и процесите на постапување по добиените жалби, фокусирајќи се на вклучување на најдобрите практики и потенцијалните предизвици со кои притоа се соочуваат фармацевтските компании.

Овој труд го опишува процесот на постапување по жалба што фармацевтска компанија ја добила од странска регулаторна агенција. Жалбата се однесува на чувство на печење во очите по нанесување на маст за очи што содржи 1% хлорамфеникол и промена на мирисот на маста. По спроведување на детално истражување, беше потврден квалитетот на лекот и беше докажано дека не постои ризик за здравјето на пациентот.