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Comparative Analysis of Retention Sample Handling for Sorbitol and Sucrose Excipients at PT X

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Abstract: The handling of raw material retention samples is a critical component of pharmaceutical quality assurance because it supports traceability, safety, and material quality throughout manufacturing. Studies specifically comparing retention-sample handling for sorbitol and sucrose excipients in industrial practice remain limited. This study aimed to compare the handling of sorbitol and sucrose retention samples at PT X and evaluate conformity with applicable procedures and Good Manufacturing Practice requirements. A qualitative approach was used through one month of direct observation, in-depth interviews with a sampling officer, a Quality Control analyst, and the Quality Control Raw Material Inspection Supervisor, and review of company procedures. The findings showed that sampling, labeling, storage, documentation, testing, retention-period control, and destruction were implemented in accordance with established procedures. Sucrose and sorbitol differed in sampling tools, retained quantities, physical form, sampling duration, and supplier packaging. Material traffic in the sampling room was identified as an operational constraint, particularly during sucrose sampling. The study demonstrates that excipient-specific handling requirements can be implemented within one integrated retention-sample system while maintaining traceability and quality-control effectiveness.

Keywords: *Retention Sample, Excipient, Sucrose, Sorbitol*

Indonesian Abstract: Penanganan sampel pertinggal bahan baku merupakan bagian penting dari penjaminan mutu farmasi karena mendukung ketertelusuran, keamanan, dan mutu bahan selama proses produksi. Penelitian yang secara khusus membandingkan penanganan sampel pertinggal eksipien sorbitol dan sucrose dalam praktik industri masih terbatas. Penelitian ini bertujuan menganalisis perbandingan penanganan sampel pertinggal sorbitol dan sucrose di PT X serta mengevaluasi kesesuaiannya dengan prosedur yang berlaku dan ketentuan Cara Pembuatan Obat yang Baik. Penelitian menggunakan pendekatan kualitatif melalui observasi langsung selama satu bulan, wawancara mendalam dengan petugas sampling, analis Quality Control, dan QC Raw Material Inspection Supervisor, serta penelaahan prosedur perusahaan. Hasil menunjukkan bahwa pengambilan sampel, pelabelan, penyimpanan, dokumentasi, pengujian, pengendalian masa simpan, dan pemusnahan telah dilaksanakan sesuai prosedur. Perbedaan sorbitol dan sucrose terdapat pada alat sampling, jumlah sampel pertinggal, bentuk fisik, lama pengambilan sampel, dan kemasan pemasok. Aktivitas keluar-masuk bahan di ruang sampling menjadi kendala operasional, terutama pada sampling sucrose. Temuan

menunjukkan bahwa kebutuhan penanganan spesifik eksipien dapat diterapkan dalam satu sistem sampel pertinggal yang tetap mendukung ketertelusuran dan efektivitas pengawasan mutu.

Keywords: Sampel Pertinggal, Eksipien, Sucrose, Sorbitol.

INTRODUCTION

Raw material handling is an essential element of a quality assurance system, particularly in industries that implement Good Manufacturing Practice (GMP) standards and other quality management systems. One aspect that still receives relatively limited attention is the handling of retention samples. Retention samples serve as reference materials for retesting and for investigations of deviations or product complaints. Therefore, their handling must follow the company's established Standard Operating Procedures (SOPs) and comply with GMP requirements to ensure the quality, integrity, and traceability of raw materials (Setiawan et al., 2022).

Quality Control has overall responsibilities that include establishing, validating, and implementing all quality control procedures; supervising the control of reference samples and/or retention samples of materials and other products when necessary; ensuring the accuracy of labels on material and product containers; ensuring the proper implementation of product stability monitoring; and participating in investigations of complaints related to product quality (Badan Pengawas Obat dan Makanan Republik Indonesia [BPOM RI], 2024). One of these responsibilities is controlling reference or retention samples as part of efforts to ensure product quality, safety, and consistency throughout the storage period (BPOM RI, 2024).

A retention sample is a quantity of material retained from each batch of raw material for future retesting or investigation. It is stored under conditions equivalent to those of the original material so that it remains representative. Retention sample handling includes sampling, labeling, storage, documentation, and control of the retention period. Proper handling must meet the principles of traceability, data integrity, and compliance with applicable quality standards (BPOM RI, 2024). Thus, retention sample control applies not only to active substances but also to excipients because these components play a significant role in determining the quality, stability, and performance of pharmaceutical products (Ansel, 2021).

Retention samples of active substances and excipients have equally important roles in investigations. Based on cases encountered in practice, complaints or production problems that require investigation of retained samples do not always point to active substances; in some cases, excipients must also be examined. Therefore, all retention samples of active substances and excipients must be stored and managed appropriately to ensure traceability throughout the investigation process (PT X, 2024).

Excipients are inactive substances added to a dosage form together with the active substance to facilitate manufacturing, maintain product stability, and improve product acceptability. In principle, excipients play an important role in producing products with appropriate compactibility, disintegration, and stability (Nur'assyfa et al., 2024).

Based on their functions, excipients may be classified according to their use in solid and liquid dosage forms. In solid dosage forms, excipients include diluents, which increase tablet mass and facilitate compression, such as microcrystalline cellulose derivatives (Avicel PH 101 and Avicel PH 102); binders, which increase interparticle adhesion, such as methylcellulose, sucrose, gelatin, acacia gum, and microcrystalline cellulose; disintegrants, which accelerate tablet disintegration after administration, such as Starch 1500; lubricants, which reduce friction during compression, such as magnesium stearate; and coating agents,

which protect tablets from environmental effects and improve dosage-form stability, such as methylcellulose and hydroxypropyl methylcellulose (Pratiwi et al., 2023; Kurniasari et al., 2021; Anindhita et al., 2022).

In liquid dosage forms, excipients are classified according to their roles in maintaining product stability, safety, and acceptability. These include preservatives that inhibit microbial growth, such as antioxidants (vitamin E, vitamin C, butylated hydroxyanisole, and butylated hydroxytoluene), antimicrobials (sodium benzoate and methylparaben), and chelating agents (citric acid and polyphosphates); wetting agents that assist the dispersion of hydrophobic active substances, such as lecithin, Tween 80, and sorbitan; colorants, including carotenoids, carmine, curcumin, and beet red; sweeteners that improve palatability and mask unpleasant drug taste, including sorbitol, mannitol, and fructose; flavoring agents that improve aroma, including oleum cinnamomi, oleum citri, and oleum menthae piperitae; emulsifiers that combine two immiscible liquid phases, such as pulvis gummi arabici; suspending agents that maintain particle stability in suspensions, such as acacia, tragacanth, pectin, and alginate; and solvents that act as carriers for active substances, such as purified water, aromatic water, and alcohol (Nasri et al., 2023).

In addition, co-solvents are excipients used to increase the solubility of poorly soluble active substances so that optimal solubility can be achieved. Co-solvents commonly used in liquid formulations include glycerol, propylene glycol, polyethylene glycol, and alcohol. The use of each excipient must be adjusted to the characteristics of the active substance, the dosage form, and the formulation objective so that drug quality, stability, safety, and effectiveness can be maintained (Nasri et al., 2023).

Sorbitol is a sugar alcohol derived from carbohydrates through the hydrogenation of glucose with hydrogen gas. Sorbitol, also known as glucitol, has a sweet taste and is readily soluble in water. It is also produced in human tissues through the aldose-reductase-catalyzed conversion of D-glucose, in which the aldehyde group (CHO) in the glucose molecule is converted into an alcohol group (CH2OH) (Nur'assyfa et al., 2024).

Sucrose, or table sugar, is a disaccharide that yields glucose and fructose upon hydrolysis. It functions as a sweetener in syrups. Because sucrose is readily soluble in water, it is first dissolved in hot water during syrup preparation to produce a homogeneous formulation (Kurniawaty & Rawar, 2023).

Based on observations and interviews with relevant personnel at PT X, sucrose is used as a sweetener in Sirplus syrup products with various flavors (melon, grape, strawberry, and grape) and in Sirplus tablets with original and strawberry flavors. Sorbitol is generally used as a solvent and as a wetting agent that reduces surface tension between solid drug particles (Nasri et al., 2023).

The handling of raw material retention samples is part of the quality assurance system and aims to ensure the traceability and safety of materials used in production. Within a quality system, raw materials must not only meet specifications at the time of receipt but must also remain traceable through retention samples if quality deviations, complaints, investigations, or product recalls occur (Anjani & Suryani, 2023).

In practice, retention sample handling may still encounter constraints, including nonconformity with storage procedures, documentation that has not been optimally maintained, and inadequate control of storage periods and storage conditions. These issues may pose risks to raw material traceability, quality validity, and regulatory compliance. A structured and well-documented retention sample handling system is therefore necessary to ensure product safety and quality (Rahmawati et al., 2021).

Research on raw material management in the pharmaceutical industry has been widely conducted; however, most studies have focused on quality management systems, risk control, warehouse management, and process efficiency in Quality Control laboratories. Studies specifically examining raw material retention sample handling, particularly through a

comparison of the handling procedures for sorbitol and sucrose excipients, remain limited. Few studies have evaluated differences in the handling of these two excipients based on actual implementation of procedures in the pharmaceutical industry.

Accordingly, this study aimed to analyze and compare the handling of sorbitol and sucrose excipient retention samples at PT X as an evaluation of procedural conformity with GMP requirements and to provide information that may support improvements in the quality assurance system for raw material retention sample management.

METHODS

This study used a qualitative method with in-depth interviews conducted with an analyst, a sampling officer, and a supervisor to obtain comprehensive information on differences in the handling of sorbitol and sucrose excipient retention samples at PT X.

The study was conducted in the retention sample room at PT X in February 2026. Because the study was qualitative, it did not use a statistical population or sample; instead, informants were selected based on their direct involvement in the handling of starting-material retention samples. The informants were the QC Raw Material Inspection Supervisor, a sampling officer, and a QC analyst responsible for retention sample management. The study variable was the difference in retention sample handling between sorbitol and sucrose excipients, covering sampling, labeling, storage, documentation, and control of the retention period. The study did not involve system development.

RESULTS AND DISCUSSION

Based on the observations and interviews with the analyst, sampling officer, and QC Raw Material Inspection Supervisor, the following data were obtained.

Table 1. Interview Results with the Sampling Officer

No.	Question	Answer
1	What is the first action you take when materials arrive at the warehouse?	Verify the documents and inspect the physical condition before the material enters the quarantine area.
2	What tools do you use to sample sucrose and sorbitol? Have these tools undergone cleaning validation to prevent cross-contamination?	Sucrose is sampled using a stainless-steel spoon and a thief sampler. Liquid sorbitol is sampled using a liquid sampler. Each sampling tool has been validated and labeled as clean to prevent cross-contamination.
3	How do you ensure that the sample container used for a retention sample meets the required standard?	The container used is an amber bottle that has previously been sterilized in the microbiology laboratory.
4	What constraints do you frequently encounter when sampling large quantities of excipient materials?	The main constraint during sucrose sampling is the movement of goods into and out of the sampling room.
5	What is the retention sample labeling procedure after sampling? What information must be included to ensure accurate traceability?	Labels are prepared before sampling and printed in the prescribed format, including raw material identification and sample quantity.
6	Under what conditions would you decide to reject or postpone sampling?	When the physical condition of the material is unacceptable, such as a damaged or open seal or mismatched identification.

Table 2. Interview Results with the QC Raw Material Inspection Supervisor

No.	Question	Answer
1	How important are retention samples of excipients compared with retention samples of active substances?	Retention samples of active substances and excipients are equally important for investigation purposes.
2	What is the company policy for determining the quantity of excipient retention samples to be stored? Are there specific considerations for sucrose and sorbitol?	In general, one container from one batch is retained; however, for certain solvents, all containers from one batch are retained.
3	What procedure is followed when a test-result deviation occurs in a raw material or excipient, and what is the role of the retention sample in the investigation?	An investigation is conducted to determine the cause of the deviation. The retention sample functions as a comparator.
4	How are unused retention samples destroyed while complying with environmental regulations and the company's quality management system?	Raw material retention samples are stored for five years and documented in an official record. Destruction is performed according to hazardous and toxic waste procedures.

Table 3. Interview Results with the Analyst Responsible for Retention Samples

No.	Question	Answer
1	How are retention samples received and numbered?	Retention samples are numbered according to the sequence in which raw materials were sampled, rather than the date the materials arrived.
2	What specific SOP criteria govern the environmental conditions (temperature and humidity) for storing sucrose and sorbitol?	The retention sample storage room must remain locked and its temperature must be monitored.
3	What documentation system is used to ensure traceability if a product investigation is required?	At PT X, all retention sample documentation is maintained in a spreadsheet to facilitate investigations.

Table 4. Observation Results

No.	SOP for Handling Starting-Material and Packaging-Material Retention Samples No. P6.24.065-R5	Observation Result
1	The quantity of raw material retention sample stored must be sufficient for at least two complete examinations and representative of each receipt.	Compliant
2	One container of sucrose retention sample is taken per batch.	Compliant
3	All containers from one batch of sorbitol are retained as samples.	Compliant
4	Sampling tools (thief sampler and liquid sampler) have undergone cleaning validation to avoid cross-contamination.	Compliant
5	Documents are verified and the material is physically inspected before entering the quarantine area.	Compliant
6	The container used is an amber bottle previously sterilized in the microbiology laboratory at 90 °C.	Compliant

7	Retention sample labels are printed in the prescribed format and include the material name, date of receipt, internal batch number, supplier batch number, manufacturing date, expiry date or retest date, manufacturer or supplier, total quantity, sample quantity, container number, sampling officer's initials, and sampling date.	Compliant
8	When raw materials arrive at the warehouse, their physical condition is inspected, the seal is confirmed to be securely closed, and the identification is checked for conformity.	Compliant
9	The retention sample storage room must remain locked and its temperature must be monitored.	Compliant
10	All retention sample documentation at PT X is maintained in a spreadsheet to facilitate investigations.	Compliant
11	Retention samples are stored for five years before destruction.	Compliant
12	Retention samples are destroyed according to hazardous and toxic waste destruction procedures.	Compliant

Table 5. Differences in the Handling of Sucrose and Sorbitol Samples

No.	Difference	Sucrose	Sorbitol Solution
1	Sampling tool	Thief sampler	Liquid sampler
2	Retention sample quantity	1 container	All containers from one batch
3	Physical form	Powder	Liquid
4	Sampling time	2 minutes per container	1 minute per container
5	Supplier packaging/container	Sack with one inner plastic liner	Plastic drum

Following one month of observation and interviews with relevant personnel, the findings showed that retention sample handling was performed in accordance with the applicable SOP. The handling of raw material retention samples included sampling, labeling, storage, documentation, and control of the retention period. Sampling was performed by the sampling officer in a quantity sufficient for at least two complete examinations and representative of each receipt (PT X, 2025).

After sampling, each sample was labeled for identification. Labeling of retention samples provides identification and essential information so that the sample can be recognized, traced, and managed appropriately throughout testing and storage (Almaniar et al., 2025). Raw material sample labels contain the material name, date of receipt, internal batch number, supplier batch number, manufacturing date, expiry date or retest date, manufacturer or supplier, total quantity, sample quantity, container number, sampling officer's initials, and sampling date (PT X, 2025).

Retention samples were then stored under appropriate conditions to maintain their quality and stability. Starting-material retention samples were stored under conditions consistent with those required for the corresponding starting materials (PT X, 2025). Sorbitol and sucrose were stored at temperatures below 30 °C, while potassium clavulanate was stored at 20–25 °C to prevent raw material degradation (Sundalian et al., 2022). The storage and use of starting-material retention samples classified as psychotropics, precursors, and certain other drugs were recorded on starting-material retention sample stock cards (PT X, 2024).

In addition to storage, retention sample documentation is an important component of the quality control system to ensure sample traceability and integrity throughout the retention period. Each excipient retention sample, including sorbitol and sucrose, was accompanied by identification data. Retention-period control was implemented by storing samples for the period established by the company, namely five years for raw materials, in accordance with

applicable quality requirements. Storage conditions were also monitored periodically to ensure that temperature, humidity, and other environmental factors remained within the required limits (PT X, 2025).

Discussion of Table 1. Interview Results with the Sampling Officer

Based on the observations, raw material handling began with receipt of the goods, followed by document verification against the purchase order, delivery note, and Certificate of Analysis (CoA). Verification was performed to ensure conformity of the material name, supplier batch number, quantity, supplier, and expiry or retest information. After document verification, an initial visual inspection was conducted to confirm that the packaging was intact (not leaking, damaged, or open) and that the label was clear and complete (PT X, 2024).

If the initial inspection met the requirements, the process continued with sampling. Sucrose was sampled using a stainless-steel spoon and a thief sampler, with an average sampling time of approximately 2 minutes per container. Sorbitol solution was sampled using a liquid sampler, and the time required was relatively shorter than for sucrose. This difference occurred because sorbitol is liquid and can be sampled directly at the midpoint using a liquid sampler, whereas sucrose is a solid and must be sampled from three points—top, middle, and bottom—to obtain a representative sample (Aliza et al., 2024). All sampling tools had undergone cleaning validation by the validation team. Cleaning validation was performed to confirm that the established cleaning method was adequate for cleaning sampling tools (PT X, 2024; Fatimah & Muchtaridi, 2023).

The collected samples were then placed in amber bottles for storage. The amber bottles were first washed with purified water in the production area and then sterilized in the microbiology laboratory at 90 °C for 30 minutes to prevent cross-contamination, eliminate or reduce microorganisms on the bottle surface, and ensure container cleanliness. The bottle closures consisted of aluminum foil, which was sterilized directly without prior washing in accordance with the applicable procedure (PT X, 2025; BPOM RI, 2024).

Before sampling began, labels for each sample were prepared and printed according to the specified format. The information included the material name, date of receipt, internal batch number, supplier batch number, manufacturing date, expiry date or retest date, manufacturer or supplier, total quantity, quantity sampled, container number, sampling officer's initials, and sampling date (PT X, 2025).

Nevertheless, operational constraints were still encountered during sampling. The most frequent constraint in sucrose sampling was the movement of goods into and out of the sampling room. This was associated with the relatively large volume of incoming sucrose, approximately 100 containers per shipment, which could also be divided into two receipts or two batches. In addition, the staging area was limited to a maximum of two pallets, with each pallet containing 10 sacks. These conditions made the sampling process less optimal because of the high level of goods movement, although warehouse personnel assisted the process.

Sampling was not performed or was postponed when the material did not meet the physical acceptance requirements, such as damaged or open seals, leaking containers, or mismatched identification (PT X, 2025).

Discussion of Table 2. Interview Results with the QC Raw Material Inspection Supervisor

Based on observations and interviews, retention samples of active substances and excipients were considered equally important in the investigation process. In several cases at PT X, production complaints or problems requiring investigation of retained samples did not always involve the active substance and sometimes required examination of excipients. Therefore, all retention samples of active substances and excipients were stored and managed properly to ensure traceability during investigations.

For retention sample quantity, PT X generally stores one container (container number one) consisting of a composite sample combined from all received containers, with a final quantity sufficient for at least two complete tests. However, for several materials or solvents identified as having potentially hazardous contaminants—such as raw materials at risk of ethylene glycol (EG) and diethylene glycol (DEG) contamination, including sorbitol, glycerin, and propylene glycol, and raw materials at risk of N-nitrosodimethylamine (NDMA) contamination, such as metformin and ranitidine—the quantity of retained samples is adjusted. The retained quantity must be sufficient for at least two complete examinations and representative of each receipt.

When a test-result deviation occurs, the first action is to conduct an investigation to identify the cause of the nonconformity. The investigation includes tracing possible procedural errors, human error, and nonconformity in raw material quality. If the deviation is caused by a procedural or human error, the material is retested until the raw material meets the standard. If the raw material is out of specification, the QC unit issues a complaint letter to the supplier, and no retention sample of that raw material is stored (PT X, 2024).

Raw material retention samples are stored for five years in accordance with company requirements. After five years, the samples are destroyed and an official destruction record is prepared. Destruction is carried out according to hazardous and toxic waste procedures and separated by raw material category; for example, an amoxicillin retention sample is destroyed together with penicillin waste. After destruction, the material is treated as hazardous and toxic waste and transferred to the Engineering unit responsible for such waste. At PT X, hazardous and toxic waste destruction is conducted by a third party in cooperation with the company. The raw materials are collected by the Engineering unit and then sent to Wastex for destruction (PT X, 2024).

Discussion of Table 3. Interview Results with the Analyst Responsible for Retention Samples

Based on interviews with the relevant personnel, retention sample numbering was assigned according to the sequence in which raw materials were sampled rather than the date on which the goods arrived. After sampling was completed, the sample and the starting-material sample logsheet were submitted to the laboratory and received by the analyst responsible for retention samples. The sample was first sent to the microbiology section for microbiological testing, such as total microbial count or endotoxin testing. After microbiological testing was completed, the sample was distributed to the raw material analyst for chemical and physical testing in accordance with the applicable Raw Material Testing Method. After testing was completed and the material met the requirements for release, the sample was returned to the retention sample analyst for storage. Meanwhile, the logsheet was submitted to the administration section so that an analysis number could be assigned according to the raw material sampling sequence.

Retention samples were stored in a room that remained locked to maintain security, and the room temperature was monitored periodically to prevent sample deterioration. The samples were arranged in trays or master boxes according to their analysis numbers. Sucrose and sorbitol were stored in the retention sample room at room temperature, below 30 °C (PT X, 2025).

All retention sample documentation at PT X was maintained electronically using a spreadsheet to facilitate traceability when an investigation was required. The documentation included the sampling date, material name, internal batch number, analysis number, analyst name, type of test performed, microbiological test results, and the retention sample storage location, such as the box or tray number. Complete and well-maintained documentation supports traceability and improves the effectiveness of investigations when quality deviations occur in the future.

The distinguishing finding of this study is the direct comparison of excipient-specific retention sample handling for sucrose and sorbitol within the same pharmaceutical quality system. Although both materials follow the same overall sequence of document verification, physical inspection, sampling, labeling, storage, documentation, retention-period control, and destruction, their handling differs in sampling equipment, retained quantity, physical form, sampling time, and supplier packaging. This comparison shows that material-specific characteristics and contamination-risk considerations can require different operational handling while the overall retention-sample process remains aligned with the company SOP and GMP principles.

CONCLUSIONS AND RECOMMENDATIONS

Conclusion

Based on the observations comparing the handling of sucrose and sorbitol retention samples at PT X, the retention-sample process comprises document verification upon material receipt, physical inspection, sampling, labeling, storage, documentation, retention-period control, and destruction. Sampling is performed by designated sampling personnel in a quantity sufficient for at least two complete examinations and representative of each raw-material receipt. The principal difference between sorbitol and sucrose lies in the sampling method: sucrose is sampled using a stainless-steel spoon and a thief sampler, whereas sorbitol solution is sampled using a liquid sampler, resulting in a shorter average sampling time for sorbitol. Overall, the handling of raw material and excipient retention samples at PT X is implemented in accordance with the company's SOPs, which refer to GMP requirements.

Limitations

This study was limited to retention-sample handling at a single pharmaceutical company, PT X, during a one-month observation period, and focused specifically on the comparison of two excipients, sucrose and sorbitol. The qualitative information was obtained from personnel directly involved in the process, namely the QC Raw Material Inspection Supervisor, a sampling officer, and a QC analyst responsible for retention samples. The findings should therefore be interpreted within this defined operational context.

Recommendations

Based on the observed operational constraint, the movement of materials into and out of the sampling room, particularly during high-volume sucrose sampling, should be managed more efficiently while maintaining the established sampling, traceability, and quality-control procedures. The existing compliant practices for labeling, storage, electronic documentation, retention-period control, and hazardous-waste destruction should be maintained consistently.

Author Contributions

All authors made significant contributions to this study and approved the final version of the manuscript for publication.

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