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Quantitative Analysis and Health Risks of Mercury in Solid-Form Herbal Medicines in Bali Province

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ABSTRACT / ABSTRAK

Herbal Medicines (OBA) are widely used as complementary or alternative treatments globally. Their popularity stems from the perception that they are natural, accessible, and have fewer side effects than synthetic drugs. However, high demand raises concerns regarding heavy metal contamination (As, Cd, Pb, Hg), which can occur through soil absorption, manufacturing, or intentional addition. This study analyzed Mercury (Hg) levels in solid OBA across Bali. Samples collected from various traditional medicine depots were tested using microwave digestion and atomic absorption spectroscopy (AAS). Results showed that 108 out of 214 samples—primarily in powder form—contained detectable Mercury. Nevertheless, these concentrations remained below official safety thresholds, with results ranging from 0.02 to 0.16 ppm. Based on the risk evaluation through the Estimated Daily Intake (EDI) indicator with a range of results of 2.86×10^{-6} - 2.29×10^{-5}*, Target Hazard Quotient (THQ) of 0.01 - 0.08, and Cancer Risk (CR), with a value of* 2.43×10^{-11} - 1.94×10^{-10} *it can be concluded that the OBA solid dosage forms sampled in Bali Province in 2025 are safe for consumption.*

Masyarakat secara luas memanfaatkan Obat Bahan Alam (OBA) sebagai instrumen pengobatan komplementer maupun alternatif di samping metode medis konvensional. Tingginya minat terhadap OBA, baik di level domestik maupun global, didorong oleh persepsi bahwa produk alami lebih mudah diakses dan minim efek samping dibandingkan obat sintetik. Namun, lonjakan konsumsi ini membawa perhatian serius pada aspek standarisasi mutu, khususnya risiko kontaminasi logam berat seperti Arsen (As), Kadmium (Cd), Timbal (Pb), dan Merkuri (Hg). Unsur berbahaya ini dapat masuk ke dalam produk melalui mekanisme serapan tanah oleh tanaman, polusi selama manufaktur, hingga penambahan unsur metaloid tertentu. Penelitian ini memfokuskan analisis pada keberadaan cemaran Merkuri (Hg) pada sediaan OBA padat di Provinsi Bali. Melalui pengumpulan sampel dari berbagai penyedia jamu dan toko obat tradisional di seluruh kabupaten di Bali, pengujian dilakukan menggunakan teknik digesti gelombang mikro yang dikombinasikan dengan instrumen *Atomic Absorption Spectroscopy* (AAS). Hasil menunjukkan bahwa dari 214 sampel, terdapat 108 produk yang terdeteksi mengandung Merkuri. Kendati demikian, konsentrasi logam tersebut masih di bawah batas aman yang diizinkan dengan rentang hasil 0.02 - 0.16 ppm. Berdasarkan evaluasi risiko melalui indikator *Estimated Daily Intake* (EDI) dengan rentang hasil 2.86×10^{-6} - 2.29×10^{-5}, *Target Hazard Quotient* (THQ) sebesar 0.01 – 0.08, dan *Cancer Risk* (CR), dengan nilai 2.43×10^{-11} - 1.94×10^{-10} dapat disimpulkan bahwa OBA sediaan padat yang tersampling di Provinsi Bali tahun 2025 aman untuk dikonsumsi.

ERUDITIO Vol. 6, No. 1, Desember 2025, pp. 43-52
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Keywords: *AAS, Contamination, Herbal Medicines, Mercury, Risk Assessment, Estimated Daily Intake (EDI), Target Hazard Quotient (THQ), Cancer Risk (CR)*
Kata Kunci: AAS, Cemaran, Merkuri, Obat Bahan Alam, Penilaian Risiko, Perkiraan Asupan Harian (EDI), Target Rasio Bahaya (THQ), dan Risiko Kanker (CR)

1. Introduction

Natural Medicinal Products (OBA), are substances, formulations, or products derived from and formulated using natural biodiversity, including plant, animal, and mineral components, or other materials, or mixtures thereof, whose efficacy, safety, and quality have been empirically proven for maintaining health, promoting health, preventing disease, treating illness, and/or restoring health (BPOM, 2023). OBA have long been used by the Indonesian people as alternative treatments or as a complement to modern medicine, a practice known as "complementary medicine". To this day, OBA is still widely used by both the Indonesian public and people abroad because it is considered natural, easily accessible, and has relatively fewer side effects compared to modern drugs—not only due to cultural traditions passed down through generations and the history of our ancestors, but also because of the significant therapeutic potential of this natural treatment. Many phytochemical constituents in herbal medicines such as alkaloids, glycosides, flavonoids, tannins, sap, oils, resins, and their derivative metabolites—exhibit various pharmacological activities within the human body (To, Nhat D, et al. 2025). Specifically, flavonoids and phenolic acids (such as ferulic acid) play key roles as antioxidants and anti-inflammatory agents, protecting cellular integrity against oxidative damage. Furthermore, alkaloids contribute to analgesic and antibacterial effects, while tannins support accelerated tissue healing through their antimicrobial properties. Lignans, found in grains, wheat, and vegetables, are also known for their antioxidant and anticancer effects. Glycosides, particularly cardiac glycosides, are believed to be essential for maintaining heart health.

However, as interests and demands for OBAs in the form of more practical finished products have grown, concerns have arisen regarding their standards and efficacy. One potential hazard associated with the use of OBA—whether taken on its own or as a complementary therapy—is the presence of heavy metals (and metalloids) such as arsenic (As), cadmium (Cd), lead (Pb), and mercury (Hg), which may be present in OBA or its raw materials. These heavy metals (and metalloids) in traditional medicines and their raw materials can originate from absorption by the roots of medicinal plants, cross-contamination during processing or production, and the therapeutic introduction of metals (and metalloids).

One heavy metal found in OBA and its raw materials is mercury (Hg), commonly known as quicksilver. Mercury is a naturally occurring element found in the environment (air, water, and soil); it exists in various forms, including metallic; inorganic (e.g., mercury chloride); and organic (e.g., methyl- and ethyl mercury), with varying levels of toxicity to the nervous system, digestive system, immune system, internal organs, skin, and eyes (WHO, 2024). Mercury is a widespread global pollutant that is toxic to the environment and living organisms, significantly impacting ecosystems and human health. Its chemical and toxicological properties contribute to environmental contamination through natural processes, such as volcanic eruptions, and human activities, such as industrial emissions, mining, and agriculture. The phenomena of bioaccumulation and biomagnification in the food chain make mercury a serious threat to food safety and human health, particularly in aquatic ecosystems, which significantly impacts the food safety of people who consume

ERUDITIO Vol. 6, No. 1, Desember 2025, pp. 43-52
P-ISSN: 2580-7722 | E-ISSN: 2807-6222

marine life (Naik, Suresh R., et al. 2022). Human activities are the primary cause of mercury releases into the environment, particularly coal-fired power plants, household coal combustion (e.g., cooking, space heating), industrial processes, waste incinerators, and the mining of mercury, gold, and other metals (WHO, 2024).

Heavy metal contamination in both OBA raw materials and finished OBA products poses a threat to public health, especially when levels exceed established regulatory thresholds. Excessive consumption of heavy metals can lead to poisoning and cause organ damage, such as to the liver and kidneys, and may cause cancer. Mercury can cause birth defects in the fetus. In addition, mercury poisoning can cause clinical symptoms. Reported symptoms of mercury poisoning from both organic and inorganic compounds include headaches, loss of balance, incoordination (gait disturbances), tremors, muscle weakness, a "pins-and-needles" sensation—typically in the hands, feet, and around the mouth—atypical movements, paresthesia in the distal extremities, speech, hearing, and gait disturbances, hallucinations, seizures, impaired attention, fine motor function, and verbal memory, and even death (Naik, Suresh R., et al. 2022). In addition, effects on the kidneys have also been reported, ranging from proteinuria to kidney failure (WHO, 2024).

Unlike pharmaceutical chemicals (BKO), which are often intentionally added to enhance the effects and efficacy of OBA, heavy metal contamination in OBA is generally unintentional and results from environmental contamination. Contamination can occur due to unhygienic product storage, inappropriate packaging, and exposure to contaminated environments such as soil, water, or air—particularly in areas with industrial, mining, or agricultural pollution (Farida, M. et al., 2024). Therefore, to ensure the safety and quality of OBA, the herbal medicine or OBA industry must implement Good Manufacturing Practices for Traditional Medicines (CPOTB) at every stage of production. CPOTB is a crucial guideline designed to ensure that every stage of traditional medicine production—from the selection of raw materials to the distribution processes conducted safely and hygienically, and that it meets established quality standards (Gultom, Yosi E. E., et al., 2025). Through the implementation of CPOTB, it is hoped that mercury contamination in both the raw materials and finished products of traditional herbal medicines can be minimized and controlled.

To ensure the quality, efficacy, and safety of OBA, and to enforce CPOTB in the OBA industry, the Indonesian Food and Drug Authority (BPOM) also conducts post-market surveillance of OBA products sold to the public. BPOM periodically collects samples in accordance with applicable sampling guidelines, establishes mandatory test parameters, and conducts testing on OBA products, including both qualitative tests (BKO tests) and quantitative tests, one of which is a test to determine heavy metal contamination levels. The heavy metals tested are arsenic (As), lead (Pb), cadmium (Cd), and mercury (Hg). BPOM has also established regulations setting permissible limits for heavy metal contamination in finished OBA products. Based on the Indonesian Food and Drug Authority Regulation No. 29 of 2023 concerning Safety and Quality Requirements for Natural Medicines, the maximum permissible limits for heavy metal contamination are listed in Table 1.

With advances in analytical technology, the determination of heavy metal concentrations in a product can now be performed with a very high degree of accuracy. One of the standard methods used for quantitative analysis is Atomic Absorption Spectrophotometry (AAS). This instrument operates on the principle of Spectrophotometer analysis, in which the concentration of a chemical element (analyte) is determined through the absorption of light

ERUDITIO Vol. 6, No. 1, Desember 2025, pp. 43-52
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radiation by free atoms in the gas phase. In analytical chemistry, AAS is the method of choice due to its ability to selectively detect free metal ions, for both qualitative and quantitative purposes (Paudel, Santosh, et al. 2021). The advantages of AAS include high sensitivity, more precise and rapid analysis.

Table 1. Maximum Limits for Heavy Metal Contaminants in Herbal Medicines

Types of Heavy Metals	Maximum Limits for Herbal Medicines
Lead (Pb)	≤ 10 mg/kg or mg/L or ppm
Camium (Cd)	≤ 0,3 mg/kg or mg/L or ppm
Arsenic (As)	≤ 5 mg/kg or mg/L or ppm
Mercury (Hg)	≤ 0,5 mg/kg or mg/L or ppm

Recently, studies integrating data on mercury (Hg) contamination levels in solid herbal medicine dosage forms with public health risk assessments in Bali Province remain very limited. However, the risk of mercury exposure from medicinal plant crude drugs contaminated by soil or during production also requires close attention to ensure public health. So far, scientific publications and monitoring related to heavy metal contamination in the Province of Bali have predominantly focused on marine food products and coastal ecosystems; for example, analyses of the bioaccumulation of heavy metals—including lead (Pb) and cadmium (Cd)—have largely centered on marine biota, such as fishery products intended for export (Kurniawati, Dwi., et al. 2023) as well as heavy metal contamination in fish caught in rivers in the city of Denpasar (Palgunadi, et al. 2022).

This study aims to fill this scientific gap by conducting a comprehensive toxicological risk assessment. The evaluation was conducted by calculating **the Estimated Daily Intake (EDI)** to determine the estimated daily intake, **the Target Hazard Quotient (THQ)** to assess non-carcinogenic risks, and **the Cancer Risk (CR)** to estimate the potential risk of cancer resulting from long-term exposure.

The primary focus of this study is to map mercury (Hg) contamination levels in solid oral dosage forms sampled in the Province of Bali during 2025, including pills, capsules, granules, powders, tablets, granules, and caplets. All types of solid dosage forms were included in the study provided they met the inclusion criteria, which involved testing for mercury (Hg) contamination using Atomic Absorption Spectrophotometry (AAS-HVG). The data obtained were then correlated with a health risk assessment to provide an overview of product safety for consumers. Data collection was conducted using representative sampling techniques, in which samples were obtained from various traditional medicine providers and herbal medicine depots spread across all regencies in Bali Province, covering a wide range of claimed benefits, trademarks, and different manufacturers.

2. Methods

The methodology of this study involved collecting data from laboratory test results on herbal medicines (OBA) in solid oral dosage forms, including pills, capsules, granules, powders, tablets, granules, caplets, and param. The samples were collected through sampling activities conducted by the Denpasar Central Office for Drug and Food Control (BBPOM) on OBA in market within the Province of Bali during 2025. A total of 214 samples met the inclusion criteria were used in this study; specifically, samples for which mercury (Hg) contamination testing parameters were available, measured using AAS instrument with the

ERUDITIO Vol. 6, No. 1, Desember 2025, pp. 43-52
P-ISSN: 2580-7722 | E-ISSN: 2807-6222

Hydride Vapor Generator (AAS-HVG) technique. Samples lacking testing parameters for mercury contamination were excluded from the study. Prior to analysis, the samples were digested to separate the mercury from its matrix. Subsequently, mercury levels were quantitatively analyzed using AAS with the FIAS (Flow Injection Analysis System/Cold Vapor Technique) method, in accordance with the ASEAN Cosmetics Method (ACM) THA 05, 2005.

2.1.Equipments

The equipment used includes a microwave digestion system (Millestone brand, Ethos Up model); an AAS system using the cold vapor technique (Flow Injection Analysis System - AAS (Cold Vapor Technique), Thermo iCE 3000 model); Electrodeless Discharge Lamp or Hollow Cathode Lamp: Mercury; and vessels made of quartz or tetrafluoromethane (TFM).

2.2.Materials and Reagents

The materials used were various samples of solid OBA dosage forms purchased from traditional medicine stores and herbal medicine depots across the province of Bali during 2025. The reagents used were deionized water with a resistivity of no less than 18.2 Mohm; 0.5% nitric acid solution; 3% hydrochloric acid solution; 0.5% sodium hydroxide solution; 0.2% sodium borohydride solution (0.20 g of sodium borohydride was weighed, then dissolved in 0.5% sodium hydroxide solution and diluted to a volume of 100 mL); the mercury standard used was the Supelco (Merck®).

2.3.Procedure

Prepare the test solution; weigh 0.15–0.20 g of the sample (in duplicate) and place it in a 50 mL vessel. Then, using a micropipette, add 5 mL of concentrated nitric acid, 1 mL of concentrated HCl, and 1 mL of 30% H_2O_2 solution. Next, the solution was allowed to stand for 15 minutes to ensure the reaction was complete; the vessel was then sealed and digested in a microwave digestion system set to a maximum power of 800 W, a temperature of 160 °C, a ramp time of 15 minutes, and a holding time of 60 minutes. After completion, the mixture was cooled to room temperature. Next, deionized water was added to the digested solution; if necessary, the solution was filtered through Whatman No. 1 filter paper. The solution was then transferred to a 50 mL volumetric flask. The blank solution was prepared using the same procedure as the test solution, but without adding a sample. The blank solution consists of 5 mL of concentrated nitric acid (HNO_3), 1 mL of concentrated hydrochloric acid (HCl), and 1 mL of 30% hydrogen peroxide (H_2O_2) solution. Next, the blank solution undergoes the same destruction, dilution, and analysis steps as the test solution. A 1000 µg/mL mercury standard solution is diluted to prepare a series of solutions with concentrations of 0.5 ppb, 1 ppb, 2 ppb, 3 ppb, and 5 ppb. Then, the blank solution, the standard series, and the test solution were each measured sequentially in the AAS system at a wavelength of 253.7 nm. The mercury concentration in the OBA sample was determined based on the calibration curve of the prepared standard solution. The limit for mercury in OBA samples is ≤ 0.5 mg/kg (or ≤ 0.5 mg/L or ≤ 0.5 ppm). The solution was transferred to a 50 mL volumetric flask. If necessary, the solution was first filtered using Whatman No. 1 filter paper. Deionized water was then added to the mark, and the solution was homogenized.

ERUDITIO Vol. 6, No. 1, Desember 2025, pp. 43-52
P-ISSN: 2580-7722 | E-ISSN: 2807-6222

2.4.Health Risk Assessment of Mercury Heavy Metal Contamination in OBA

Estimated Daily Intake (EDI), Target Hazard Quotient (THQ), and Cancer Risk Estimation (CR) were calculated to evaluate the potential health impacts of the studied OBA consumption.

2.4.1. Estimated Daily Intake (EDI)

Estimated Daily Intake (EDI) is the amount of heavy metal contamination expected to enter the human body through daily consumption of OBA.

$$EDI = \frac{C * IR * EF * ED}{BW * AT}$$

where C is the concentration of mercury metal contamination in OBA (mg/kg), IR is the ingestion rate (kg/day) (0.008 kg/day for adults), EF is the frequency of exposure (365 days/year), ED is the duration of exposure (70 years for adults), BW is the average body weight (kg) which is 70 kg, and AT is the average time of exposure for non-carcinogenic impacts (365 days/year x ED) (Phiri, Ontlametse H. E., et. al. 2025).

2.4.2. Target Hazard Quotient (THQ)

Target Hazard Quotient (THQ) is an assessment of the level of non-carcinogenic risk due to exposure to heavy metal contamination.

$$THQ = \frac{EDI}{RfD}$$

where RfD is the estimated maximum daily dose of heavy metal contaminants that does not pose a health risk (mg/kg/day). The RfD value for mercury contaminants is 0.0003. If the THQ value is <1, it indicates that the metal contaminant is still within safe limits for consumption and does not pose a significant non-carcinogenic health risk to the population (Al-Keriawy et al., 2023).

2.4.3. Cancer Risk Estimation (CR)

Cancer Risk Estimation is calculated to indicate carcinogenic risk. The standard value for CR is $\leq 1 \times 10^{-6}$. If the CR value exceeds the standard value, there is a carcinogenic risk.

$$CR = EDI\ x\ CSF$$

Carcinogenic risk is assessed from the CR value with the following criteria: CR > 1×10^{-4} indicates a carcinogenic risk; 1×10^{-4} > CR 1×10^{-6} indicates an acceptable carcinogenic risk; and CR < 1×10^{-6} indicates a negligible carcinogenic risk. The CSF (carcinogenic slope factor) value for mercury contamination is 8.5×10^{-6} (Fangjun Peng et al., 2022).

3. Results and Discussion

Quantitative analysis of mercury levels in solid OBA samples was conducted on 214 solid OBA samples using an AAS instrument with a cold steam technique. Based on the test results and data calculations (Table 2), the mercury contamination profile in the samples is as follows:

- **Detected Samples**: A total of 108 samples showed mercury metal contamination, with results ranging from 0.02 to 0.16 ppm.

ERUDITIO Vol. 6, No. 1, Desember 2025, pp. 43-52
P-ISSN: 2580-7722 | E-ISSN: 2807-6222

- **Undetectable Samples**: A total of 106 samples were below the instrument detection limit (non-detectable).

A crucial point of this finding is that although 108 samples tested positive for mercury, all levels were below the required maximum limit. Therefore, all products were classified as **Compliance (MS)**. This indicates that mercury contamination in the tested solid oral OBA dosage forms has a safety and quality profile suitable for public distribution and consumption.

The mercury content profile of the OBA samples tested can be seen in Table 2 below:

Table 2. Profile of the Number of Solid Dosage OBA Samples

Dosage Form	Number of Samples Detected with Mercury Metal Contamination	Number of Samples Not Detected of Mercury Metal Contamination
Pill	18	12
Capsule	15	14
Granule	5	3
Powder	58	67
Tablet	9	8
Cut material	1	0
Caplet	2	2
Total	108	106

Mercury Metal Contamination Limits according to BPOM RI No. 29 of 2023: ≤ 0,5 mg/kg (or ≤ 0,5mg/L or ≤ 0,5 ppm).

The average mercury metal contamination content in various types of solid OBA dosage forms can be seen in Table 3 below:

Table 3. Average Mercury Content Based on Dosage Form

Dosage Form	Amount of Data	Replication	Average (ppm)	SD
Pill	18	2	0.16	0.141
Capsule	15	2	0.06	0.050
Granule	5	2	0.11	0.062
Powder	58	2	0.08	0.095
Tablet	9	2	0.06	0.044
Cut material	1	2	0.03	0.001
Caplet	2	2	0.02	0.006

Mercury Metal Contamination Limits according to BPOM RI: ≤ 0,5 mg/kg (or ≤ 0,5 mg/L or 0,5 ppm)

An evaluation of seven variants of solid OBA dosage forms showed varying contamination distributions. This is due to different sources of contamination based on the processing methods of each dosage form. For dried cut herbs materials, processing does not require many stages, so sources of contamination are influenced by the raw material source and environmental conditions at the plants, including soil mixed with volcanic eruptions, contamination from industrial activities, gold mining, battery waste, and agricultural sources. For powder dosage form, the production process uses a grinding machine, so if CPOTB is not implemented, it can become a source of contamination. Meanwhile, the manufacturing process for tablets, capsules, and pills is more complex because it uses additional ingredients and more sophisticated production equipment (Luo, Lu et al., 2021).

ERUDITIO Vol. 6, No. 1, Desember 2025, pp. 43-52
P-ISSN: 2580-7722 | E-ISSN: 2807-6222

Other research on mercury contamination analysis has focused only on herbal medicines for aches and pains sold in Banda Aceh (Mutia Farida et. al., 2025).

Samples in powder dosage form were the most sampled type and had an average mercury metal contamination content of 0.08 mg/kg, while the least sampled was dried cut herbs, which were only sampled 1, with a Mercury metal contamination content of 0.03 mg/kg **(Table 3).** Though the samples analyzed and detected with Mercury metal contamination, the content level still below the contamination threshold required in BPOM Regulation No. 29 of 2023, namely ≤ 0.5 mg/kg, so it can be concluded that solid OBA dosage forms circulating in Bali Province still meet the Requirements (MS) both in terms of safety and quality for distribution and consumption by the public. When compared to the European Medicines Agency standard (0.1 mg/kg), the Mercury metal contamination standard in Indonesia is still high, so it is necessary to review the existing regulations, considering the increasing evidence about the health effects of long-term exposure to low doses of Mercury metal contamination (Mutia Farida et.al. 2025).

This can also serve as a benchmark for the optimal implementation of Good Manufacturing Practices (GMP) by OBA producers, minimizing and controlling factors that could contribute to mercury contamination in both OBA raw materials and finished products during production. Implementing Good Manufacturing Practices (GMP) can prevent cross-contamination during the production process.

The EDI value (**Table 4**) of Mercury metal contamination for OBA solid dosage forms that are directly consumed (pills, capsules, granules, powders, tablets, and caplets) and cut herbal materials brewed with hot water is below the THQ value <1 (Al-keriawy, et.al. 2023). This indicates that Mercury metal contamination does not pose a dangerous risk to health. Table 4 shows the highest THQ value for the pill dosage form, while the lowest is for the cut herbal materials. Of all the dosage forms tested, a THQ value <1 indicates that Mercury exposure in the OBA remains within safe limits and does not pose significant non-carcinogenic health risks to the population. The CR value for all OBA solid dosage forms is $<1x10^{-6}$, indicating a negligible carcinogenic risk. Based on the EDI, THQ, and CR values, it can be concluded that the mercury metal contamination in the solid oral OBA dosage form sampled in Bali Province is safe and suitable for public consumption.

Table 4. Health Risk Assessment of Mercury Heavy Metal Contamination in OBA

Dosage Form	EDI	THQ	CR
Pill	2.29×10^{-5}	0.08	1.94×10^{-10}
Capsule	8.57×10^{-6}	0.03	7.29×10^{-11}
Granule	1.57×10^{-5}	0.05	1.34×10^{-10}
Powder	1.14×10^{-5}	0.04	9.71×10^{-11}
Tablet	8.57×10^{-6}	0.03	7.29×10^{-11}
Cut material	4.29×10^{-6}	0.01	3.64×10^{-11}
Caplet	2.86×10^{-6}	0.01	2.43×10^{-11}

As a preventive measure and follow-up, the researchers recommend conducting similar research to determine the mercury (Hg) contamination profile in liquid OBA dosage forms. Furthermore, monitoring of other persistent heavy metals, such as arsenic (As), lead (Pb),

ERUDITIO Vol. 6, No. 1, Desember 2025, pp. 43-52
P-ISSN: 2580-7722 | E-ISSN: 2807-6222

and cadmium (Cd), in solid and liquid OBA dosage forms circulating in Bali Province is also necessary.

4. Conclusion

The content of mercury metal contamination in the sample of OBA solid oral dosage forms sampled with a total of 214 samples in Bali Province meets the requirements in terms of both safety and quality in accordance with the BPOM RI Regulation, namely the average results of Mercury metal contamination content with a range of results 0.02 - 0.16 ppm (below the required value ≤ 0.5 mg/kg) and does not have a significant health risk, namely the standard value of THQ < 1 and the standard value of CR $\leq 1 \times 10^{-6}$ so that it is considered suitable and safe for consumption by the public.

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