Proceedings of the Pakistan Academy of Sciences: A Physical and Computational Sciences 62(3): 209-220 (2025)

ISSN (Print): 2518-4245; ISSN (Online): 2518-4253
http://doi.org/10.53560/PPASA(62-3)695

Pakistan Academy of Sciences

Research Article

Assessment of Heavy Metal Contamination and Associated Health Risks in Drugs Administered to Newborns in Iraq

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Abstract: In this research, heavy metals such as lead (Pb), cadmium (Cd), and chromium (Cr) were determined in two types of drug samples, namely syrups and injections that were administered to newborns in Iraqi hospitals, during 2024. 30 samples of drugs were collected to investigate heavy metals using a Shimadzu AA-7000 atomic absorption spectrometer (AAS). The current study used the US Environmental Protection Agency model to calculate the carcinogen and non-carcinogen risk criteria for heavy metals in all medical samples. The average values of Pb, Cd, and Cr in syrup drug samples were 1.65 ± 0.47 mg/L, 0.34 ± 0.06 mg/L, and 1.17 ± 0.09 mg/L, respectively. For injection drug samples, the corresponding average concentrations were 1.71 ± 0.45 mg/L, 0.45 ± 0.04 mg/L, and 1.26 ± 0.04 mg/L, respectively. All measured values of the concentrations of Pb, Cd, and Cr in syrup drug and injection drug were within international permissible limits; though, some injection samples showed elevated Pb levels. However, the TNCR and TCCR results for all samples were within the globally recommended limits by the US Environmental Protection Agency. Although measured concentrations of Pb, Cd, and Cr were within international permissible limits, carcinogenic and non-carcinogenic risk assessments indicate the need for continued monitoring of neonatal drugs, particularly those with elevated Pb levels.

Keywords: Heavy Metals, Medical Drugs, Health Risks, New-born, Carcinogen.

1. INTRODUCTION

Heavy metals are defined as elements with a density greater than 5 g/cm³ [1]. Heavy metals can be found ubiquitously in the natural realm. Nevertheless, their existence in the environment can be augmented due to human-induced actions. The global community is deeply concerned about the environmental contamination caused by heavy metals [2]. Their toxicity increases, even at low concentrations, due to various activities that pollute the environment, water, and soil, and then living organisms through the food chain, causing the formation of stable and non-degradable toxic compounds in bodies, which leads to the destruction of their vital functions [3]. Heavy metals are essential minerals for human, but in small proportions, depending on the type of metal and the body's need for it, which may be a few milligrams per day, and their increase causes health problems. Among the most important minerals necessary for humans are calcium (Ca), phosphorus (P), iron (Fe), magnesium (Mg), copper (Cu), zinc (Zn), manganese (Mn), iodine (I), sodium (Na), potassium (K), and chlorine (Cl) [4]. On the other hand, there are toxic heavy metals whose presence in the human body poses a risk. These include chromium (Cr), cadmium (Cd), lead (Pb), mercury (Hg), etc. [1]. Numerous independent investigations have raised concerns about the presence of pollutants, including heavy metals, in various drug products specifically formulated for children, especially newborns. The susceptibility to both carcinogenic and non-carcinogenic impacts of excessive exposure to heavy metals is a concern for all individuals; however, infants, toddlers, and children are particularly at risk due to their underdeveloped physiological systems [5, 6].

Although environmental exposure to heavy metals is widely documented, their presence in pharmaceutical products used for newborns is of greater concern. In particular, oral syrups and injectable medications may be direct pathways for heavy metal consumption during treatment [7, 8].

Received: July 2025; Revised: August 2025; Accepted: September 2025
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Heavy metals are harmful because the body does not metabolize them. They accumulate in soft tissues, which may enter newborns through food, water, air, or absorption through the skin [9]. Heavy metal concentrations in drug samples were studied by many scientists worldwide using different technical [10-12]. 30 types of medications used to treat newborns from the most common diseases affecting this category of children in Iraq.

Since no previous studies have assessed heavy metal levels in drugs used by newborns and available in Iraqi hospitals, the current work provides the first baseline data. Therefore, this work aims to determine Pb, Cd, and Cr levels using atomic absorption spectrometry (AA-7000, Shimadzu, Japan) in medical medications available in Iraq. Carcinogen and non-carcinogen risk parameters such as chronic daily intake (CDI), hazard ratio (HQ), chronic risk index (HI), cancer risk (CR), and total cumulative cancer risk (TCCR) were also calculated in all samples of the current study. This study not only addresses a critical public health issue but also provides valuable insights for policymakers and healthcare providers to ensure safer pharmacy practices.

2. MATERIALS AND METHODS

2.1. Drugs Samples

Drug samples in the present work included syrups and injectable drugs that are commonly used and administered to neonates in Iraqi hospitals. Selection criteria were based on their frequency of prescription and availability in neonatal wards, ensuring representativeness of routine clinical practice. Initial quality control properties, such as labeling, packaging, and expiry, were performed. All drug samples were securely packaged to prevent moisture absorption and reduce microbial contamination. To maintain sample integrity, all medications were stored in their original sealed containers under recommended storage conditions (at room temperature and away from direct sunlight) until analysis. These samples were collected from November 01, 2024, to December 01, 2024. The sources of these samples (30 samples) were chosen from various countries and obtained from the Iraqi hospitals. The medical drug samples were divided into 8 syrups and 22 injections at different manufacturing facilities (Table 1).

2.2. Drugs Preparation and Digestion

In the present study, 5-10 ml of the drug samples were taken and put in the digestion vessel, and 5-8 ml of nitric acid (HNO_3 65%) and 1-2 ml of hydrogen peroxide (H_2O_2 30%) were added to speed up the reaction. Then the digestion vessel is placed in the heating device at 180-220 °C for 20-45 minutes. After the reaction is complete, we transfered the resulting solution to a volumetric flask, added distilled water (50 - 100 ml), then employed an atomic absorption device (AAS) [13-16].

To ensure analytical accuracy and precision, three other vials were taken to digest the blank sample, using the same mixture of acids used in the samples, but without adding them to it. These were used to compare the changes between acids in the absence and presence of the sample. The blank sample was used to calibrate the zero to set the spectrophotometer [duha drugs]. Recovery rates ranged within the acceptable limits (80-120%), confirming the reliability of the digestion and measurement procedures.

2.3. Atomic Absorption Spectrometer

Heavy metals (lead, cadmium, and chromium) were analyzed using a flame atomic absorption spectrometer (AA-7000, Japan) model SHIMADZU. Concentrations of lead, cadmium, and chromium are determined using heating. Atomic spectrometers measured at wavelengths of 283.3 nm, 228.8 nm, and 357.9 nm, respectively, and lamp currents of 10 mA, 8 mA, and 10 mA, respectively. The calibration standards of solutions for Pb and Cr were 0.2, 0.5, and 1 ppm, while for Cd were 0.1, 0.5, and 1 ppm. It was calculated that the background level of the blank was 0.01 ppm. Also, the limits of detection for the three heavy metals of the present study were for Pb <0.01, for Cd <0.01, and for Cr 0.09 ppm.

To ensure quality control (QA/QC), the certified reference materials (CRM) of plant origin for metal analysis are also used, and the recovery test is conducted with the best digestion method for each metal. QA/QC procedures included analysis of blanks, duplicates, and spiked samples, and all measurements were performed in triplicate to ensure precision and accuracy.

Table 1. Drug sample information in the present work.

S. No.	Type of drugs	Sample name	Sample code	Origin
1	Syrups	Baby Gas drops 30 ml	SD1	Iraq
2		Paracetamol Syrup	SD2	Iraq
3		Brufemol Syrup	SD3	Iraq
4		Spasmo - drop	SD4	Iraq
5		Butadin Syrup	SD5	Iraq
6		Safaprim Syrup	SD6	Iraq
7		Piodol drop 30 ml	SD7	Iraq
8		Nystatin drops 30 ml	SD8	Iraq
9	Injections	Glucose/ Dextrose 5%	ID1	Iraq
10		Glucose/ Dextrose 10%	ID2	Iraq
11		Difen 10 mg/ml	ID3	Iraq
12		Piodol 10 mg/ml	ID4	Iraq
13		Ciprofloxacin 200 mg/100 ml	ID5	Iraq
14		Ceftriaxone 1mg	ID6	Iraq
15		Meropenem 1000 mg	ID7	Germany
16		Ondansetron 2 mg/ml	ID8	Iraq
17		Piopenem 1000 mg	ID9	Iraq
18		Omnip Aque 350mg/ml	ID10	Ireland
19		TZD Ceftazidime 1000 mg/vail	ID11	India
20		Vancotech 1mg/vial	ID12	India
21		Glucose 50% W/V	ID13	Iraq
22		Flagyl 100 ml	ID14	Iraq
23		Amoxicillin	ID15	Iraq
24		Vanconeer IV	ID16	Iraq
25		Glueose 50% W/V 20 ml	ID17	Germany
26		Tavoctamo piperacillin	ID18	Iraq
27		Potassium chloride 15%	ID19	Iraq
28		Calcium Cluconate 10 ml	ID20	Germany
29		Aminophyline 250 mg/10 ml	ID21	Cyprus
30		Ampicillin 500 ml	ID22	India

2.4. Calculation of Healthy Risk Assessments

The health risk parameters were calculated due to Pb, Cd, and Cr concentrations in drug samples in the present study, which can be classified into two parts (non-carcinogen and carcinogen parameters), as follows:

2.4.1. Non - carcinogen parameters

Three health risk parameters for non-carcinogens were assessed as follows:

a. Chronic daily intake for non-carcinogens (CDI nca) [17]:

$$CDI_{nca}\left(\frac{mg}{kg}.d^{-1}\right) = \frac{Cs \times IR \times EF \times ED \times CF}{BW \times AT(nca)} \quad (1)$$

b. Hazard quotient (HQ) [17]:

$$HQ = \frac{CDI_{nca}}{RFD_O} \quad (2)$$

c. Hazard index (HHI) or total non-carcinogens risk (TNCR) [18, 19]:

$$HI = \sum_1^K \frac{CDI_k}{RFD_k} \quad (3)$$

where Cs is concentrations of Pb, Cd, and Cr concentrations (mg/L), IR is ingestion rate consumption of drugs (1.25 ml/day) for injection [20] and (5.250 ml/day) for syrups [21], EF is exposure frequency (350 day/year) [22], ED is exposure duration (30 years), CF is conversion factor 10^{-6} kg/mg) [17], BW is the average of body weight of newborn (5.7 kg) [23], AT (nca) is the average time for non-carcinogens (365 × 30 days) [22], and RFD_0 is "chronic reference dose of the toxicant" (Pb = 0.004 mg/kg/day, Cd = 0.001 mg/kg/day, and Cr = 0.003 mg/kg/day) [24].

2.4.2. Carcinogen parameters

There are three health risk parameters for carcinogens assessed as follows:

a. Chronic daily intake for carcinogens (CDI_{ca}) [17]:

$$CDI_{ca}\left(\frac{mg}{kg}.d^{-1}\right) = \frac{Cs \times IR \times EF \times ED \times CF}{BW \times AT(na)} \quad (4)$$

b. Cancer risk (CR) [25]:

$$CR = CDI_{ca} \times SF \quad (5)$$

c. Total cumulative cancer risk (TCCR) [18]:

$$TCCR = \sum_1^k CDI_k \times SF_k \quad (6)$$

where, AT (ca) is average time for carcinogens (365×70 days) [22], and SF is "slope factor" (Pb= 0.0085 mg/kg/day, Cd= 6.7 mg/kg/day, and Cr = 0.5 for Pb, Cd, and Cr mg/kg/day) [26].

It should be noted that the selected criteria (IR, EF, ED, and BW) are primarily derived from neonatal studies and EPA guidelines. However, because the EPA equations were originally developed for the general population, their direct application to neonates may raise some concerns; therefore, in this work, we relied on neonatal-specific references whenever possible.

3. RESULTS AND DISCUSSION

Table 2 presents the results of drug samples showing concentrations of Pb, Cd, and Cr. The range value of Pb, Cd, and Cr concentrations (mg/L or ppm) in syrup drug samples were 0.01-3.43, 0.01-0.57, and 0.69-1.62, respectively, with average values of 1.65 ± 0.47, 0.34 ± 0.06, and 1.17 ± 0.09. Whereas, the range values of Pb, Cd, and Cr concentrations (mg/L or ppm) in injection drug samples were 0.001-10.1, 0.13-0.8, and 0.76-1.69, respectively, with average values of 1.71 ± 0.45, 0.45 ± 0.04, and 1.26 ± 0.04. All samples' average Pb, Cd, and Cr concentrations were 1.7 ± 0.35, 0.42 ± 0.03, and 1.23 ± 0.04, respectively. Figure 1 shows the Comparison of the Concentration (mg/L) of Pb, Cd, and Cr in drug samples between the syrups and injections with the safe limit.

Figure 2 shows the percentage values of Pb concentrations in drug samples (syrups and

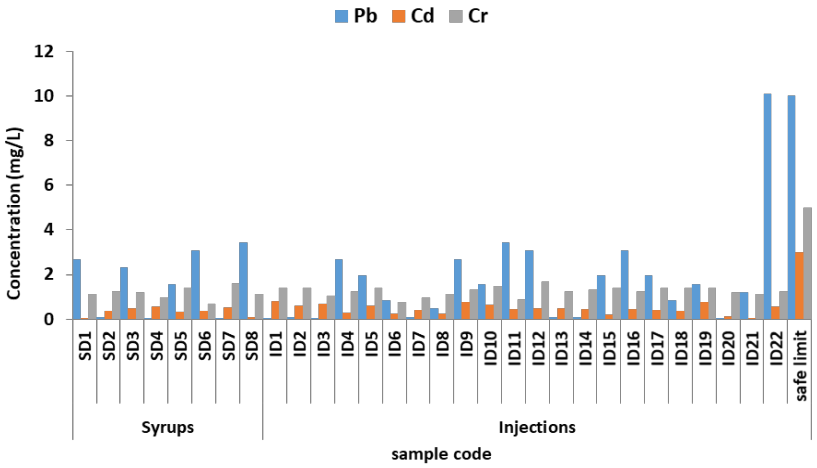

Fig. 1. Comparison of the Concentration (mg/L) of Pb, Cd, and Cr in drugs samples between the syrups and injections with safe limit.

Table 2. Results of heavy metals in drugs sample in the present work.

S. No.	Type of drugs	Sample code	Concentration (mg/L)		
			Pb	**Cd**	**Cr**
1	Syrups	SD1	2.69	0.01	1.12
2		SD2	0.09	0.38	1.26
3		SD3	2.32	0.49	1.19
4		SD4	0.01	0.57	0.98
5		SD5	1.58	0.33	1.40
6		SD6	3.06	0.38	0.69
7		SD7	0.03	0.51	1.62
8		SD8	3.43	0.08	1.12
9	Injections	ID1	0.03	0.80	1.40
10		ID2	0.09	0.60	1.40
11		ID3	0.02	0.69	1.05
12		ID4	2.69	0.28	1.26
13		ID5	1.95	0.60	1.40
14		ID6	0.84	0.26	0.76
15		ID7	0.09	0.40	0.98
16		ID8	0.47	0.24	1.12
17		ID9	2.69	0.76	1.33
18		ID10	1.58	0.64	1.48
19		ID11	3.43	0.44	0.90
20		ID12	3.06	0.48	1.69
21		ID13	0.07	0.48	1.26
22		ID14	0.09	0.44	1.33
23		ID15	1.95	0.22	1.40
24		ID16	3.06	0.44	1.26
25		ID17	1.95	0.40	1.40
26		ID18	0.84	0.37	1.40
27		ID19	1.58	0.76	1.40
28		ID20	0.001	0.13	1.19
29		ID21	1.21	0.01	1.12
30		ID22	10.10	0.55	1.26
Avearge±S.D.(Syrups)			1.65 ± 0.47	0.34 ± 0.06	1.17 ± 0.09
Avearge±S.D.(Injections)			1.71 ± 0.45	0.45 ± 0.04	1.26 ± 0.04
Avearge±S.D.(All)			1.7 ± 0.35	0.42 ± 0.03	1.23 ± 0.04

injections) in the present work. While, Figure 3 shows the percentage values of Cd concentrations in the present samples. Whereas, Figure 4 shows the percentage values of Cr concentrations in the present samples. Figures 2 illustrates that the maximum percentage of Pb concentrations was 17% in ID22 (Ampicillin 500ml, made in India). Figure 5 shows the difference in the average heavy metals in drug samples between syrups and injections. The average of all heavy metals (Pb, Cd, and Cr) in injection samples is higher than in syrup samples. Because when the medicine (needles) is

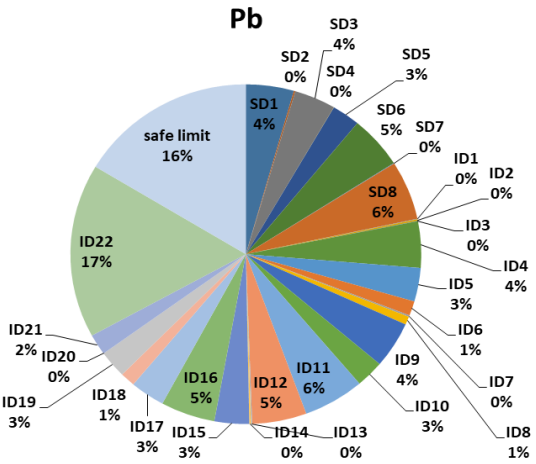

Fig. 2. The percentage value of Lead in drugs samples in the present study.

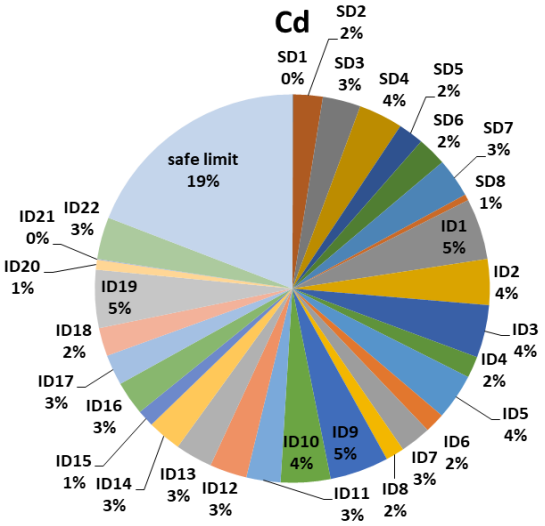

Fig. 3. The percentage value of cadmium in drugs samples in the present study.

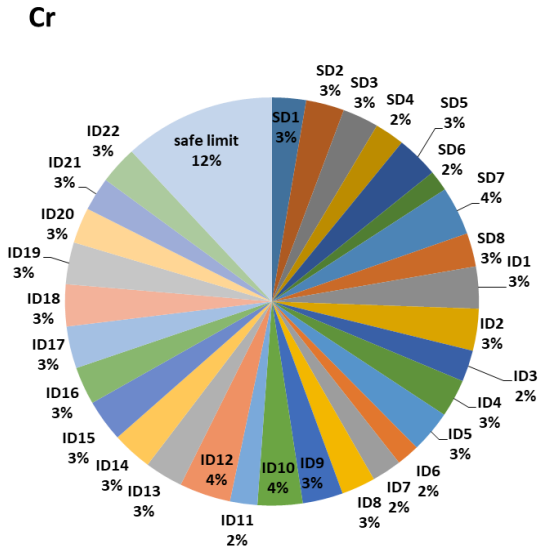

Fig. 4. The percentage value of chromium in drugs samples in the present study.

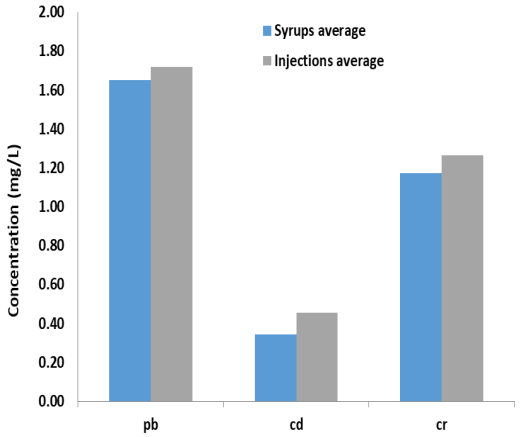

Fig. 5. Comparison of the average of Pb, Cd, and Cr in drugs samples between the syrups and injections.

given intravenously, it immediately reaches the bloodstream, while the medicines (drinks) that are given orally are convenient, safe, and less expensive, as absorption begins from the mouth, stomach, then the small intestine, and the liver proceeds before transporting it through the bloodstream to its location. The injection medicine shows its effectiveness within 5-10 minutes, while the swallowing medicine shows its effectiveness within 45-60 minutes. The study showed that the average lead, cadmium, and chromium for drug samples were within the global limit (Pb = 10 ml/L, Cd = 3 ml/L, and Cr = 5 ml/L) [27]. The Pb detection in injection ID22 at 10.1 mg/L from Table 2 indicates a possible risk from outlier samples. Leaching from packing or equipment, contamination during manufacturing, or inadequate quality control might all be the cause of this abnormally high Pb level. These outliers highlight the necessity of rigorous monitoring, even while the majority of samples fall within safe bounds. To avoid these kinds of incidents, it is crucial to maintain appropriate production and storage conditions. Even while the average Pb levels in each injection are within acceptable bounds, large amounts in specific batches may still be harmful to a newborn's health. To avoid exposure to harmful heavy metals, this emphasises the significance of strict quality control, frequent drug batch monitoring, and adherence to safety protocols.

Table 3 displays the results of non-carcinogen parameters, Chronic Daily Intake (CDInca), Hazard Quotient (HQ), and Hazard Index (HI) for the Pb, Cd, and Cr concentrations in the present study. The average values of CDInca (unit µg/L/day) for Pb, Cd, and Cr concentrations were 0.653 ± 0.159, 0.151 ± 0.024, and 0.470 ± 0.066, respectively. The average values of HQ of Pb, Cd, and Cr concentrations were 0.163 ± 0.039, 0.151 ± 0.024, and 0.156 ± 0.022, respectively. At the same time, as presented in Table 3, the results of HI vary from 0.111 in sample ID20 (Calcium Cluconate 10 ml, Germany) to 1.298 in sample SD3 (Brufemol Syrup, Iraq), with an average of 0.471± 0.065.

The carcinogen parameters, chronic daily intake (CDIca), Carcinogenic Risk (CR), and Total Carcinogenic Risk (TCR) of newborns from

Table 3. Results of non-carcinogen parameters for drug samples in the current study.

S. No.	Sample code	CDI_{nca} (ng/L/day)			$HQ\times10^{-3}$			$HI\times10^{-3}$
		Pb	Cd	Cr	Pb	Cd	Cr	
1	SD1	2.374	0.008	0.988	0.594	0.008	0.329	0.931
2	SD2	0.083	0.340	1.114	0.021	0.340	0.371	0.732
3	SD3	2.047	0.436	1.051	0.512	0.436	0.350	1.298
4	SD4	0.011	0.500	0.862	0.003	0.500	0.287	0.790
5	SD5	1.392	0.292	1.240	0.348	0.292	0.413	1.053
6	SD6	2.701	0.340	0.610	0.675	0.340	0.203	1.218
7	SD7	0.025	0.452	1.429	0.006	0.452	0.476	0.934
8	SD8	3.029	0.068	0.988	0.757	0.068	0.329	1.154
9	ID1	0.005	0.168	0.295	0.001	0.168	0.098	0.268
10	ID2	0.020	0.127	0.295	0.005	0.127	0.098	0.230
11	ID3	0.004	0.146	0.220	0.001	0.146	0.073	0.220
12	ID4	0.565	0.058	0.265	0.141	0.058	0.088	0.288
13	ID5	0.409	0.127	0.295	0.102	0.127	0.098	0.327
14	ID6	0.176	0.054	0.160	0.044	0.054	0.053	0.152
15	ID7	0.020	0.085	0.205	0.005	0.085	0.068	0.158
16	ID8	0.098	0.050	0.235	0.024	0.050	0.078	0.153
17	ID9	0.565	0.161	0.280	0.141	0.161	0.093	0.396
18	ID10	0.332	0.134	0.310	0.083	0.134	0.103	0.320
19	ID11	0.721	0.092	0.190	0.180	0.092	0.063	0.336
20	ID12	0.643	0.100	0.355	0.161	0.100	0.118	0.379
21	ID13	0.015	0.100	0.265	0.004	0.100	0.088	0.192
22	ID14	0.020	0.092	0.280	0.005	0.092	0.093	0.191
23	ID15	0.409	0.047	0.295	0.102	0.047	0.098	0.247
24	ID16	0.643	0.092	0.265	0.161	0.092	0.088	0.341
25	ID17	0.409	0.085	0.295	0.102	0.085	0.098	0.285
26	ID18	0.176	0.077	0.295	0.044	0.077	0.098	0.219
27	ID19	0.332	0.161	0.295	0.083	0.161	0.098	0.342
28	ID20	0.001	0.028	0.250	0.000	0.028	0.083	0.111
29	ID21	0.254	0.003	0.235	0.063	0.003	0.078	0.145
30	ID22	2.124	0.115	0.265	0.531	0.115	0.088	0.734
Avearge±S.D.		0.653 ±0.159	0.151 ±0.024	0.470 ±0.066	0.163 ±0.039	0.151 ±0.024	0.156 ±0.022	0.471 ±0.065

drug samples are given in Table 4. It is observed that the average values of CDIca due to Pb, Cd, and Cr concentrations in unit (µg/L/day) were 0.28 ± 0.068, 0.064 ± 0.010, and 0.201 ± 0.028, respectively. While, the average value of CR was 2.379 ± 0.58 for Pb concentrations, 434.029 ± 69.047 for Cd concentrations, and 100.930 ± 14.162 for Cr concentrations. Also, the results of TCR, as presented in Table 4 ranged from 59.60 in the sample DI21 (Aminophyline 250 mg/10 ml, Cyprus) to 1619.38 in the sample SD4 (Spasmodrop, Iraq), with an average value of 537.34 ± 79.63.

The safe limits of Chronic Daily Intake (CDI) for non-carcinogenic risk (CDI_nC_a) are as follows:

Table 4. Results of carcinogen parameters for drug samples in the current study.

S. No.	Sample code	CDI_{ca} (ng/L/day)			$CR\times10^{-9}$			$TCR\times10^{-9}$
		Pb	Cd	Cr	Pb	Cd	Cr	
1	SD1	1.017	0.004	0.423	8.65	24.35	211.68	244.68
2	SD2	0.036	0.146	0.477	0.30	975.11	238.67	1214.09
3	SD3	0.877	0.187	0.450	7.46	1250.78	225.18	1483.41
4	SD4	0.005	0.214	0.369	0.04	1434.64	184.70	1619.38
5	SD5	0.597	0.125	0.531	5.07	837.40	265.68	1108.16
6	SD6	1.158	0.146	0.261	9.84	975.11	130.70	1115.65
7	SD7	0.011	0.194	0.612	0.09	1296.68	306.16	1602.93
8	SD8	1.298	0.029	0.423	11.03	194.26	211.68	416.98
9	ID1	0.002	0.072	0.127	0.02	483.72	63.26	547.00
10	ID2	0.009	0.054	0.127	0.07	363.44	63.26	426.77
11	ID3	0.002	0.062	0.094	0.01	418.15	47.19	465.35
12	ID4	0.242	0.025	0.114	2.06	166.59	56.83	225.48
13	ID5	0.175	0.054	0.127	1.49	363.44	63.26	428.19
14	ID6	0.075	0.023	0.069	0.64	155.60	34.33	190.58
15	ID7	0.009	0.036	0.088	0.07	243.10	43.98	287.15
16	ID8	0.042	0.022	0.101	0.36	144.68	50.40	195.43
17	ID9	0.242	0.069	0.120	2.06	461.86	60.04	523.96
18	ID10	0.142	0.058	0.133	1.21	385.30	66.47	452.98
19	ID11	0.309	0.040	0.082	2.63	265.02	40.76	308.40
20	ID12	0.276	0.043	0.152	2.34	286.88	76.11	365.33
21	ID13	0.006	0.043	0.114	0.05	286.88	56.83	343.76
22	ID14	0.009	0.040	0.120	0.07	265.02	60.04	325.13
23	ID15	0.175	0.020	0.127	1.49	133.75	63.26	198.49
24	ID16	0.276	0.040	0.114	2.34	265.02	56.83	324.19
25	ID17	0.175	0.036	0.127	1.49	243.10	63.26	307.85
26	ID18	0.075	0.033	0.127	0.64	221.24	63.26	285.14
27	ID19	0.142	0.069	0.127	1.21	461.86	63.26	526.33
28	ID20	0.000	0.012	0.107	0.00	79.04	53.61	132.66
29	ID21	0.109	0.001	0.101	0.92	8.27	50.40	59.60
30	ID22	0.910	0.049	0.114	7.74	330.59	56.83	395.15
Avearge±S.D.		0.28 ±0.068	0.064 ±0.010	0.201 ±0.028	2.379 ±0.58	434.029 ±69.047	100.930 ±14.162	537.34 ±79.63

Pb = 0.004 mg/kg/day, Cd = 0.001 mg/kg/day, and Cr = 0.003 mg/kg/day [24]. Figure 6 compares the CDI_nC_a values for Pb, Cd, and Cr concentrations in all drug samples (syrups and injections) with their respective safe limits. The results indicate that all values are within the safe limits [24]. Similarly, Figure 7 compares the CDI values for carcinogenic risk ($CDIc_a$) in all drug samples under study with the established safe limits, showing that they also fall within acceptable ranges [24].

Also, the values of HQ and HI in the present study samples were smaller than the safe limit of 1, as established globally by the EPA [28]. Figure 8 compares the results of HI with the safe limit. While Figures 9 compare the results of TCR with the safe limit.–On the other hand, the range of safe limits of cancer risk (CR) and total cancer risk (TCR) for heavy metals, according to US EPA reports, was from 10^{-6} to 10^{-4} [29, 30]. From Table 4 it is found that some, such as CR and TCR of risk values, were numerically higher than1000, but they remain within the EPA acceptable range (10^{-6} to 10^{-4}). This indicates that, despite the high values in some samples, the overall carcinogenic risk for newborns from these drugs is considered acceptable.

Statistically, a Pearson Correlation calculates the correlation and p-value between three heavy metals (Pb, Cd, and Cr), these results are given in Table 5, it is noted that the value is not significant. Pearson correlation of Pb, Cd, and Cr, together with the Positive Pearson correlation analysis of Pb with Cd and Cr, drugs can be seen as ores of which one mineral is the host of several elements, including the metals. Positive correlations may imply a similar source of contamination and/or a common absorption and/or accumulation pattern in the newborns, while low or negative correlations may imply independent sources, or differences regarding the absorption, distribution, and metabolism of each of the metals. Familiarity with these trends would facilitate the discernment of possible toxicological implications and quality control.

The results presented in Table 6 show the comparison of the concentrations of Pb, Cd, and Cr in drug samples that were used by children from Iraq and other countries. It is found that Pb concentration was lower than in Turkey and higher than Iran and Bangladesh. While Cd concentration was higher than Bangladesh and lower than Iran and Turkey. Whereas, Cr concentration was higher than Nigeria and Bangladesh, but lower than Turkey.

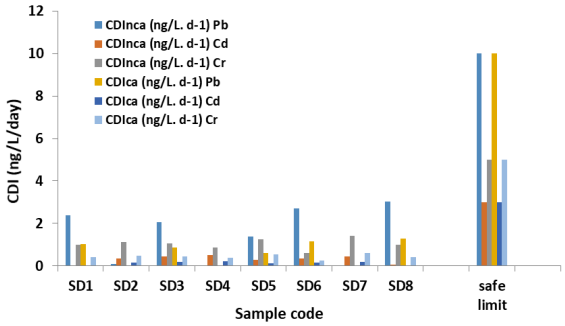

Fig. 6. Comparison of CDI (nca and ca) the samples syrups drugs of the present study and safe limit.

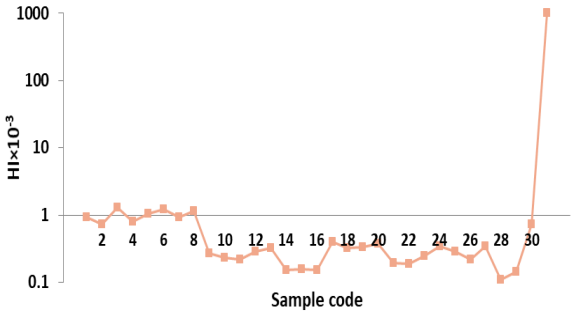

Fig. 8. Comparison of HI in drugs samples between the samples of the present study and safe limit.

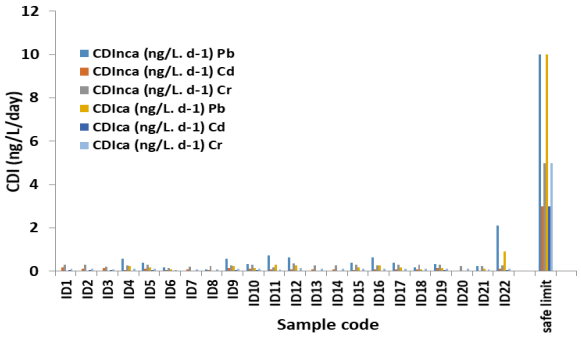

Fig. 7. Comparison of CDI (nca and ca) the samples injections drugs of the present study and safe limit.

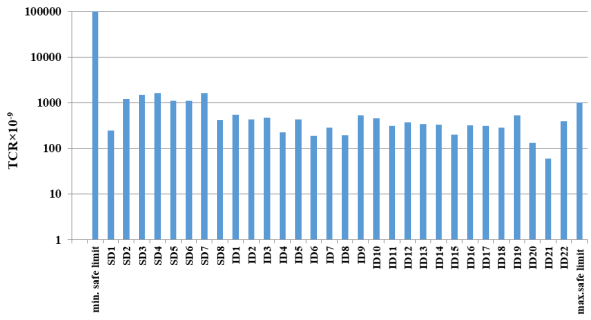

Fig. 9. Comparison of TCR in drugs samples between the samples of the present study and safe limit.

Table 5. Correlation and p-value between Pb, Cd and Cr in all samples in the present study.

Heavy metals		**Pb**	**Cd**	**Cr**
Pb	Correlation	1.00	-0.02924	-0.02644
	p-value	0.5	0 .000490	0.107403
Cd	Correlation	-0.02924	1.00	0.316026
	p-value	0 .000490	0.5	<0 .00001.
Cr	Correlation	-0.02644	0.316026	1.00
	p-value	0.107403	<0 .00001.	0.5

Table 6. Comparison of the average values of heavy metals in pediatric drugs with previous studies from other countries.

	Concentrations (mg/L)			
Country	**Pb**	**Cd**	**Cr**	**Reference**
Iran	1.69	0.89	-----	[31]
Nigeria	-----	-----	0.9	[32]
Turkey	3.4	5	4	[33]
Bangladesh	<0.1	<0.1	0.7	[34]
Iraq	1.7	0.42	1.23	Present study

4. CONCLUSIONS

The present work estimated the concentrations of Pb, Cd, and Cr, and their health risk parameters (non-carcinogenic and carcinogenic) in two types of drugs: syrups and injections used by newborns in Al-Najaf Governorate, Iraq. The concentrations of Pb, Cd, and Cr in all drug samples in the present study were lower than the drug standards set by the U.S. Food and Drug Administration. Also, the results showed that the non-carcinogenic and carcinogenic results were low risk. It can be concluded that most samples of drugs in Al-Najaf Governorate were within the safe limits, but elevated Pb levels in certain injections samples highlight the need for strict quality control and ongoing monitoring.

5. ACKNOWLEDGEMENTS

We are grateful to the University of Kufa and individuals for their invaluable support in completing this work.

6. ETHICAL STATEMENT

The ethical statement is not required as the experiments were conducted on drug samples only.

7. CONFLICT OF INTEREST

There is no conflict of interest.

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