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IN-VITRO COMPARATIVE STUDY AND QUALITY ANALYSIS OF DIFFERENT MARKETED BRAND OF METFORMIN HCL TABLETS AVAILABLEIN INDIA WITH BRAND AVAILABLE IN JAN AUSHADHI STORES

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ABSTRACT: The objective of this research study is to assess the quality standards of various brands of Metformin hydrochloride tablets that are locally available in Hyderabad, India, by comparing and contrasting them with the brand available in the Jan Aushadhi stores in India (MET-3). Eight brands of Metformin tablets (500 mg) were selected and compared for their physical and chemical parameters as per the official method. The physiochemical equivalence of all tablet brands was assessed through evaluation of both official and non-official standards such as size, shape, uniformity of weight, friability, hardness, disintegration, assay, and dissolution rate. In contrast to the generic drug of metformin available at Jan Aushadhi Kendra (MET-3), the other seven brands of Metformin hydrochloride tablets have all met the requirements of the official I.P. specification regarding weight variation, friability, hardness, disintegration, assay, and dissolution rate. It was concluded that the generic drug of metformin available in Jan Aushadhi Kendra (MET-3), whose price is almost 70% less than the other seven brands of Metformin hydrochloride, is officially similar to the other seven brands of the same drug that are available in Hyderabad, meets the I.P. specification for quality control analysis, and is interchangeable.

INTRODUCTION: With the growth in pharmaceutical industries, the numbers of pharmaceutical products (branded and generic) are increasing in the market so to maintain its quality is the most primary concern for manufacturers. Several brands of Metformin tablets are available on the market leading to confusion about quality and prices. The same generic drug can be manufactured by several pharmaceutical companies, which may look like or be different from the original. It is sold under different brand names and at different prices.

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The aim of this study was to assess and analyze the quality and standard of available brands of metformin hydrochloride (HCl) and compare the results with Jan Aushadhi brand available in Jan Aushadhi Kendra.The literature reveals that in many countries, people suffer not because of diseases, but because they are unable to afford the cost of medication for their diseases. As a result, the present study aims to dispel the blind belief that branded drugs are more therapeutic than generics.

Generic drugs are also bioequivalent to ethical drugs if all quality control parameters are maintained [1-2]. As per pharmaceutical standards, parameters like weight variation, hardness, friability, disintegration, dissolution and content uniformity should be checked to assure the effectiveness of any drug. The Jan Aushadhi Scheme was launched by the Department of Pharmaceuticals, Ministry of Chemicals &

Fertilizers, and Government of India in November 2008. Till May 2014, only 80 'Jan Aushadhi Stores' operated in selected states. The Government revamped the 'Jan Aushadhi Scheme' in September 2015 as 'Pradhan Mantri Jan Aushadhi Yojana' (PMJAY). To further boost the scheme, it was renamed Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). Till 31st January 2022, 8675 PMBJP Kendras are functional across the country. PMBJP Objectives

1. To make available quality medicines, consumables and surgical items at affordable prices for all and reduce the out of pocket expenditure of consumers/patients.
2. To popularize generic medicines among the masses and dispel the prevalent notion that low-priced generic medicines are of inferior quality or less effective.
3. Ensure women across India have easy access to menstrual health services (Janaushadhi 'Suvidha' sanitary napkins).
4. Generate employment by engaging individual entrepreneurs in PMBJP Kendra opening [3-4].

MATERIAL AND METHODS: Metformin hydrochloride 500mg of seven different brands was purchased from reputed pharmaceutical stores and one from Jan Aushadhi Stores.

Apparatus and Equipment: Electronic Balance (Scale-Tec), Vernier Calipers, Friability Test Apparatus (DBK), Disintegration Test Apparatus (DBK), Dissolution Test Apparatus (Lab India), Hardness Test (Fizer F-20), and UV-Visible Spectrophotometer were used.

Method: Various quality control tests were done according to USP and BP specifications. Metformin hydrochloride 500 mg of seven different brands was purchased from reputed pharmaceutical stores and one from Jan Aushadhi Stores. All the medicines can code Met 1 to Met 8.

TABLE 1: DIFFERENT BRANDS OF METFORMIN TABLETS

S. no.	Company name	Brand code	Batch code	Mfg date	Expiry date	Pack size	Price of pack	Unit price (Rupee)
1	Franco indian pharma pvt. Ltd	MET-1	18183	Aug 2018	July 21	20	31.48	1.574
2	Cipla	MET-2	E780773	Sep 2018	August 21	20	20.84	1.042
3	Navketan pharmapvt. Ltd **(Jan Aushadhi)**	MET-3	NP18121	July 2018	June 21	10	4.00	0.40
4	Micro Labs Limited	MET-4	MEAS0023	April2018	March 21	20	31.58	1.579
5	Glenmark pharmaceutical pvt. Ltd	MET-5	05181697	Sep 2018	August 21	15	23.61	1.57
6	Coroma Remedies pvt. Ltd	MET-6	CORAA8007	July 2018	June 2023	15	23.60	1.573
7	Aristo pharmaceutical	MET-7	D101J037	Sep 2018	August2023	10	9.87	0.98
8	USV pvt. Ltd	MET-8	28017953	Dec 2018	Nov 2021	10	15.79	1.579

Visual Inspection: The shape, colour and texture of the different brands of metformin tablets were examined visually [5]. The results are shown in **Table 2.**

Thickness Test: Tablet thickness is measured with the help of a verniercaliper. Ten tablets were randomly selected; their thickness was measured, and the result was expressed as a mean and unit in millimetres. The thickness of a tablet should be controlled within ±5% variation of a standard value depending on the size of the tablet. Tablet thickness is determined by the diameter of the die, the amount of fill permitted to enter the die cavity, the compaction characteristics of the fill material, and the force or pressure applied during compression [6]. The outcomes are given in **Table 3.**

Hardness Test: The hardness of different brands of tablets was determined by a Monsanto hardness tester and measured in terms of kg/cm^2. Three sample tablets of each brand were taken; a tablet

was placed between the spindle of the Monsanto hardness tester until the tablet broke and the pressure required to break the tablet was recorded [7]. The result was given in **Table 4.**

Friability Test: A friability test can be performed to evaluate the ability of the tablets to withstand abrasion during packing, handling, and transporting. The friabilator consists of a plastic chamber divided into two parts and revolves at 25 rpm. A fixed number of tablets are weighed, placed in the tumbling chamber, and rotated for four minutes of 100 revolutions. During each revolution, the tablets fall from a distance of six inches to undergo shock. After 100 revolutions, the tablets are again weighed [8-9]. The loss in weight indicates friability. It was calculated in percentage by the following formula:

$$\% \text{ Friability (f)} = (\text{Initial weight-final weight}) / (\text{initial weight}) \times 100$$

The acceptable limits of weight loss should not be more than 0.5-1%. The outcomes are given in the **Table 5.**

Weight Variation Test: Sample tablets (20) of each brand were weighed individually on a digital analytical balance. The average weight was determined and the percentage (%) deviation of the individual tablets from the mean weight was determined. In order to pass the weight variation test, the tablet should be within the limits of the percentage deviation allowed by I.P [10]. The outcomes are given in **Table 6.**

$$\% \text{ of weight variation} = (\text{Average weight-individual weight}) / (\text{average weight})) \times 100$$

Disintegration Test: Six tablets were randomly taken from each brand and put into the cylinders of the disintegration baskets with a disc positioned in a 1-litre beaker containing distilled water to maintain a temperature of 37.5 °C. The instrument was operated with a motor driven device with a 28–32 cycle/minute frequency. When the entire particle from all 6 tubes passed from the tube mesh to the outer beaker, the time was noted as disintegration time. After that, the average time was noted, and this process was repeated for all 8 different brands of metformin hydrochloride tablets [11-12]. For the uncoated tablets, the disintegration time is 15 minutes. The outcomes are given in **Table 7.**

Dissolution Test: The dissolution rate of each brand of tablet was determined using an 8-compartment (lab India) dissolution test apparatus using a paddle stirrer at 100 rpm and a temperature of 37±0.5°C. Phosphate buffer pH 6.8 (900 ml) was used as dissolution fluid. One tablet (500 mg) was used in each test. A sample of dissolution fluid (10 ml) was withdrawn at intervals of 5, 10, 15, 30, 45, and 60 minutes. A fresh 10 ml dissolution medium was replaced after each sampling to maintain sink conditions. Each of the withdrawn samples was filtered and the filtrate diluted. The absorbance was measured at λmax 232nm using U.V. UV-visible double beam spectrophotometer (Systronic 2201). The concentration was determined against a standard solution of metformin hydrochloride in the same medium [13-15]. From the concentration, the percentage (%) of drug release was determined at a specified time interval. Each dissolution experiment was run in triplicate (n=3). The percentage of drugs released is calculated using a formula. The outcomes are given in **Table 8.**

Content Uniformity: The test for assay is done to find out the actual amount of active ingredient present in the tablet and whether it is the same as the labeled amount. 20 tablets from each brand were weighed and finely powdered, followed by an accurately weighed portion of powder equivalent to 100mg Metformin hydrochloride was transferred to a 100-ml volumetric flask, 70 ml of distilled water was added and shook mechanically for 15 minutes, then diluted to the volume and filtered. 10 ml of the filtrate was transferred to a 100-ml volumetric flask and further diluted to 100 ml with distilled water. Then 10 ml was transferred to another 100 ml volumetric flask, and the volume was completed with distilled water. An accurately weighed 100mg of RS powder is added to a 1000 ml volumetric flask, then transferred 10 ml by bulb pipette to a 100 ml volumetric flask, and complete the volume is completed with distilled water to get 10µg/ml concentration [16-17]. The absorbance of the standard preparation and assay preparation was concomitantly determined at λ_{max} 232nm with the UV-3300PC Spectrophotometer using water as a blank. The outcomes are given in **Table 9.**

RESULTS:

Visual Inspection: The shape, and size were examined visually and the results are shown in **Table 2.**

TABLE 2: OBSERVATION FOR VISUAL INSPECTION OF DIFFERENT BRANDS

Brand Code	Shape	Size (Diameter)
MET 1	Cylindrical	1.60 cm
MET 2	Cylindrical	1.70 cm
MET 3	Round	1.30 cm
MET 4	Cylindrical	1.60 cm
MET 5	Cylindrical	1.80 cm
MET 6	Cylindrical	1.65 cm
MET 7	Cylindrical	1.80 cm
MET 8	Round	1.40 cm

Thickness Test:

TABLE 3: OBSERVATION FOR THICKNESS OF DIFFERENT BRANDS

Brand	Thickness in mm (±SD
MET 1	6.4±0.31
MET 2	7.2±0.24
MET 3	6.5±0.76
MET 4	7.1±0.33
MET 5	6.6±0.18
MET 6	6.5±0.61
MET 7	6.8±0.38
MET 8	6.4±0.24

*Average of three observations (n=3). *All the values are expressed as mean ± SD.

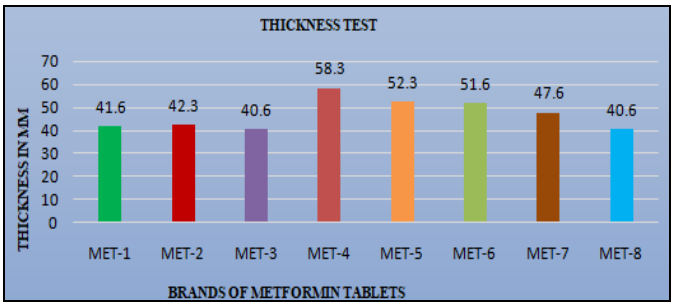

FIG. 1: GRAPHICAL REPRESENTATION 0F THICKNESS

Hardness Test:

TABLE 4: HARDNESS (KG/CM^2) OF DIFFERENT BRANDS

Brand	(Kg/cm^2)*
MET 1	17.0±0.29
MET 2	13.8±0.41
MET 3	18.3±0.41
MET 4	16.09±0.41
MET 5	16.2±0.29
MET 6	16.9±0.45
MET 7	16.43±0.24
MET 8	12.83±0.21

*Average of three observations (n=3). *All the values are expressed as mean ± SD.

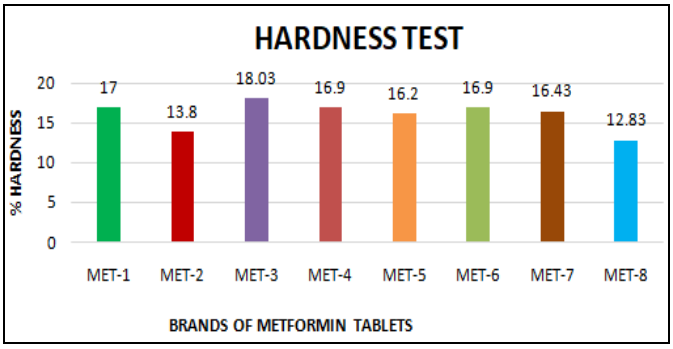

FIG. 2: GRAPHICAL REPRESENTATION OF HARDNESS TEST

Friability Test: Friability values below 1% (0.32±0.62 to 0.42±0.42%) were an indication of good mechanical resistance of the tablets shown in **Table 5.**

TABLE 5: OBSERVATION FOR FRIABILITY OF DIFFERENT BRANDS

Brand	Friability (%)*
MET 1	0.27±0.34
MET 2	0.91±0.41
MET 3	0.61±0.36
MET 4	0.23±0.23
MET 5	0.31±0.21
MET 6	0.39±0.45
MET 7	0.073±0.24
MET 8	0.92±0.42

*Average of three observations (n=3). *All the values are expressed as mean ± SD.

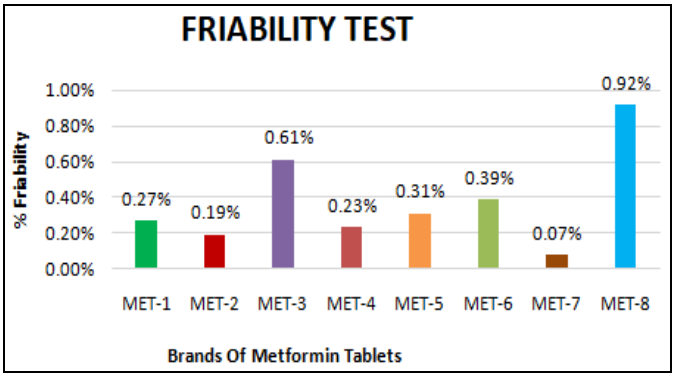

FIG. 3: GRAPHICAL REPRESENTATION OF PERCENTAGE FRIABILITY

Weight Variation Test: The experiments were done with three different brands of metformin hydrochloride.

After the test, it was determined that all the tablets of each brand passed the test of weight variation with not more than ± 5% deviation for tablets above 250 mg (as per IP/USP)

TABLE 6: OBSERVATION FOR WEIGHT VARIATION OF DIFFERENT BRANDS

	% Weight Variation							
Tablet No.	**MET 1**	**MET2**	**MET 3**	**MET 4**	**MET 5**	**MET6**	**MET7**	**MET 8**
T1	-2.7%	4.58%	-3.14%	0%	4.76%	3.48%	-0.29%	0.84%
T2	-2.7%	2.67%	3.846%	0%	-1.58%	-2.84%	-0.29%	0.84%
T3	-2.7%	-1.15%	-3.14%	1.56%	4.76%	-2.84%	-0.29%	-0.84%
T4	2.7%	-1.14%	-1.39%	1.56%	0%	-1.26%	1.17%	0.84%
T5	0.9%	-3.05%	-4.89%	1.56%	1.58%	0.31%	1.17%	-0.84%
T6	0.90%	-1.14%	0.349%	1.56%	0%	0.31%	-0.29%	-0.84%
T7	0.90%	0.76%	-1.39%	1.56%	0%	-2.84%	1.17%	0.84%
T8	-0.90%	-3.05%	2.09%	0%	0%	-1.26%	-0.29%	2.52%
T9	0.90%	2.67%	3.84%	1.56%	0%	3.48%	1.17%	0.84%
T10	0.90%	0.70%	0.349%	4.68%	1.58%	1.898%	-0.29%	2.52%
T11	0.90%	0.70%	0.349%	0%	3.170%	-1.26%	-0.29%	0.84%
T12	0.90%	2.671%	0.349%	3.12%	-3.17%	-1.26%	-0.29%	0.84%
T13	-0.90%	2.671%	0.349%	1.56%	0%	0.31%	-0.29%	0.84%
T14	-0.90%	2.671%	-1.39%	3.12%	0%	0.31%	-0.29%	2.52%
T15	-0.90%	0.70%	0.349%	3.12%	-1.58%	-2.84%	1.17%	0.84%
T16	-0.90%	0.70%	2.097%	0%	3.170%	1.898%	-0.29%	0.84%
T17	-0.90%	0.70%	2.097%	3.12%	-1.58%	-1.26%	-0.29%	2.52%
T18	2.70%	2.671%	2.097%	0%	1.58%	0.31%	-0.29%	2.52%
T19	0.90%	2.671%	2.097%	1.56%	1.58%	1.89%	1.17%	0.84%
T20	0.90%	2.671%	2.097%	0%	1.58%	4.74%	1.17%	-0.84%

*Average of three observations (n=3). *All the values are expressed as mean ± SD.

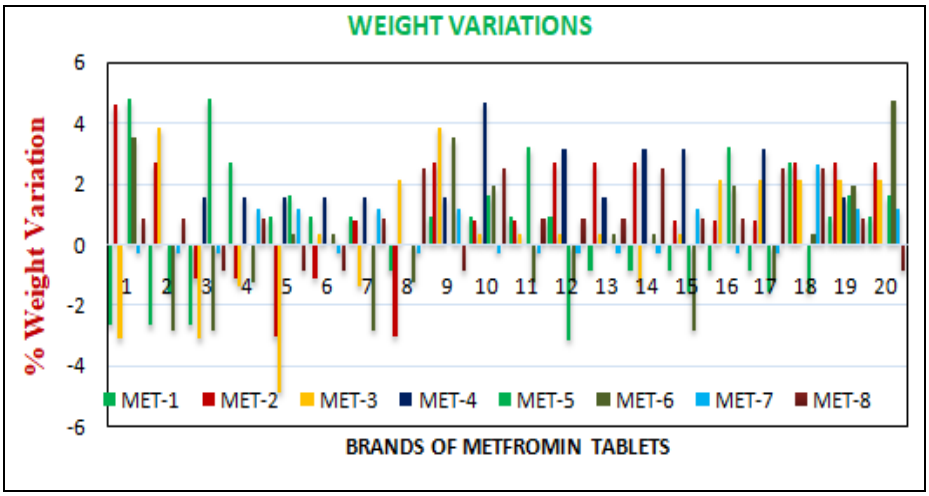

FIG. 4: GRAPHICAL REPRESENTATION OF PERCENTAGE OF WEIGHT VARIATION

Disintegration Test: All eight brands of metformin tablets are film coated. The disintegration time for a film coated tablet is 30 minutes.

TABLE 7: DISINTEGRATION TIME (MIN) OF DIFFERENT BRANDS

Brand	Disintegration time (min)*
MET-1	6.49±0.12
MET-2	15.15±0.41
MET-3	14.23±0.41
MET-4	9.68±0.41
MET-5	4.66±0.29
MET-6	3.67±0.45
MET-7	2.96±0.24
MET-8	2.88±0.21

*Average of three observations (n=3). *All the values are expressed as mean ± SD

All 8 brand tablets disintegrated within 30 minutes without showing much disparity.

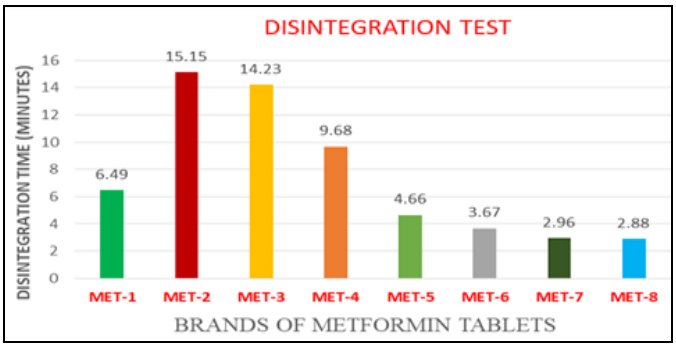

FIG. 5: GRAPHICAL REPRESENTATION OF DISINTEGRATION TIME

Dissolution Test:

TABLE 8: OBSERVATION FOR % DRUG RELEASE OF DIFFERENT BRANDS

	% Drug release							
Time (Min.)	**MET1**	**MET-2**	**MET-3**	**MET-4**	**MET-5**	**MET-6**	**MET-7**	**MET-8**
5 min	28.72±0.4	33.84±0.52	30.14±0.42	32.18±0.21	29.82±0.63	27.77±0.12	25.22±0.62	22.75±0.27
10 min	41.40±0.6	39.98±0.33	49.06±0.39	44.92±0.50	40.52±0.72	35.75±0.12	35.88±0.46	33.00±0.28
15 min	61.20±0.3	55.98±0.60	68.04±0.42	67.04±0.12	50.00±0.42	45.55±0.12	46.55±0.12	44.25±0.42
30 min	84.60±0.4	73.21 ±0.28	85.07±0.44	82.16±0.22	66.60±0.36	65.50±0.12	52.55±0.33	49.88±0.32
45 min	91.16±0.2	84.30±0.29	92.12±0.12	86.08±0.19	70.70±0.44	78.33±0.12	60.00±0.52	58.12±0.82
60 min	99.92±0.3	98.20±0.30	97.05±0.28	100.92±0.72	98.79±0.12	92.45±0.12	97.77±0.36	97.21±0.41

*Average of three observations (n=3). *All the values are expressed as mean ± SD.

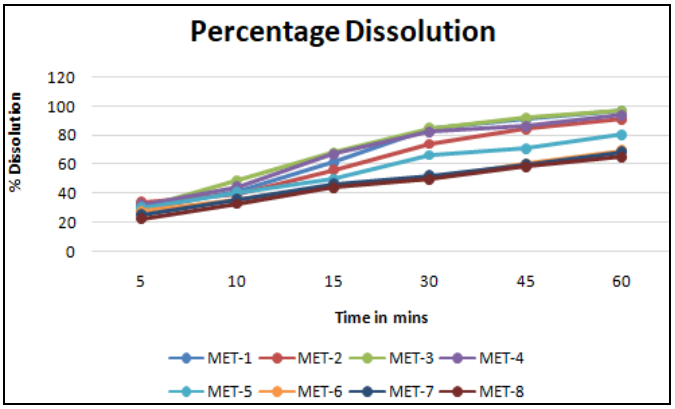

FIG. 6: PERCENTAGE OF DRUG DISSOLVES VS. TIME

Assay of Metformin Hydrochloride Tablets: The amounts of drug content for all 8 brands were calculated. The drug content of the individual tablets should fall within specific limits in terms of percentage of deviation from the mean (85% to 115% of the label claim). The assay determined that the potency of all 8 brands was within 94.66±0.29 to 100.21±0.41. All brands are within the official limit.

TABLE 9: OBSERVATION FOR DRUG CONTENT OF DIFFERENT BRANDS

Brand	Potency
MET-1	97.60±0.12
MET-2	98.21±0.41
MET-3	99.54±0.41
MET-4	100.21±0.41
MET-5	94.66±0.29
MET-6	97.67±0.45
MET-7	98.96±0.24
MET-8	97.88±0.21

*Average of three observations (n=3). *All the values are expressed as mean ± SD.

DISCUSSION: The objective of this research was to evaluate and analyse the quality and standard of various brands of metformin hydrochloride (HCl) and to compare them with the Jan Aushadhi brand (MET-3) available at Jan Aushadhi Kendra. It has been observed that in numerous countries, individuals suffer not due to diseases but because they are unable to afford the cost of medication for their illnesses. Therefore, this study aimed to dispel the misconception of many individuals that branded drugs are more effective than generic drugs. Eight brands of metformin tablets (500mg) were selected and examined comparatively for their physical and chemical properties as per official standards.

The physiochemical equivalence of all tablet brands was analyzed using both official and unofficial benchmarks, including size, shape, weight uniformity, fragility, hardness, disintegration, assay, and dissolution rate. In comparison to the generic MET-3 drug available at Jan Aushadhi Kendra, the other seven brands of metformin hydrochloride tablets met all official I.P. requirements. It was concluded that the MET-3 generic drug of metformin, which is priced nearly 70% lower than the other brands, is similar to the other seven metformin hydrochloride brands available in Hyderabad and satisfies I.P. standards for quality control analysis, making it interchangeable.

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CONFLICTS OF INTEREST: None

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