

Quality of Aspirin

By Lester Hankin

In 1983 retail sales of aspirin (acetylsalicylic acid) in the United States were \$726 million or 1.4% of the total sales of all prescription and non-prescription drugs and toiletries (5). Although acetylsalicylic acid was first prepared in 1859, it was introduced in 1899 under the name aspirin as a therapeutic agent for mild aches and pains, and as an analgesic, antipyretic, and anti-inflammatory drug (1).

In non-prescription aspirin products acetylsalicylic acid may be the only ingredient, or other active ingredients may be added to enhance pain-relieving capabilities. These added active materials are usually caffeine, acetaminophen, or salicylamide, alone or in combination. Some aspirin products contain an alkaline buffer to increase the rate of dissolution, but there is no evidence that buffered aspirin provides a more rapid onset or greater degree of pain relief than unbuffered aspirin (2).

Coated tablets do not dissolve until they reach the more alkaline pH of the small intestine, preventing gastric distress associated with dissolution in the stomach (2). Time-release products are used to slow dissolution and to prolong the analgesic action (2). Acetaminophen and salicylamide are other analgesic materials with essentially the same effect as aspirin (2). Caffeine is a stimulant and diuretic (3).

Standards for medications are defined by the United States Pharmacopeia (USP) (6). Aspirin tablets must contain not less than 95 percent and not more than 105 percent of the labeled amount of $C_9H_8O_4$ (acetylsalicylic acid). The same percentage applies for $C_8H_9NO_2$ (acetaminophen).

If more than 0.3 milligrams of non-aspirin salicylates per 100 grams of aspirin are found in a non-buffered product, excessive deterioration since manufacture has occurred. If the product is buffered, 3.0 milligrams of non-aspirin salicylates indicates excessive deterioration.

The USP also defines standards for variation in weight among non-coated tablets, capsules, and powders. For non-coated tablets the weight of an individual tablet should not vary more than 10 percent from the average of 20 tablets if the average weight is 130 mg or less, 7-1/2 percent if the average weight is from 130 to 324 mg, and 5 percent if the average weight is more than 324 mg. The weight requirement for capsules is met if each of the individual weights is within 90 to 110 percent of the average weight of 20 capsules. For powders the weight of an individual container or packet should be within 90 to 95 percent of the

average weight of 10 packets; 90 percent if the labeled amount is more than 60 grams or less and 95 percent if the labeled amount is more than 60 but less than 150 grams. Coated tablets are exempt from the tolerance of weight.

This Bulletin reports on the chemical analysis of 68 products containing aspirin alone or aspirin in combination with other active ingredients.

METHODS

Sixty-eight samples of aspirin tablets, capsules, and powders were collected in June 1984 at drug and food stores by inspectors of the Drug Division of the Connecticut Department of Consumer Protection. Acetylsalicylic acid (aspirin), acetaminophen, caffeine, and salicylamide were analyzed by wet chemical methods and high-performance liquid-chromatography (HPLC) as described in the USP (6) except that for the HPLC acetonitrile was added to the acetic acid-methanol solvent (4). Variation in weight among individual tablets, capsules, and powders was determined as described in the USP (6).

RESULTS AND DISCUSSION

The chemical analyses of the aspirin products are shown in Table 1. In the Table, the brand name and type is followed by the name of the manufacturer or distributor and the guaranteed amount and type of active ingredients. The percentage of active ingredient found by analysis follows.

Thirty-six different brands from 31 manufacturers or distributors are represented. In all, 58 were tablets, including 14 buffered and seven coated. Eight were capsules, including four buffered. Also included were two powders.

Fifty-four products contained only aspirin as the active ingredient, six contained caffeine in addition to aspirin, and six others contained both caffeine and acetaminophen in addition to aspirin. Two samples contained salicylamide and caffeine in addition to aspirin.

No samples were deficient in aspirin. The percentage of the guarantee ranged from 96 to 105 percent with an average of 100 percent. All samples containing acetaminophen were within the prescribed tolerance and averaged 99 percent of guarantee with a range from 96 to 104 percent. The average percentage of caffeine was 101 percent of guarantee with a range from 95 to 111 percent. The tolerance for caffeine in combination with aspirin is 90 to 110 percent of guarantee. One sample

contained 111 percent of the guarantee, but was sufficiently close to be acceptable. Samples declaring salicylamide were found to contain the guaranteed amount.

All samples were within USP specified variation in weight for individual tablets, capsules, and powders. The expiration date for a few products already had passed when the samples were collected and some passed during our analysis. No samples, however, contained an excess of non-aspirin salicylates, which indicates that little deterioration had occurred.

The aspirin in each product, excluding formulations for children (samples 11, 54, and 61), ranged from 227 to 650 milligrams (mg); acetaminophen from 194 to 250 mg; and caffeine from 15 to 65 mg. The 15 samples labeled as "extra, maximum, or super strength" and "arthritis formula" averaged about 34 percent more aspirin than the 48 products labeled only as aspirin. In two cases, however, "extra strength" products contained one-quarter less aspirin than ordinary products of the same manufacturer, but other ingredients were added to enhance pain-relieving capability; examples are samples 20 and 23 and 62 and 64.

SUMMARY

Sixty-eight aspirin tablets, capsules, or powders representing 36 different brands and 31 manufacturers or distributors were tested for amount of active ingredient. Active ingredients included aspirin, acetaminophen, caffeine, and salicylamide.

All samples met United States Pharmacopeia specifications for aspirin and acetaminophen. All samples were within weight tolerances for individual tablets, capsules, or powders.

ACKNOWLEDGMENTS

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TABLE 1. ANALYSIS OF ASPIRIN TABLETS, CAPSULES, AND POWDERS

NO.	BRAND AND TYPE	MFG. OR DISTRIBUTOR	ACTIVE INGREDIENTS, TYPE AND AMOUNT				FOUND, % OF GUARANTEE			
			ASPIRIN	ACETAMINOPHEN	CAFFEINE	SALICYLAMIDE	ASPIRIN	ACETAMINOPHEN	CAFFEINE	SALICYLAMIDE
1	ANACIN, TABLETS	WHITEHALL LABORATORIES	400 MG ^A		32 MG	97		100		
2	ANACIN, MAXIMUM STRENGTH, TABLETS	WHITEHALL LABORATORIES	500 MG		32 MG	99		99		
3	ANACIN, ARTHRITIS PAIN FORMULA, TABLETS, BUFFERED	WHITEHALL LABORATORIES	7 1/2 GRN			96				
4	ANACIN, ARTHRITIS PAIN FORMULA, COATED TABLETS	WHITEHALL LABORATORIES	500 MG			96				
5	ANACIN, CAPSULES	WHITEHALL LABORATORIES	400 MG		32 MG	102		99		
6	ANACIN, MAXIMUM STRENGTH, CAPSULES	WHITEHALL LABORATORIES	500 MG		32 MG	100		103		
7	BC, POWDERS	BLOCK DRUG	650 MG		32 MG	105		103	98	
8	BAYER, TABLETS	BAYER/STERLING DRUG	325 MG			103				
9	BAYER, MAXIMUM, TABLETS	BAYER/STERLING DRUG	500 MG			102				
10	BAYER, ARTHRITIS, TIME RELEASE, TABLETS	BAYER/STERLING DRUG	650 MG			99				
11	BAYER, CHILDREN, CHEWABLE, TABLETS	BAYER/STERLING DRUG	81 MG			97				
12	BRADLEES, TABLETS	BRADLEES/STOP & SHOP	325 MG			102				
13	BIOLINE, TABLETS	BIOLINE LABORATORIES	5 GRN			105				
14	BUFFERIN, TABLETS, BUFFERED	BRISTOL-MEYERS	324 MG			100				
15	BUFFERIN, EXTRA STRENGTH, TABLETS, BUFFERED	BRISTOL-MEYERS	500 MG			99				
16	BUFFERIN, CAPSULES, BUFFERED	BRISTOL-MEYERS	325 MG			102				
17	BUFFERIN, CAPSULES, BUFFERED	BRISTOL-MEYERS	325 MG			99				
18	BUFFERIN, EXTRA STRENGTH, CAPSULES, BUFFERED	BRISTOL-MEYERS	500 MG			96				
19	CVS, TABLETS	CVS/MELVILLE CORP.	325 MG			100				
20	CVS, TABLETS, BUFFERED	CVS/MELVILLE CORP.	5 GRN			97				
21	CVS, ADULT ANALGESIC, TABLETS	CVS/MELVILLE CORP.	400 MG		32 MG	103		105		
22	CVS, ENTERIC COATED, TABLETS	CVS/MELVILLE CORP.	325 MG			101				
23	CVS, SUPER STRENGTH, TABLETS	CVS/MELVILLE CORP.	250 MG	250 MG	65 MG	96	104	95		
24	CALDOR, TABLETS	CALDOR	5 GRN			102				
25	CALDOR, TABLETS, BUFFERED	CALDOR	5 GRN			98				
26	CAMA, ARTHRITIS STRENGTH, TABLETS, BUFFERED	DORSEY LABORATORIES	500 MG			95				
27	COSPRIN, ENTERIC RELEASE, TABLETS	BAYER/STERLING DRUG	325 MG			98				
28	ECOTRIN, SAFETY COATED, TABLETS	MENLEY & JAMES/SMITH KLINE & FRENCH	325 MG			98				
29	ECOTRIN, MAXIMUM STRENGTH, CAPSULES	MENLEY & JAMES/SMITH KLINE & FRENCH	500 MG			98				
30	EMPIRIN, TABLETS	BURROUGHS WELLCOME	325 MG			100				
31	EXCEDRIN, EXTRA STRENGTH, TABLETS	BRISTOL-MEYERS	250 MG	250 MG	65 MG	101	103	95		
32	EXCEDRIN, EXTRA STRENGTH, CAPSULES	BRISTOL-MEYERS	250 MG	250 MG	65 MG	105	96	99		
33	1ST COLONY TABLETS	ZAYRE CORP.	5 GRN			97				
34	GENERIC, TABLETS	CERTIFIED ASPIRIN	5 GRN			105				
35	GENNIN, TABLETS, BUFFERED	GENERIX DRUG CORP.	325 MG			98				
36	GENACOTE, ENTERIC COATED, TABLETS	GENERIX DRUG CORP.	325 MG			101				
37	GENPRIN, TABLETS	GENERIX DRUG CORP.	325 MG			100				
38	GENOVESE, TABLETS	GENCO DISTRIBUTORS	5 GRN			98				
39	GENOVESE, TABLETS, BUFFERED	GENCO DISTRIBUTORS	5 GRN			102				
40	GOOD HEALTH, TABLETS, BUFFERED	PENNEX PRODUCTS	5 GRN			96				
41	LILLY ASA, TABLETS	ELI LILLY	5 GRN			102				
42	K-MART, TABLETS	K-MART CORP.	5 GRN			101				
43	MEDIC, TABLETS	CMC	5 GRN			104				
44	MEDI-MART, TABLETS	MEDI-MART/STOP & SHOP	5 GRN			100				
45	MEDI-MART, TABLETS, BUFFERED	MEDI-MART/STOP & SHOP	5 GRN			98				
46	MEDI-MART, ENTERIC COATED, TABLETS	MEDI-MART/STOP & SHOP	325 MG			104				
47	MERIT, TABLETS	HERMAN	5 GRN			103				
48	NORWICH, TABLETS	NORWICH EATON PHARMACEUTICALS	5 GRN			101				
49	PHARMACITY, TABLETS	PURITY SUPREME	325 MG			103				
50	PHARMACITY, ENTERIC COATED, TABLETS	PURITY SUPREME	325 MG			103				
51	PRESCOTT, TABLETS	PRESCOTT DRUG & CHEMICAL	5 GRN			102				
52	QUIK AID, TABLETS	LEE'S NIAGARA DRUG CORP.	5 GRN			100				
53	QUIK AID, TABLETS, BUFFERED	LEE'S NIAGARA DRUG CORP.	5 GRN			103				
54	QUIK AID, CHILDREN, TABLETS	LEE'S NIAGARA DRUG CORP.	1 1/4 GRN			101				
55	RITE AID, TABLETS	RITE AID CORP.	5 GRN			99				
56	RITE AID, TABLETS, BUFFERED	RITE AID CORP.	5 GRN			99				
57	RITE AID ENTERACIN, ENTERIC COATED, TABLETS	RITE AID CORP.	325 MG			97				
58	RITE AID, ARTHRITIC PAIN FORMULA, CAPS., BUFFERED	RITE AID CORP.	7 1/2 GRN			99				
59	RITE AID, ANALGESIC, TABLETS	RITE AID CORP.	400 MG		32 MG	101		108		
60	RITE AID APC, TABLETS	RITE AID CORP.	3 1/2 GRN	2 1/2 GRN	1/2 GRN	100	98	111		
61	ST. JOSEPHS, CHILDREN, TABLETS	PLOUGH	1 1/4 GRN			101				
62	SHOP RITE, TABLETS	WAKEFERN FOOD CORP.	325 MG			101				
63	SHOP RITE, TABLETS, BUFFERED	WAKEFERN FOOD CORP.	324 MG			100				
64	SHOP RITE, SUPER STRENGTH, TABLETS	WAKEFERN FOOD CORP.	250 MG	250 MG	65 MG	97	97	99		
65	STANBACK, POWDERS	STANBACK	650 MG		15 MG	103		99	102	
66	TOPCO, TABLETS	TOPCO ASSOCIATES	5 GRN		200 MG	100	98	101		
67	VANQUISH, TABLETS, BUFFERED	GLENBROOK/STERLING DRUG	227 MG	194 MG	33 MG	101				
68	WEST & WARD, TABLETS	CONN. VETERANS HOME	325 MG			97				

^A GRAINS [GRN] OR MILLIGRAMS [MG] ARE SHOWN AS ON LABEL; 81 MG EQUALS 1-1/4 GRN, 227 MG EQUALS 3-1/2 GRN, 324 MG EQUALS 5 GRN, AND 486 MG EQUALS 7-1/2 GRN.