

*The
Connecticut
Agricultural
Experiment
Station,
New Haven*

Analysis of
Products Containing
Acetaminophen

BY LESTER HANKIN

Bulletin 841

October 1986

A cooperative study by The Connecticut
Agricultural Experiment Station and
the Drug Division of the Connecticut
Department of Consumer Protection

Analysis of Products Containing Acetaminophen

BY LESTER HANKIN

Acetaminophen ($C_8H_9NO_2$) is formulated into tablets, capsules, and elixirs and sold as an analgesic (reliever of pain) and antipyretic (allayer or preventer of fever) (2,3,4).

Although acetaminophen was first synthesized at Johns Hopkins University in 1877 and first used in medicine in 1893, its use did not become extensive until 1950 when it was marketed in the United States as a substitute for phenacetin in an analgesic mixture. From 1950 to 1955 acetaminophen was available only by prescription, but since 1955 it has been sold without prescription (1).

Acetaminophen produces analgesia by elevation of the pain threshold and antipyresis through action of the hypothalamic heat-regulating center (4). One reason for its popularity is that it provides pain relief and does not cause some of the adverse effects experienced by some people who take aspirin (1,4).

Standards for medications are stated in the United States Pharmacopeia (USP) (4). Acetaminophen tablets, capsules, and elixirs must contain not less than 95 percent and not more than 105 percent of the labeled amount of acetaminophen. Caplets are tablets coated purportedly to make them easier to swallow.

The USP also states standards for variation in weight among non-coated tablets and capsules. The range in weight among all non-coated tablets and capsules tested must be between 85 and 115 percent of the average. Coated tablets or caplets are exempt from the criteria for variation in weight.

Because elixirs are solutions, no criteria for variation in weight are imposed. Ethyl alcohol may be used in elixirs, but its content must be between 6.5 and 10.5 percent.

Extra or maximum strength tablets and capsules usually guarantee 500 milligrams of acetaminophen per dose. This is about 33 percent more acetaminophen than the 325 milligrams in regular strength tablets. Products for small children generally guarantee 80 milligrams per half teaspoon or 0.8 milliliters or 160 milligrams per dose in products for older children.

This Bulletin reports the analysis of 61 products containing acetaminophen.

METHODS

The 61 samples containing acetaminophen were collected on September 16, 1985 by inspectors of the Drug Division of the Connecticut Department of Consumer Protection. Acetaminophen and variation in weight were determined by methods described in the USP (5).

Ethyl alcohol was determined by gas chromatography. The sample was diluted and injected into a Varian Aerograph gas chromatograph equipped with a thermal conductivity detector and a stainless steel column packed with Poropak QS (80-100 mesh). Injection temperature was 200C and column temperature 150C.

RESULTS

The chemical analyses of the 61 products containing acetaminophen are reported in Table 1. In the Table, the brand name and type of product are followed by the name of the manufacturer or distributor. The guaranteed amount of acetaminophen is followed by the percentage of acetaminophen found by analysis.

Twenty-five different brands from 19 manufacturers or distributors are represented in Table 1. In all, 35 were tablets, 11 were capsules, 12 were elixirs, and three were caplets. Included were 18 products designated for children, from infants to juniors.

No samples were deficient in acetaminophen. The percentage of the guaranteed amount ranged from 96 to 106 percent with an average of 101 percent. Although one sample was 106 percent of guarantee, and thus not within USP prescribed limits, it was sufficiently close to be acceptable.

All samples were within USP specified variation in weight for individual units.

Seven of the 12 elixirs contained ethyl alcohol as stated on the label. The seven elixirs with alcohol are marked with an asterisk (*) in Table 1. All were within the USP limits of 6.5 to 10.5 percent. The average percentage of alcohol was 8.6 percent with a range from 7.3 to 10.4.

SUMMARY

Sixty-one products containing acetaminophen (tablets, capsules, liquids) and representing 25 different brands from 19 manufacturers or distributors were tested for amount of acetaminophen. All samples met United States Pharmacopeia specifications for amount of active ingredient and were within weight

tolerance for individual tablets and capsules. Elixirs labeled as containing ethyl alcohol averaged 8.6 percent and were within United States Pharmacopeia Standards.

ACKNOWLEDGMENTS

Analyses were carried out by Joseph Mongillo and Dennis Migneault. Inspectors Michael Galasyn and Francis Pallazoni, under the direction of Division Chief William Ward, of the Drug Division of the Connecticut Department of Consumer Protection collected the samples.

REFERENCES

1. Ameer, B. and D.J. Greenblatt. 1977. Acetaminophen. *Annals of Internal Medicine* 87:202-209.
2. *Analgetics*. 1965. Volume 5 edited by G. deStevens, Academic Press, New York.
3. *Merck Index*. 10th edition, Merck and Co., Rahway, NJ.
4. *Physicians Desk Reference*, 39th edition, 1985. Medical Economics Co., Oradell, NJ.
5. *United States Pharmacopeia*, 21st edition, 1985. United States Pharmacopeial Convention, Rockville, MD.

Acetaminophen

5

TABLE 1--ANALYSIS OF TABLETS, CAPSULES AND ELIXIRS CONTAINING ACETAMINOPHEN

Brand and type	Manufacturer or distributor	Acetaminophen guarantee	% found,
TABLETS			
Anacin 3 - Maximum Str	Whitehall Laboratories	500 mg/tab ^b	101
Anacin 3 - Childrens Chewable	Whitehall Laboratories	80 mg/tab	101
Arthritis Pain Formula	Whitehall Laboratories	500 mg/tab	102
Congesprin For Children Cold	Bristol-Myers	81 mg/tab	98
Cotylenol Childrens Chewable Cold	McNeil	80 mg/tab	105
CVS Regular Str Pain Rel	Melville Corp	325 mg/tab	99
CVS Extra Str Pain Rel	Melville Corp	500 mg/tab	98
Datril Extra Str	Bristol-Myers	500 mg/tab	103
Excedrin P.M.	Bristol-Myers	500 mg/tab	97
K-NOL Childrens Chewable	K Mart Corp	80 mg/tab	103
K-NOL	K Mart Corp	325 mg/tab	101
K-NOL Extra Str	K Mart Corp	500 mg/tab	102
Medi-Mart Pain Rel	Medi Mart/Stop & Shop	325 mg/tab	102
Medi-Mart Extra Str Pain Rel	Medi Mart/Stop & Shop	500 mg/tab	103
Moore Analgesic	Drug Exchange	325 mg/tab	99
No Frills Extra Str Pain Rel	Supermarkets General	500 mg/tab	101
Panadol Maximum Str	Glenbrook Lab/Sterling	500 mg/tab	101
Panadol Childrens Chewable	Glenbrook Lab/Sterling	80 mg/tab	101
Pathmark Regular Str ^a	Supermarkets General	325 mg/tab	101
Pathmark Regular Str ^a	Supermarkets General	325 mg/tab	99
Percogesic	Richardson-Vicks	325 mg/tab	100
Pharmacy Extra Str Pain Rel	Purity Supreme	500 mg/tab	105
Rite Aid Regular Str	Rite Aid	325 mg/tab	100
Rite Aid Childrens Chewable	Rite Aid	80 mg/tab	106
St. Joseph For Children	Plough	80 mg/tab	98
Shop Rite Pain Rel	Wakefern Foods	325 mg/tab	104
Shop Rite Childrens Chewable	Wakefern Foods	80 mg/tab	100
Sinarest Three-way Sinus Relief	Pennwalt/Pharmacraft	325 mg/tab	97
Tylenol Childrens Chewable	McNeil	80 mg/tab	102
Tylenol Extra Str	McNeil	500 mg/tab	101
Tylenol Regular Str	McNeil	325 mg/tab	101
Tylenol Junior Str Swallowable	McNeil	160 mg/tab	99
T-Zone Cough/Cold	Carter Wallace	500 mg/tab	98
T-Zone Maximum Str Cough/Cold	Carter Wallace	500 mg/tab	102
Vicks Headway	Richardson Vicks	325 mg/tab	97
CAPSULES			
Anacin 3 Maximum Str	Whitehall Laboratories	500 mg/cap	101
Datril Extra Str	Bristol-Myers	500 mg/cap	103
Generic Combination Cold	Pharmacy	325 mg/cap	100
K-NOL Extra Str	K Mart Corp	500 mg/cap	100
Medi-Mart Extra Str Pain Rel	Medi Mart/Stop & Shop	500 mg/cap	101
Panadol Maximum Str	Glenbrook Lab/Sterling	500 mg/cap	101

TABLE 1--Continued

Brand and type	Manufacturer or distributor	Acetaminophen	
		guarantee	% found,
CAPSULES (CONTINUED)			
Pathmark Extra Str	Supermarkets General	500 mg/cap	97
Pharmacy Extra Str Pain Rel	Purity Supreme	500 mg/cap	99
Rite Aid Athenol Regular Str	Rite Aid	325 mg/cap	100
Shop Rite Extra Str Pain Rel	Wakefern Foods	500 mg/cap	100
Tylenol Maximum Str Sinus Medicat	McNeil	500 mg/cap	99
ELIXIRS			
Congesprin For Children*	Bristol-Myers	130 mg/5 ml	96
Cotylenol Childrens*	McNeil	160 mg/5 ml	99
K-NOL Childrens Elixir*	K Mart Corp	80 mg/1/2 tsp	102
Liquiprin	Norcliff-Thayer	80 mg/1.66 ml	103
Medi-Mart Elixir For Children*	Medi Mart/Stop & Shop	80 mg/1/2 tsp	96
Panadol Childrens Infant Drops	Glenbrook Lab/Sterling	80 mg/0.8 ml	102
Panadol Childrens Fruit Flavored	Glenbrook Lab/Sterling	80 mg/1/2 tsp	99
St. Joseph Elixir For Children*	Plough	80 mg/1/2 tsp	98
Tempra Drops For Children*	Mead Johnson	80 mg/0.8 ml	101
Tylenol Childrens Elixir	McNeil	80 mg/1/2 tsp	98
Tylenol Extra Str Adult*	McNeil	500 mg/1/2 fl oz	97
Tylenol Infant Drops	McNeil	80 mg/0.8 ml	102
CAPLETS			
Panadol Jr. For Ages 6-14	Glenbrook Lab/Sterling	160 mg/caplet	100
Pathmark Pathinol Extra Str	Supermarkets General	500 mg/caplet	103
Tylenol Extra Str	McNeil	500 mg/caplet	99

^a Both products contain the same amount of acetaminophen but other non-active ingredients differ.

^b Abbreviations: cap, capsules; fl oz, fluid ounce; Medicat, Medication; mg, milligrams; ml, milliliter; Rel, Reliever; Str., Strength; tab, tablets; tsp, teaspoon

* Indicates product contains alcohol.



The Connecticut Agricultural Experiment Station,
founded in 1875, is the first experiment station in America. It is chartered
by the General Assembly to make scientific inquiries and experiments
regarding plants and their pests, insects, soil and water, and to perform analyses for State
agencies. The laboratories of the Station are in New Haven and Windsor; its Lockwood
Farm is in Hamden. Single copies of bulletins are available free upon request to Pub-
lications; Box 1106; New Haven, Connecticut 06504.

ISSN 0097-0905