

COMPARISONS OF HEAT TREATED
CONCENTRATES*

<u>IN-VIVO HALF-LIFE</u>	
<u>MANUFACTURER</u>	<u>HALF-LIFE</u>
Cutter	10.2 HOURS
Armour	10.8 HOURS
Hyland	8.2 HOURS
Alpha	11.1 HOURS

<u>IN-VIVO RECOVERY</u>	
<u>MANUFACTURER</u>	<u>% RECOVERY</u>
Cutter	98.2% +
Armour	99.9%
Hyland	87.5%
Alpha	73%

+2%/unit/kg exactly as expected.

The data established that Koate®-HT does not have a loss of coagulant activity.

*Presented at "New Concepts in Hemophilia Treatment" Meeting of Region IX Comprehensive Hemophilia Care Program. This was held in Sacramento, California March 15-16, 1984.

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INDUSTRIES RESPONSIBILITIES

Industry has a responsibility to supply safe, pure and potent concentrates. In order to do so, the following conditions should be met.

First, a carefully screened, high quality plasma source is necessary.

In this regard Cutter is a leader in the industry with control of over 80 plasma centers throughout the country. (Please review section on Plasma Donor Screening for more detail on AIDS precautions.) All product made from Cutter has traceability to each donor of every lot of material produced. All screening for hepatitis and other contaminants is performed on a routine basis.

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Second, industry is obligated to protect plasma in transit to insure changes do not occur between collection and processing.

All Source Plasma is immediately put under tightly controlled refrigerated conditions. The material is maintained in a controlled environment beginning right after collection in the plasma center, through transportation, and while in stock at the production facilities awaiting final processing.

Third, an effective proven fractionation scheme is a must.

Cutter is a world leader in fractionation. Cutter was in the forefront of perfecting the Cohn Fractionation Method on an industry scale and as a result introduced the first albumin fraction to the marketplace in 1942. Since then Cutter has continually updated its facilities and techniques which most recently resulted in the introduction of Koate-HT into the market.

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Fourth, process controls must be maintained to insure reproducibility of the process being utilized.

Through extensive protocols, checks and balances, and state-of-the-art equipment, Cutter has been able to maintain a competent, controlled process.

Fifth, an independent quality assurance unit should be in place to audit and maintain mandated conditions whether during collection, processing, or testing.

Cutter maintains quality assurance guidelines through all production activities to ensure a safe, pure and potent product for the end user.

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