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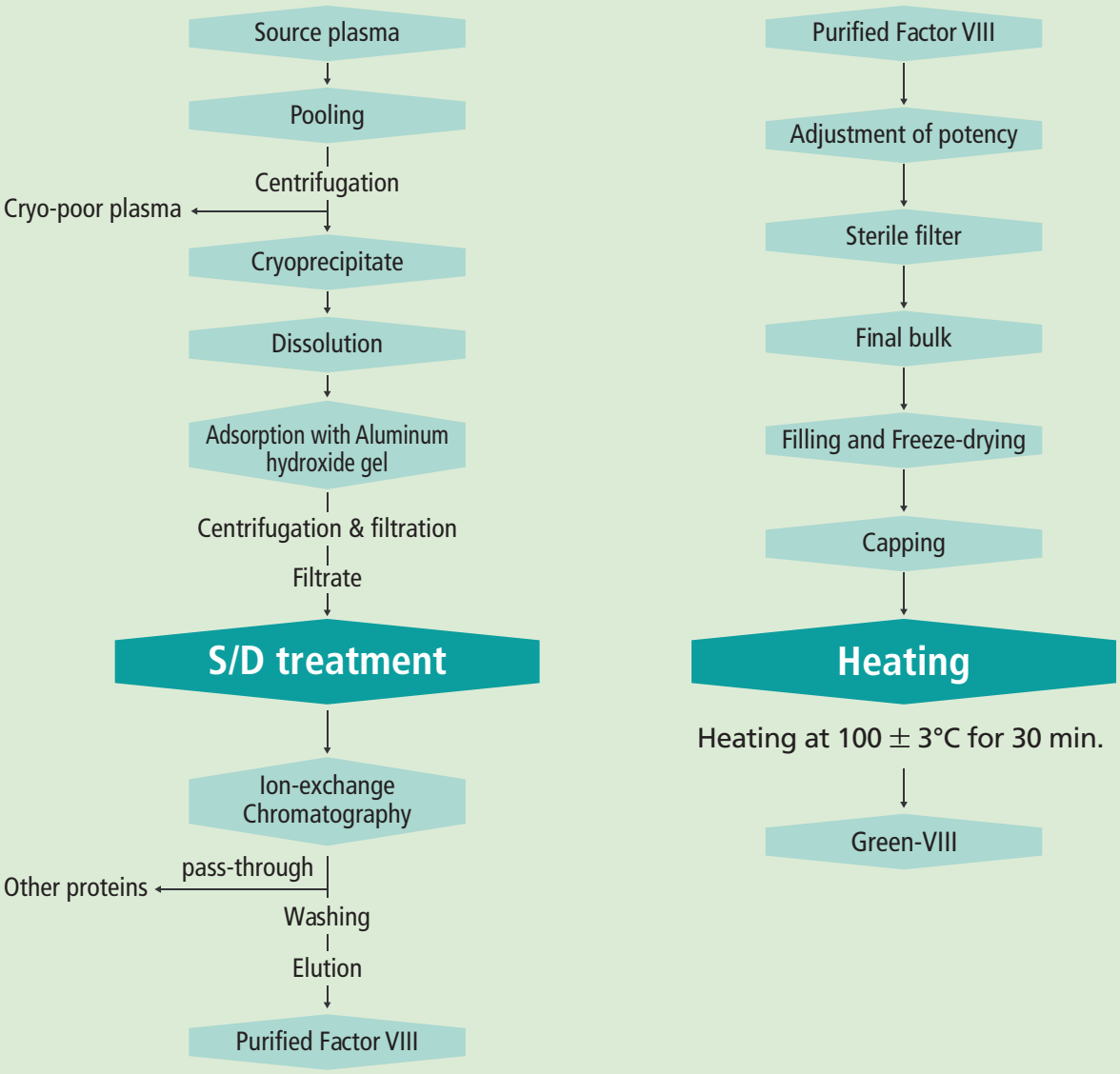
Human Coagulation Factor Ⅷ

GREEN-Ⅷ inj.

GREEN CROSS

Double virus inactivation
(S/D treatment + Heating)



Virus inactivation

SUMMARY OF RESULTS(Virus Reduction Factors)

STEP	VIRUS REDUCTION FACTOR(Log10)	
	RUN1	RUN2
Tween80/TNBP Inactivation (Solvent/Detergent Trearment)	≥5.37±0.33	≥5.63±0.38
Lyophilisation and Dry Heat	≥4.93±0.35	≥5.37±0.33

SUMMARY OF RESULTS(Virus Clearance Factors)

STEP	VIRUS CLEARANCE FACTOR(Log10)	
	RUN1	RUN2
Tween80/TNBP Inactivation (Solvent/Detergent Trearment)	≥5.50±0.29	≥6.12±0.35
Lyophilisation and Dry Heat	≥4.80±0.29	≥4.80±0.29

Description

Green-VIII inj. is a high concentrate of human anti-haemophilic factor VIII prepared from pooled plasma of healthy donors. It is colorless or lemon yellow solution when reconstituted with water for injection. It is purified by ion exchange chromatography, and TNBP & Tween 80 and Heat Treatment method is used to inactivate the infectious viruses. All the reagents used during the manufacturing process do not remain in the finished product.

Composition

Each 1 vial (250 IU) contains

Anti-haemophilic factor VIII	250 IU
Sodium citrate	29.0 mg
Calcium chloride	1.8 mg
Aminoacetic acid	90.0 mg
Sodium chloride	128.0 mg

Indication

For the treatment of hemophilia A with supplies of blood coagulation factor VIII.

Dosage and Administration

- After reconstitution, inject 250 - 2,000 IU intravenously or by drip-infusion.
- Infusion rate should not exceed 5 ml/min.
- Each dose is determined by the condition of patients.

Storage

Store below 10°C without freezing, in hermetic container.
Maximum validity : 24 months from the date of manufacture.

How supplied

250 IU/vial
500 IU/vial

Safe & Efficacy
(Clinical)

EFFICACY RESULTS:

The primary efficacy outcome measure was the "Physician's assessment of hemostatic effects" and was "Good" in all subjects.

This implies that the "good" assessment was most frequent in all the subjects when their acute bleeding episodes were evaluated according to the 4-point scale.

The efficacy rate as defined in the protocol was 90.22% for acute bleeding, 54.10% for major bleeding, and 87.80% totally.

As for the FVIII consumption, the total number of infusions per acute bleeding episodes was 967, and the average number of infusions per acute bleeding episode was 1.14.

The average amount of FVIII consumed each month did not vary much.
There were 112 infusions for 61 major bleeding episodes, showing average 1.84 infusion per episode.

Among 849 acute bleeding episodes, outcomes from 20 episodes were assessed as "excellent" and outcome from 735 episodes were assessed "good".

151 recovery tests were done for 51 subjects. 50 subjects participated in test 3 times and 1 subject participated only once. Outcomes from these tests were 5 "excellent" assessments and 136 "good" assessments.

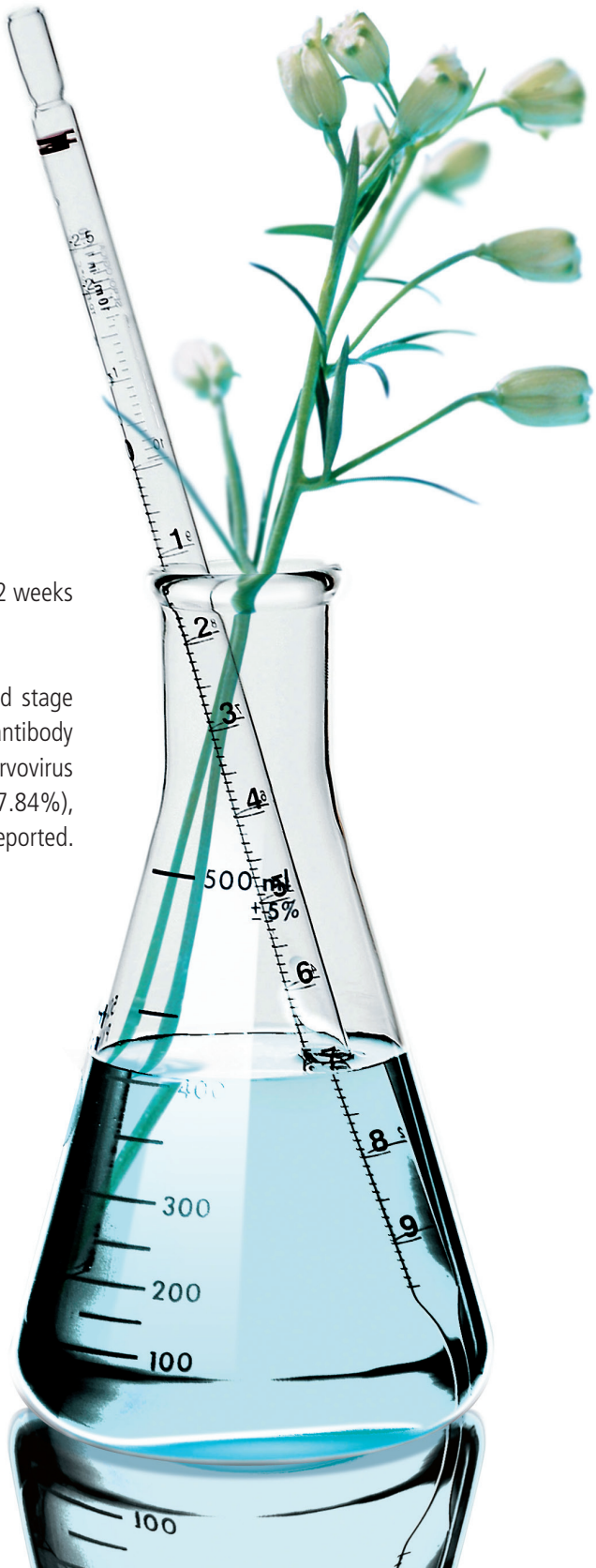
diseases

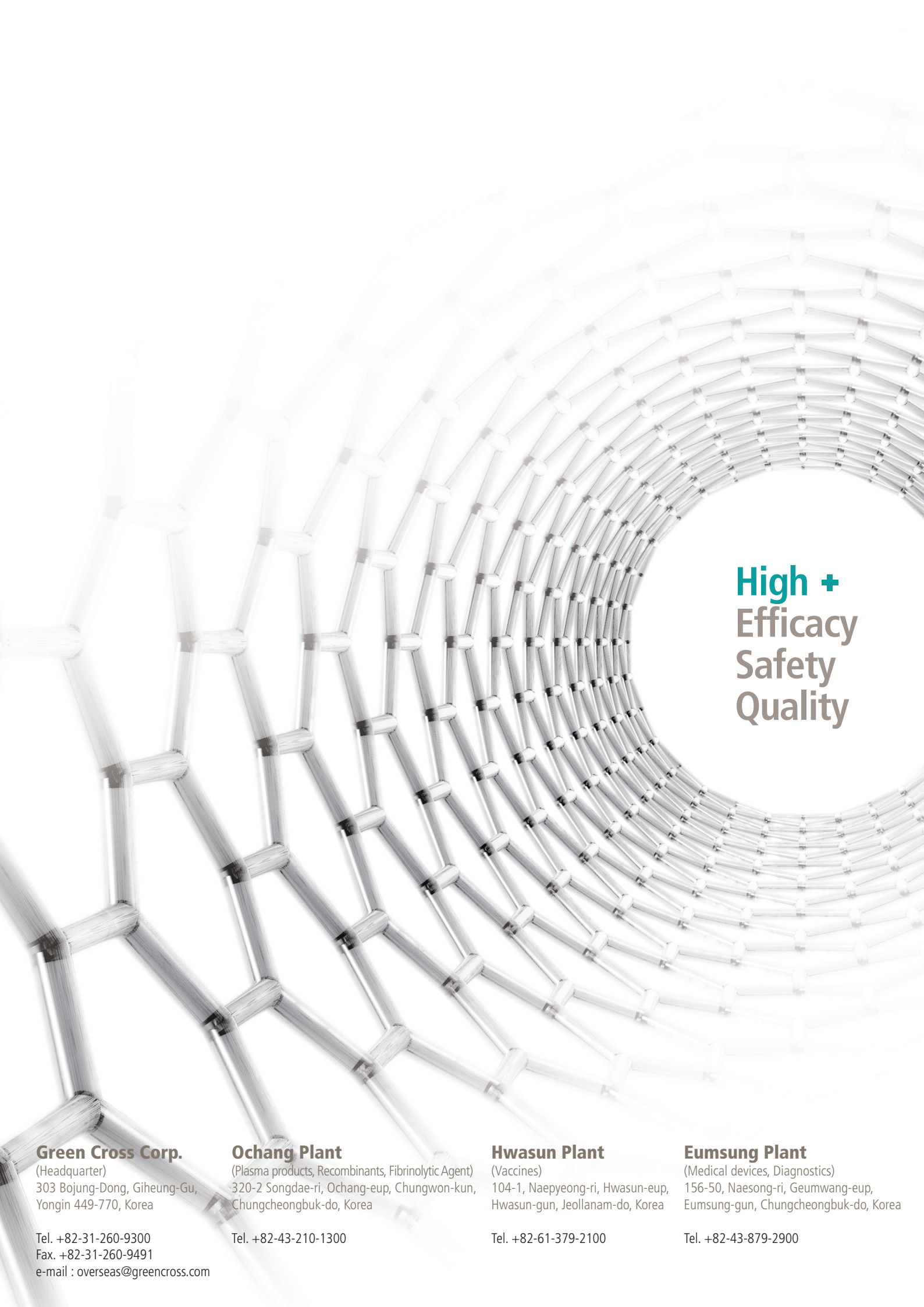
Total Health Care
GREEN CROSS

SAFETY RESULTS:

All adverse events were collected from the time of informed consent to 2 weeks after the last treatment.

Totally, 27 adverse events in 21 subjects were reported in stage I and stage II. The most frequent adverse drug reaction was "Anti factor VIII antibody positive"(9pts, 17.65%). Eosinophil count increased (6pts, 11.76%), Parvovirus B19 scrology positive (5pts, 9.80%), Hepatic enzyme increased (4pts, 7.84%), Pyrexia, Proteinuria and Hemoturia (respectively 1pt, 1.96%) were also reported.





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