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The Comparison of Quality between Domestic and Imported 5% Albumin Products

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The quality of three domestic (A~C) and one imported (D) human serum albumin product (5% formulations) was compared in terms of albumin content and contaminants.

The purity and content matched to the manufacturer's indicted values (mean value of three lots) were 99.4% and 101.1% for product A, 99.1% and 98.1% for product B, 97.6% and 96.4% for product C, and 97.4% and 96.5% for product D. Differences were observed between preparations in aluminum (Al), β -D-glucan, α 1-acid glycoprotein (α 1-AG) and haptoglobin content among the measured items. A very small amount of

Al, which may cause toxicity through accumulation in the body, was detected in product C, whereas a small amount of α 1-AG, which may show an immunosuppressive effect, was detected in product D. However, the influence of these contaminants on physiological condition appeared to be small. Because the β -D-glucan content in product D was high, it may influence the diagnosis of deep mycosis. Furthermore, haptoglobin content in product D was high enough to induce an anaphylactic reaction in haptoglobin-deficient patients with haptoglobin antibody.

These findings suggest that differences were observed in property comparisons between domestic and imported products; particularly, domestic preparations were preferred for haptoglobin-deficient patients. In addition, the slight differences present between the domestic products may serve as a reference in selecting formulations when the user has detailed information on each of the characteristics.

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