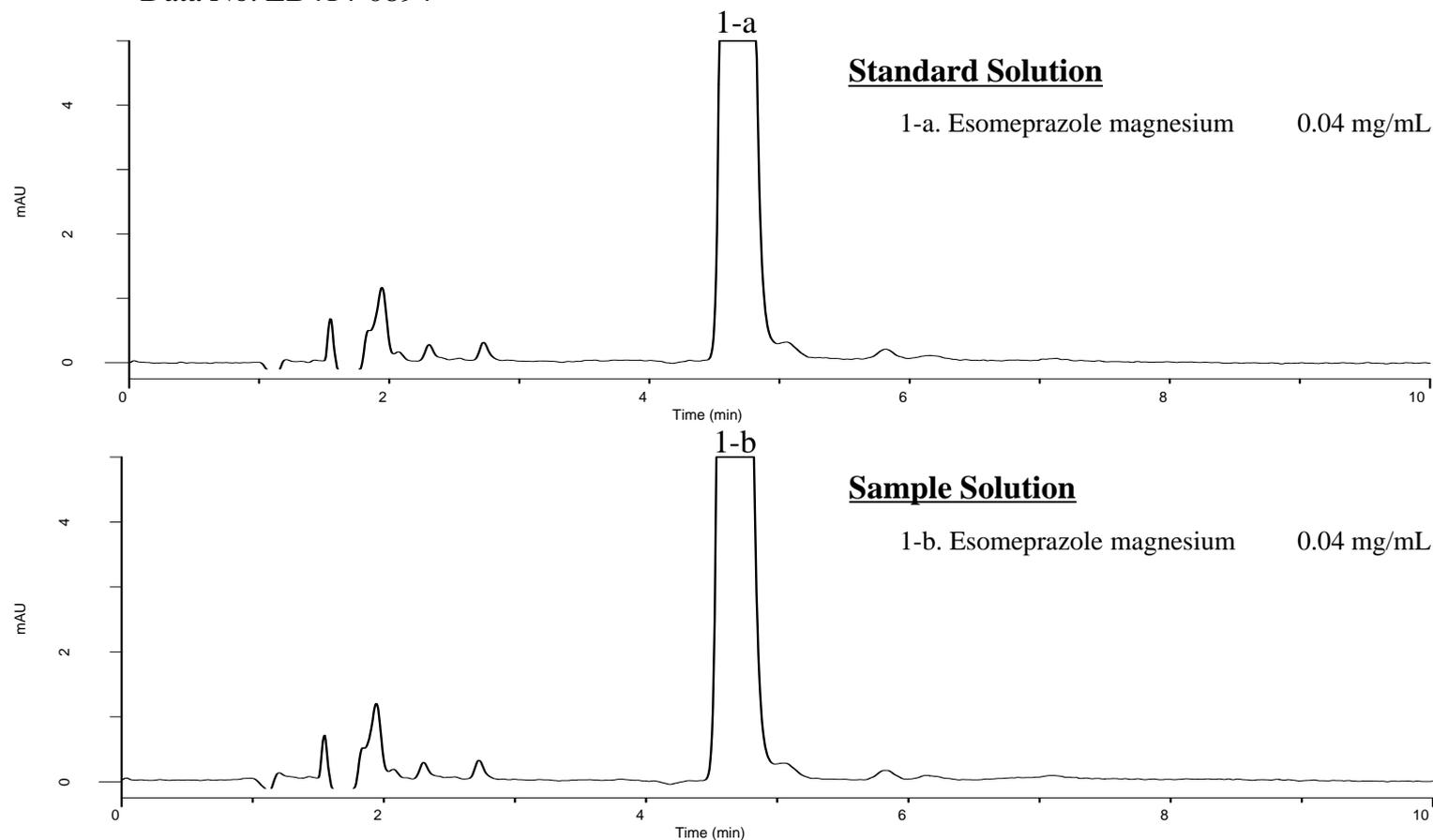


Analysis of Esomeprazole magnesium

(Under the Condition of USP 38-NF33,
Esomeprazole magnesium Extended-release Tablets)

Data No. LB414-0894



Conditions

Column : InertSustain C18
(5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-07345
Eluent : A) CH₃CN
B) Buffer*
C) H₂O
A/B/C = * *

Flow Rate : 1.0 mL/min

Detection : UV 302 nm

Injection Vol. : 20 μ L

Sample : Esomeprazole magnesium Delayed release capsules

*Prepare a pH 7.3 phosphate buffer by mixing 10.5 mL of 1.0 M monobasic sodium phosphate buffer and 60 mL of 0.5 M dibasic sodium phosphate buffer, and diluting with water to 1000 mL.

**Mix 350 mL of acetonitrile and 500 mL of the Buffer.

Dilute with water to 1000 mL.

Analyte:

1. Esomeprazole magnesium

RSD of the
1-a area (%) (n = 6) : 0.04 (\leq 2.0)