



NISSUI PHARMACEUTICAL CO., LTD.

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Certificate of Analysis

Product Compact Dry ETB (1400) (Code 54055)

Lot No 306301

Expiry Date 2024 . 4

	Specification	Results
Appearance	Pink - Orange No particular matters.	Pass
Loss of drying	Less than 10.0%	7 . 5 %
Aseptic Test	Gamma irradiation over 16kGy	Pass
pH	7.1 ~ 7.7	7 . 6

Evaluation of Performance Specification

- ① When following test strains are inoculated to incubate at 37°C for 22 - 26 hours,
good growths and color developments should be observed.

<u>Test strain</u>	<u>Growth</u>	<u>Color development</u>
<i>Citrobacter freundii</i> ATCC 8090	+	red-purple
<i>Escherichia coli</i> ATCC 8739	+	red-purple
<i>Klebsiella oxytoca</i> ATCC 13182	+	red-purple
<i>Salmonella</i> Typhimurium ATCC 13311	+	red-purple
<i>Proteus mirabilis</i> ATCC 29906	+	red-purple

- ② When following test strains are inoculated to incubate at 37°C for 22 - 26 hours,
growths should be inhibited.

<u>Test strain</u>
<i>Bacillus subtilis</i> ATCC 6633
<i>Staphylococcus aureus</i> ATCC 6538

Judge: Acceptable quality.

Certificate issue date : 2023 . 1 . 19

Signed (QC Manager)

Emiko Takahashi