

PRODUCT: ENOXAPARIN SODIUM

ITEMS	SPECIFICATIONS
CHARACTERISTICS	White powder, moderately hygroscopic
SOLUBILITY	Freely soluble in water
IDENTIFICATION	a) ^{13}C -NMR and ^1H -NMR b) Anti-FXa/ Anti-FIIa 3.3~5.3 c) The mass-average relative molecular mass ranges between 3800 and 5000 The mass percentage of chains lower than 2000 ranges between 12.0% ~ 20.0% The mass percentage of chains between 2000 and 8000 ranges between 68.0%~82.0% d) Positive sodium reaction
APPEARANCE OF SOLUTION	a) The solution is clear and not more intensely coloured than intensity 6 of the range of reference solutions of the most appropriate colour b) The solution is not more opalescent than suspension I.
PH	6.2~7.7
SPECIFIC ABSORBANCE	The specific absorbance at 231 nm is 14.0~20.0 (dried substance)
BENZYL ALCOHOL	$\leq 0.1\%$

SODIUM	11.3%~13.5%
NITROGEN	1.5% ~ 2.5%
HEAVY METALS	≤30 ppm
LOSS ON DRYING	≤10.0%
SO₄²⁻/COO⁻	≥1.8
BACTERIAL ENDOTOXINS	≤0.01 IU/Anti-FXa IU of LMMH
MICROBIOLOGICAL EXAMINATION a) Total viable aerobic Count Fungi/yeasts b) Specific micro organisms <ul style="list-style-type: none"> • Escherichia coli • Salmonella 	≤100CFU/g ≤10 CFU/g Negative Negative
SOLVENTS ➤ Ethanol ➤ DMF	≤5000 ppm ≤880 ppm
IMPURITY (NMR)	The sample should be free from over-sulfated chondroitin sulphate (inhouse specification)
Anti-factor Xa activity (dried substance)	90.0 ~ 125.0 IU
Anti-factor IIa activity (dried substance)	20.0 ~ 35.0 IU/mg