

Certificate of Analysis

Product Name	Hydrocortisone Sodium Succinate For Injection sterile powder (5.71% buffered) usp31	Specification	1.418 kg of this dry products Equivalent to 1 kg of hydrocortisone
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Item	Standard	Result
Description	White or almost white powder	white powder
Identification	A : The infrared absorption spectrum is concordant with the reference spectrum of hydrocortisone sodium succinate	comply with the standard
	B : According to the method for thin-layer chromatography, the principal spot in the chromatogram obtained with solution(1) is similar in the position to the spot in the chromatogram obtained with solution(2)	comply with the standard
Acidity and Alkalinity	6.5 ~ 8.0	7.6
Related substances	Free hydrocortisone should be not more than 7.0%	0.9%

	Other related substances should be not more than 2.0%	1.2%
Loss on drying	2.0%	0.9%
Bacterial Endotoxin	comply with the standard	comply with the standard
Sterilization	comply with the standard	comply with the standard
Assay	95.0% ~ 105.0%	99.4%