辰 欣 药 业 股 份 有 限 公 司

Cisen Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Product: Fludarabine Phosphate for Injection	Report No.: 0000211089
Batch No.: 210405	Date of Manufacture: 04/2021
Strength: 50mg	Date of Expiry: 04/2024
Package: 1 vial/box	Batch Quantity: 1880 Vial

Reference Standard: Chp2020

Items	Acceptance criteria	Results	Conclusions
Description	A white mass or power.	A white mass or power.	Conform
Identification	Meet the requirement	Conform	Conform
Acidity	pH 7.2-8.2	7.6	Conform
Clarity and color of solution	Meet the requirement	Conform	Conform
Related substances I	impurity I NMT 1.0%(corrected)	0.41%	Conform
Related substances I	impurity II NMT 0.2%(corrected)	ND	Conform
Related substances I	Impurity (the relative retention time is about 0.42) NMT 0.4% (corrected)	ND	Conform
Related substances I	any other Impurity NMT 0.2%	0.075%	Conform
Related substances II	impurity III NMT 0.2%(corrected)	0.014%	Conform
Related substances II	Impurity (the relative retention time is about 1.9) NMT 0.2%(corrected)	0.0041%	Conform
Related substances II	any other impurity NMT 0.2%	0.027%	Conform
Total impurity	Total impurity (include Related substances I and Related substances II) NMT 2.0 (corrected)	0.55%	Conform
Water	Not more than 5.0%	2.6%	Conform

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Items	Acceptance criteria	Results	Conclusions
Bacterial endotoxin	not more than 0.1EU per mg of Fludarabine Phosphate.	Conform	Conform
Sterility	Meet the requirement	Conform	Conform
Weigh Variation	±10%	Conform	Conform
Visible particles	Meet the requirement	Conform	Conform
Particulate matter	≥10μm ≤6000 particles/vial;	Conform	Conform
Particulate matter	≥25μm ≤600 particles/vial	Conform	Conform
Assay	95.0%- 105.0%	98.6%	Conform

Conclusion: Conforms to the requirements of Chp2020

Remarks:

Approved by: Ren Zelin

Digitally signed by Guțan Ghenadie
Date: 2023.07.28 08:49:19 EEST
Reason: MoldSign Signature
Location: Moldova