



Certificate of Analysis

Inspection number Q C- C10B3- 202006007

Product name	Fluorouracil	Product Specifications	API	Product code	C10B3
Product batch	2006001H	Manufacturing date	2020.04.27	Product weight	40.11KG
Packaging specification		20kg/barrel			
Analysis date	2020.06.12	Report date	2020.06.19	Re- test date	2023.04.26

Test item specification Results

Conclusion

Characters

Appearance	White or off- white crystalline or crystalline powder	white crystalline	Complied
Solubility	Slightly dissolved in water, slightly dissolved in ethanol, almost dissolved in chloroform, not dissolved in dilute hydrochloric acid or sodium hydroxide solution	Slightly dissolved in water and in ethanol, almost dissolved in chloroform, dissolved sodium hydroxide solution	Complied
absorption coefficient	535- 568 at 265nm	537	Complied

Identification

Chemical identification(1)	Purple precipitation reaction of barium hydroxide	Positive	Complied
Chemical identification(2)	Similar oil scale reaction of chromium trioxide sulfuric acid solution	Positive	Complied
UV	Minimum absorption at 232nm, Maximum absorption at 265nm	Complied	Complied
IR	Consistent with the standard reference map	Complied	Complied

Test

Fluorine content	13.1%- 14.6%	14.3%	Complied
Solution clarity	0.1 g dissolved in 10 ml water, it shall not be turbid than No.1 standard solution	Complied	Complied

Chloride	NMT0.014%	Complied	Complied
Sulfate	NMT0.02%	Complied	Complied
Related substances	Single impurity $\leq 0.5\%$, total impurity $\leq 0.75\%$	Single impurity: 0.1%, total impurity: 0.11%	Complied
Loss on drying	NMT 0.5%	0.05%	Complied
Heavy metal	NMT20ppm	Complied	Complied
Microbial limit	Total aerobic: NMT 10^3 cfu/g; Total mould and yeast: NMT 10^2 cfu/g	Total aerobic: NMT 100 cfu/g; Total mould and yeast: NMT 100cfu/g	Complied
Assay	Calculated on dried basis, 97.0%- 103.0%	98.3%	Complied

Test conclusion: According to < Fluorouracil analysis operating procedures>(SCZ- IS- PE- A005)&< Fluorouracil quality standard>(SCZ- QS- PF- A005), this product is analyzed, and the results are complied.

Reporter: Miao Yang
Liu

Reviewer: Dongxue Liu

Director: Weiqing

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