

Certificate of Analysis

Product name	Umifenovir Hydrochloride	Mfg. Date	2020.05.09
Batch No:	KN220050902	Test date	2020.05.11
Batch quantity	200kg	Expiry date	2022. 05.08

Items	Specifications				Results
Appearance	White or almost white powder				Almost white powder
Absorption factor	Should be 385-409				399
Identification					
1	Should produce orange red precipitate				Complies
2	In the chromatogram of content determination, the retention time of the main peak of the sample solution should be consistent with that of the standard solution.				Complies
3	The infrared absorption spectra should be consistent with the standard samples.				Complies
4	The identification reaction of filtrate should be chloride.				Complies
Tests					
Clarify and color of ethanol solution	Solution clarity should be less than No.1 turbidity standard solution.				Complies
	The color should be lighter than No.3 yellow green or No.3 brown red standard color solution.				Complies
Ph	4.0 - 6.0	4.3	Burning residue	≤ 0.2%	0.1%
Water	3.0% - 4.0%	3.4%	Heavy metals	≤ 10 ppm	< 10 ppm
Residual solvents	Ethanol ≤ 0.5%				0.02%
	Acetone ≤ 0.5%				0.01%
Related substances	Single impurity ≤ 0.5%				0.2%
	Total impurity ≤ 1.0%				0.6%
Microorganism	Total number of aerobic bacteria ≤ 1000 cfu/g				20 cfu/g
	Total number of mucedines and yeasts ≤ 100 cfu/g				< 10 cfu/g
Assay	No less than 98.0% and no more than 102.0% on anhydrous, Calculate as C ₂₂ H ₂₅ Br _R N ₂ O ₃ S · HCl				100.3%
Conclusion: Complies with the Second enlarged edition of Chinese Pharmacopoeia 2010.					

