## 🔉 Taizhou Crene Biotechnology Co., Ltd.

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## Certificate of analysis

Product name:Decitabine

Cas number:2353-33-5

Molecular Formula: C8H12N404

Molecular Weight: 228.21

Date of production: May. 04, 2017

Batch N0:20170504

Exp Date:May. 03, 2019

Chemical structure:

 $NH_2$ HO

Solubility         Slightly soluble in methanol;sparingly soluble in water and soluble in dimethylaulfoxid(DMSO)         Conforms           Identification         IR spectrum         Complies with that of reference standard         Conforms           UV spectrum         Two maxima at 201nm and 243nm±2nm         λ max=201.0. 243.2           HPLC retention time         Complies with that of reference standard reference standard         Conforms           Melting point         190~196℃         192.0~194.5℃           Specific rotation         +50~+75°         +70.8°           Feated Substances         5-azacytosine<<0.15%         Undetected           Alpha isomer         0.15%         Undetected           Each unknown individual         <0.15%         Undetected           Each unknown individual         <0.10%         0.03%           Total impurity         \$1.0%         0.20%           Water         Not more than 1.0%         0.2%           Water         Not more than 0.1%         0.02%           Residues after ignition         Not more than 0.1%         0.02%           Residues solvents         Elthyl acetate <800ppm         Undetected           Hexane <800ppm         Undetected         Elthyl acetate <800ppm         Undetected	Items		Standards	Results
Solubility         soluble in water and soluble in dimethylaulfoxid(DMSO)         Conforms           Identification         IR spectrum         Complies with that of reference standard         Conforms           Identification         UV spectrum         Two maxima at 201nm and 243nm±2nm         A max=201.0, 243.2           Identification         UV spectrum         Complies with that of reference standard reference standard         Conforms           Melting point         190~196°C         192.0~194.5°C         192.0~194.5°C           Specific rotation         +50~+75°         +70.8°         +70.8°           Related Substances         5-azacytosine <0.15%	Character		White crystalline powder, odorless	White crystalline powder
IR spectrum         Complies with that of reference standard         Conforms           Identification         UV spectrum         Two maxima at 201nm and 243nm±2nm         \lambda max=201.0, 243.2           HPLC retention time         Complies with that of reference standard         Conforms           Melting point         190~196°C         192.0~194.5°C           Specific rotation         +50~+75°         +70.8°           Felated Substances         5-azacytosine ≤0.15%         Undetected           Alpha isomer         <0.15%	Solubility		soluble in water and soluble in	Conforms
Identification         HPLC retention time         Complies with that of reference standard reference standard         Conforms           Melting point         190~196°C         192.0~194.5°C           Specific rotation         +50~+75°         +70.8°           Related Substances         5-azacytosine <0.15%	Identification	IR spectrum	Complies with that of reference standard	Conforms
HPLC retention time         Complies with that of reference standard         Conforms           Melting point         190~196°C         192.0~194.5°C           Specific rotation         +50~+75°         +70.8°           Specific rotation         5-azacytosine <0.15%		UV spectrum	Two maxima at 201nm and 243nm $\pm$ 2nm	λ max=201.0、243.2nm
Specific rotation $+50 \sim +75^{\circ}$ $+70.8^{\circ}$ Related Substances5-azacytosine $\leq 0.15\%$ UndetectedAlpha isomer $\leq 0.15\%$ UndetectedDecomposition product 1 $\leq 0.15\%$ UndetectedEach unknown individual $\leq 0.10\%$ $0.03\%$ Total impurity $\leq 1.0\%$ $0.20\%$ Loss on DryingNot more than $1.0\%$ $0.22\%$ WaterNot more than $2.0\%$ $1.1\%$ Heavy MetalsNot more than $10ppm$ $<10ppm$ Residues after ignitionNot more than $0.1\%$ $0.02\%$ Methanol $\leq 2000ppm$ $700ppm$ Elthyl acetate $\leq 800ppm$ UndetectedHexane $\leq 800ppm$ UndetectedDMF $\leq 800ppm$ UndetectedDMSO $\leq 5000ppm$ Undetected				Conforms
5-azacytosine <0.15%UndetectedAlpha isomer <0.15%	Melting point		<b>190∼196℃</b>	<b>192.0∼194.5</b> ℃
Alpha isomer<0.15%UndetectedDecomposition product 1<0.15%	Specific rotation		+50~+75°	+70.8°
Related SubstancesDecomposition product 1 <0.15%UndetectedEach unknown individual <0.10%	Related Substances		5-azacytosine $\leq 0.15\%$	Undetected
Each unknown individual <0.10%			Alpha isomer $\leq 0.15\%$	Undetected
Total impurity<1.0%0.20%Loss on DryingNot more than 1.0%0.2%WaterNot more than 2.0%1.1%Heavy MetalsNot more than 10ppm<10ppm			Decomposition product 1 $\leq 0.15\%$	Undetected
Loss on DryingNot more than 1.0%0.2%WaterNot more than 2.0%1.1%Heavy MetalsNot more than 10ppm<10ppm			Each unknown individual $\leq 0.10\%$	0.03%
WaterNot more than 2.0%1.1%Heavy MetalsNot more than 10ppm<10ppm			Total impurity ≤1.0%	0.20%
Heavy Metals       Not more than 10ppm       <10ppm         Residues after ignition       Not more than 0.1%       0.02%         Methanol ≤2000ppm       700ppm         Elthyl acetate ≤800ppm       Undetected         Hexane ≤800ppm       Undetected         Ethanol ≤800ppm       Undetected         DMF≤800ppm       Undetected         DMSO≤5000ppm       Undetected	Loss on Drying		Not more than 1.0%	0.2%
Residues after ignitionNot more than 0.1%0.02%Methanol <2000ppm	Water		Not more than 2.0%	1.1%
Note       Nethanol ≤2000ppm       700ppm         Residues solvents       Elthyl acetate ≤800ppm       Undetected         Hexane ≤800ppm       Undetected         Ethanol ≤800ppm       Undetected         DMF≤800ppm       Undetected         DMSO≤5000ppm       Undetected	Heavy Metals		Not more than 10ppm	<10ppm
Residues solvents       Elthyl acetate <800ppm	Residues after ignition		Not more than 0.1%	0.02%
Hexane ≤800ppm       Undetected         Ethanol ≤800ppm       Undetected         DMF≤800ppm       Undetected         DMSO≤5000ppm       Undetected	Residues solvents		Methanol ≤2000ppm	700ppm
Residues solvents       Ethanol <800ppm       Undetected         DMF<800ppm			Elthyl acetate <800ppm	Undetected
Ethanol     <800ppm     Undetected       DMF<800ppm			Hexane ≤800ppm	Undetected
DMSO <5000ppm Undetected			Ethanol <800ppm	Undetected
			DMF≤800ppm	Undetected
Assav 98.0%~102.0% 99.8%			DMSO≤5000ppm	Undetected
	Assay		98.0%~102.0%	99.8%

## **Conclusion:** It complies with the Enterprise standard

Checker:Liu