

1886.171—2016

---

5

( )

2016 08 31

2017 01 01

---

5

( )

1

5- ( 5- )

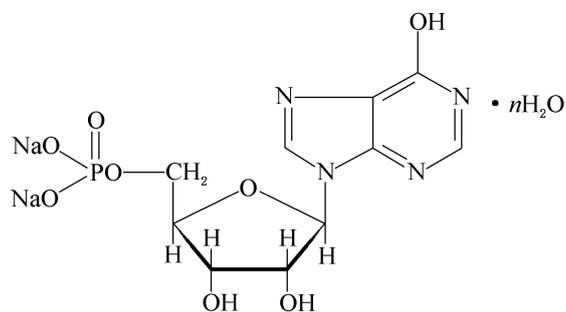
2

2.1 5 ( )

2.1.1



2.1.2



2.1.3 ( )

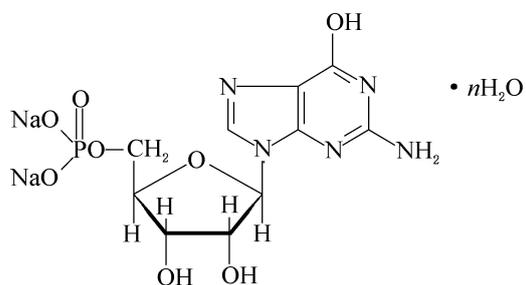
392.17 ( 2011 )

2.2 5 ( )

2.2.1



2.2.2



2.2.3 ( )

407.18 ( 2011 )

3

3.1

1

1


3.2

2

2

( ), / %	97.0 ~ 102.0	A A 2
IMP / %	48.0 ~ 52.0	A A 2
GMP / %	48.0 ~ 52.0	A A 2
, / %	25.0	GB 5009.3 <sup>a</sup>
(5% )/ %	95.0	A A 3
pH (5% )	7.0 ~ 8.5	A A 4
		A A 5
		A A 6
		A A 7
(As)/ (mg/kg)	1.0	GB 5009.76
( Pb )/ (mg/kg)	10	GB 5009.74
<sup>a</sup> 120 , 4 h		

.1

GB/T 602 GB/T 603 GB/T 6682 GB/T 601

.2 ( )

.2.1

: 0.9 mL , 1 000 mL

.2.2

( :1 nm , : ± 2.0 nm , : ± 1.0 nm , : 0.02%)

.2.3

.2.3.1

0.4 g ( 0.0001 g ) 100 mL , 250 mL ,  
5.0 mL , 250 mL ,

.2.3.2

1 cm , 250 nm  
280 nm

.2.4

.2.4.1 ( )

$$1 \frac{(1.463) \cdot 254.55 \cdot (7.976) \cdot (A.1)}{5 \cdot 47.769} \cdot \frac{100}{100} \cdot 100\% \dots (A.1)$$

5  
100  
4  
1.463 254.55 7.976 47.769

— 250 nm ;  
— 280 nm ;  
— (g) ;  
— ;  
— ;  
— , % ;

1 % 1

.2.4.2

I M P 2' (A 2) :  

$$\frac{(1.463)}{5} \frac{342.18}{5} 100\% \dots\dots\dots (A 2)$$

G M P 3' (A 3) :  

$$\frac{(7.976)}{5} \frac{62.55}{5} 100\% \dots\dots\dots (A 3)$$

(A 2) (A 3) :

— 250 nm ;  
 — 280 nm ;  
 — (g) ;  
 5 — ;  
 1.463 342.18 7.976 62.55 — , ,

I M P 1' (A 4) :  

$$1 \frac{2}{2 \quad 3} 100\% \dots\dots\dots (A 4)$$

G M P 2' (A 5) :  

$$2 \frac{3}{2 \quad 3} 100\% \dots\dots\dots (A 5)$$

(A 4) (A 5) :

2 — I M P , % ;  
 3 — G M P , % ;

1 % 1

.3 (5 )

.3.1

.3.2

1 g ( 0.0001 g), 20 mL , 1 cm ,  
 , 430 nm ,

0.5%

.4 (5 )

.4.1

.4.2

1 g ( 0.0001 g), 20 mL , pH

0.2

.5

.5.1

.5.1.1 : + + = 79 + 2 + 19

.5.1.2

.5.2

.5.2.1

.5.2.2

.5.3

1.0 g, 100 mL, 10.0 μL, 30 cm,  
( ) , 254 nm

.5.4

IMP GMP ,

.6

.6.1

: 0.5 g, 100 mL

.6.2

.6.3

0.1 g, 100 mL, 5 mL, 1 mL,  
3 min

.6.4

,

.7

.7.1

.7.1.1

.7.1.2

.7.2

0.1 g , 50 mg 1 mL ,  
5 min

.7.3

