

BIOSPECTRA

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Initiated By:	Yencho, Amy M	1.0	: Supersedes																				
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Approval:	<table border="1"> <thead> <tr> <th>Approvers</th> <th>Date</th> <th>Time</th> <th>Group</th> <th>Name</th> </tr> </thead> <tbody> <tr> <td></td> <td>26-Mar-2021</td> <td>02:53:35 PM</td> <td>EDITOR</td> <td>Yencho, Amy M</td> </tr> <tr> <td></td> <td>26-Mar-2021</td> <td>02:58:18 PM</td> <td>QUALITY</td> <td>Goheen, Joshua</td> </tr> <tr> <td></td> <td>26-Mar-2021</td> <td>03:17:05 PM</td> <td>DOC SPEC</td> <td>Hosein, Amy</td> </tr> </tbody> </table>			Approvers	Date	Time	Group	Name		26-Mar-2021	02:53:35 PM	EDITOR	Yencho, Amy M		26-Mar-2021	02:58:18 PM	QUALITY	Goheen, Joshua		26-Mar-2021	03:17:05 PM	DOC SPEC	Hosein, Amy
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ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: URACIL

Printed On:	26-Mar-2021 03:56:54 PM	Augustine, Connie M	: Printed By
Print Expiration:	Not Applicable		
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Table 1: Elemental Impurity Risk Assessment			Manufacturing Process DCN: 16-000090 Parenteral Specifications 10g/day MDD			
Element	Class	Intentionally Added?	Potential Sources?	Manufacturing Equipment Risk?	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)
Cd	1	No	No	No	0.20	0.06
Pb	1	No	No	No	0.5	0.15
As	1	No	No	No	1.5	0.45
Hg	1	No	No	No	0.3	0.09
Co	2A	No	No	No	0.5	0.15
V	2A	No	No	No	1.0	0.30
Ni	2A	No	Yes	316SS	2.0	0.60
Tl	2B	No	No	No	0.80	0.24
Au	2B	No	No	No	1.0	0.30
Pd	2B	No	No	No	1.0	0.30
Ir	2B	No	No	No	1.0	0.30
Os	2B	No	No	No	1.0	0.30
Rh	2B	No	No	No	1.0	0.30
Ru	2B	No	No	No	1.0	0.30
Se	2B	No	No	No	8.0	2.4
Ag	2B	No	No	No	1.0	0.30

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Element	Class	Intentionally Added?	Potential Sources?	Manufacturing Equipment Risk?	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)
Pt	2B	No	No	No	1.0	0.30
Li	3	No	No	No	25	7.5
Sb	3	No	No	No	9.0	2.7
Ba	3	No	No	No	70	21
¹ Mo	3	No	Yes	316SS	15	4.5
¹ Cu	3	No	No	No	5.0	1.5
Sn	3	No	No	No	60	18
¹ Cr	3	No	Yes	316SS	5.0	1.5
² Additional Elements						
Fe	4	No	Yes	316SS	N/A	N/A
Mn	4	No	No	No	N/A	N/A
Ca	4	No	No	No	N/A	N/A
K	4	No	No	No	N/A	N/A
Mg	4	No	No	No	N/A	N/A
Na	4	Yes	Addition of 1N NaOH in manufacturing process	No	N/A	N/A

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Element	Class	Intentionally Added?	Potential Sources?	Manufacturing Equipment Risk?	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)
Zn	4	No	No	No	N/A	N/A
¹ Specification calculated based on lower internal specification ² Additional Element Specifications and Results are For Informational Purposes only.						

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT			Manufacturing Process DCN: 16-000090 Parenteral Specifications 10g/day MDD			
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: UC4200-026-0121-PV Composite 1st Validation Protocol: 20-003031, ppm (µg/g)	Meets Control Threshold (Yes or No)	
Cd	1	0.20	0.06	<0.06	Yes	
Pb	1	0.50	0.15	<0.15	Yes	
As	1	1.5	0.45	<0.45	Yes	
Hg	1	0.30	0.09	<0.09	Yes	
Co	2A	0.50	0.15	<0.15	Yes	
V	2A	1.0	0.30	<0.30	Yes	
Ni	2A	2.0	0.60	<0.60	Yes	
Tl	2B	0.80	0.24	<0.24	Yes	

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Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: UC4200-026-0121-PV Composite 1 st Validation Protocol: 20-003031, ppm (µg/g)	Meets Control Threshold (Yes or No)
Au	2B	10	3.0	<3.0	Yes
Pd	2B	1.0	0.30	<0.30	Yes
Ir	2B	1.0	0.30	<0.30	Yes
Os	2B	1.0	0.30	<0.30	Yes
Rh	2B	1.0	0.30	<0.30	Yes
Ru	2B	1.0	0.30	<0.30	Yes
Se	2B	8.0	2.4	<2.4	Yes
Ag	3	1.0	0.30	<0.30	Yes
Pt	3	1.0	0.30	<0.30	Yes
Li	3	25	7.5	<7.5	Yes
Sb	3	9.0	2.7	<2.7	Yes
Ba	3	70	21	<21	Yes
¹ Mo	3	15	4.5	<4.5	Yes
¹ Cu	3	5.0	1.5	<1.5	Yes

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Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: UC4200-026-0121-PV Composite 1 st Validation Protocol: 20-003031, ppm (µg/g)	Meets Control Threshold (Yes or No)
Sn	3	60	18	<18	Yes
¹ Cr	3	5.0	1.5	<1.5	Yes
² Additional Elements					
Fe	4	N/A	N/A	<1.5	N/A
Mn	4	N/A	N/A	<1.5	N/A
Ca	4	N/A	N/A	<15	N/A
K	4	N/A	N/A	<15	N/A
Na	4	N/A	N/A	17,133	N/A
Zn	4	N/A	N/A	<1.5	N/A
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TABLE 3: ELEMENTAL IMPURITY ASSESSMENT				Manufacturing Process DCN: 16-000090 Parenteral Specifications 10g/day MDD 2 nd Validation Protocol: 21-003034			
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: UC4200-028-0121-PV, Composite ppm (µg/g)	Result Batch 2 Lot: UC4200-029-0121 Composite, ppm (µg/g)	Result Batch 3 Lot: UC4200-030-0121 Composite, ppm (µg/g)	Meets Control Threshold (Yes or No)
Cd	1	0.20	0.06	<0.06	<0.06	<0.06	Yes
Pb	1	0.50	0.15	<0.15	<0.15	<0.15	Yes
As	1	1.5	0.45	<0.45	<0.45	<0.45	Yes
Hg	1	0.30	0.09	<0.09	<0.09	<0.09	Yes
Co	2A	0.50	0.15	<0.15	<0.15	<0.15	Yes
V	2A	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ni	2A	2.0	0.60	<0.60	<0.60	<0.60	Yes
Tl	2B	0.80	0.24	<0.24	<0.24	<0.24	Yes
Au	2B	10	3.0	<3.0	<3.0	<3.0	Yes
Pd	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ir	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Os	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Rh	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ru	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Se	2B	8.0	2.4	<2.4	<2.4	<2.4	Yes

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Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: UC4200-028-0121-PV, Composite ppm (µg/g)	Result Batch 2 Lot: UC4200-029-0121 Composite, ppm (µg/g)	Result Batch 3 Lot: UC4200-030-0121 Composite, ppm (µg/g)	Meets Control Threshold (Yes or No)
Ag	3	1.0	0.30	<0.30	<0.30	<0.30	Yes
Pt	3	1.0	0.30	<0.30	<0.30	<0.30	Yes
Li	3	25	7.5	<7.5	<7.5	<7.5	Yes
Sb	3	9.0	2.7	<2.7	<2.7	<2.7	Yes
Ba	3	70	21	<21	<21	<21	Yes
¹ Mo	3	15	4.5	<4.5	<4.5	<4.5	Yes
¹ Cu	3	5.0	1.5	<1.5	<1.5	<1.5	Yes
Sn	3	60	18	<18	<18	<18	Yes
¹ Cr	3	5.0	1.5	<1.5	<1.5	<1.5	Yes
² Additional Elements							
Fe	4	N/A	N/A	4.6	<1.5	<1.5	N/A
Mn	4	N/A	N/A	<1.5	<1.5	<1.5	N/A
Ca	4	N/A	N/A	<15	<15	<15	N/A
K	4	N/A	N/A	<15	<15	<15	N/A
Na	4	N/A	N/A	16,569	1,268	310	N/A

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Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: UC4200-028-0121-PV, Composite ppm (µg/g)	Result Batch 2 Lot: UC4200-029-0121 Composite, ppm (µg/g)	Result Batch 3 Lot: UC4200-030-0121 Composite, ppm (µg/g)	Meets Control Threshold (Yes or No)
Zn	4	N/A	N/A	<1.5	<1.5	<1.5	N/A
¹ Specification calculated based on lower internal specification ² Additional Element Specifications and Results are For Informational Purposes only.							

TABLE 4: ELEMENTAL IMPURITY ASSESSMENT				Manufacturing Process DCN: 16-000090 Parenteral Specifications 10g/day MDD 2 nd Validation Protocol: 21-003034			
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: UC4200-029-0121 Drum 1, ppm (µg/g)	Result Batch 2 Lot: UC4200-029-0121 Drum 3, ppm (µg/g)	Result Batch 3 Lot: UC4200-029-0121 Drum 6, ppm (µg/g)	Meets Control Threshold (Yes or No)
Cd	1	0.20	0.06	<0.06	<0.06	<0.06	Yes
Pb	1	0.50	0.15	<0.15	<0.15	<0.15	Yes
As	1	1.5	0.45	<0.45	<0.45	<0.45	Yes
Hg	1	0.30	0.09	<0.09	<0.09	<0.09	Yes
Co	2A	0.50	0.15	<0.15	<0.15	<0.15	Yes
V	2A	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ni	2A	2.0	0.60	<0.60	<0.60	<0.60	Yes
Tl	2B	0.80	0.24	<0.24	<0.24	<0.24	Yes

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TABLE 4: ELEMENTAL IMPURITY ASSESSMENT				Manufacturing Process DCN: 16-000090 Parenteral Specifications 10g/day MDD 2 nd Validation Protocol: 21-003034			
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: UC4200-029-0121 Drum 1, ppm (µg/g)	Result Batch 2 Lot: UC4200-029-0121 Drum 3, ppm (µg/g)	Result Batch 3 Lot: UC4200-029-0121 Drum 6, ppm (µg/g)	Meets Control Threshold (Yes or No)
Au	2B	10	3.0	<3.0	<3.0	<3.0	Yes
Pd	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ir	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Os	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Rh	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ru	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Se	2B	8.0	2.4	<2.4	<2.4	<2.4	Yes
Ag	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Pt	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Li	3	25	7.5	<7.5	<7.5	<7.5	Yes
Sb	3	9.0	2.7	<2.7	<2.7	<2.7	Yes
Ba	3	70	21	<21	<21	<21	Yes
¹ Mo	3	15	4.5	<4.5	<4.5	<4.5	Yes
¹ Cu	3	5.0	1.5	<1.5	<1.5	<1.5	Yes
Sn	3	60	18	<18	<18	<18	Yes

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Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: UC4200-029-0121 Drum 1, ppm (µg/g)	Result Batch 2 Lot: UC4200-029-0121 Drum 3, ppm (µg/g)	Result Batch 3 Lot: UC4200-029-0121 Drum 6, ppm (µg/g)	Meets Control Threshold (Yes or No)
¹ Cr	3	5.0	1.5	<1.5	<1.5	<1.5	Yes
² Additional Elements							
Fe	4	N/A	N/A	4.6	<1.5	<1.5	N/A
Mn	4	N/A	N/A	<1.5	<1.5	<1.5	N/A
Ca	4	N/A	N/A	<15	<15	<15	N/A
K	4	N/A	N/A	<15	<15	<15	N/A
Na	4	N/A	N/A	1,193	639	755	N/A
Zn	4	N/A	N/A	<1.5	<1.5	<1.5	N/A
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