Screening (Day -30 to 1)

SPECTRIO PHARMACE Redefining Can	EUTICALS
Protocol No.: SP	I-QAP-306
Date patient sig	ned Informed C
Protocol version:	○ Original○ Amendment

PHARMACEUT Redefining Cancer	Oranies contesin (concennig)	
Protocol No.: SPI-	QAP-306 Site No.: Patient No.:	
Date patient signe	d Informed Consent: (DD/MMM/YYYY)	
Protocol version:	Original Amendment no:	



DEMOGRAPHIC INFORMATION (Screening)

Protocol No.: SP	PI-QAP-306 Site No.:	Patient No.:
	◯ Male ◯ Female	
Date of Birth:	(DD/MMM/YYYY)	Age: (YEARS)
Ethnicity: ☐ Hispa	anic or Latino ☐ Not Reporting ☐ Unknown	ted
Race :	☐ White☐ Black or African American☐ American Indian or Alaska Native	☐ Asian☐ Native Hawaiian or Other Pacific Islander☐ Other, Specify:
Smoking Status:	☐ Current ☐ Former ☐ Never	



ELIGIBILITY CRITERIA (Screening)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
Does the patient meet all eligibility crit	teria?			
☐ Yes				
□ No				
If 'No', indicate one or more failed incl	usion or exclu	sion criteria:		
Inclusion Criterion # :		Exclusion Criteri	on # :	_
Inclusion Criterion #:		Exclusion Criteri	on # :	_
Inclusion Criterion #:		Exclusion Criteri	on # :	_
Was patient enrolled? ☐ No ☐ Yes				
If patient was not enrolled, provide rea	ason:	☐ With	not meet eligibility ndrew consent er, specify:	

SPECTRUM PHARMACEUTICALS Redefining Cancer Care	Urine Cytology (Screen	ing)
Protocol No.: SPI-QAP-306	Site No.:	Patient No.:
☐ Mark if not done	If not done, please specify reason:	
Collection Date (DD/MMM/YYYY	<i>'</i>)	

Urine Cytology Results?

- O Positive or suspicious for High Grade Malignancy
- Negative, No evidence of Malignancy
- Other, Specify_____



Cystoscopy (Screening)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
Exam Date (DD/MMM/YYYY To	tal number of lesions not	ed:		
Were any other abnormal	ities seen?		○ No ○ Yes	
If Yes, explain:				_
OP Report uploaded to e	Caselink?		○ No ○ Yes	
Comments:				

SPECTRUM" PHARMACEUTICALS Redefining Cencer Care.	General Medical/Surgical History	
Protocol No.: SPI-QAP-306 Site No.:	: Patient No.:	
Check if there is no Medical/ Surgical History		
Sequence: Diagnosis or Procedure or th	nerapies or current medication	
and investigations as w previous 5 years.)	story of all relevant neoplastic disease, its symptoms, findings well as significant past and all co-existing diseases and curren neoplastic disease on the Bladder Cancer History page)	
Body System Code *		
Date of Onset/Procedure :	Stop Date:	☐ Ongoing
		☐ Ongoin

Body System Code1

01 HEENT **05 Renal/ Genitourinary**

13 Allergies

02 Respiratory

06 Reproductive 07 Musculoskeletal 10 Hematologic/Lymphatic

09 Endocrine/Metabolic

S Other

03 Cardiovascular **04** Gastrointestinal

08 Dermatologic

11 Neurological 12 Psychiatric

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Previous Bladder Cancer History

	o.: SPI-QAP-30	Site No).:			Patient No.:	
TURBT	History:						
	☐ No history of	TURBT					
	Date (DD/MM/YYYY)	Highest Stage (T stage)		ighest Grade 973 or 2004			
-T0				7- Papilloma		13- High Grade	
-Ta				8- G1		14- Analysis no	
-TIS(CIS)				9- G2		88- Information	n not available
-T1				10- G3			
- <u>></u> T2		:h urothelial malignai		11- PUNLUMP 12- Low Grade			
Intrave	sical Bladder Car	ncer Therapy :					
Was any	y prior Intravesical	Bladder Cancer Th	erapy	carried out?	Yes		
Was an	y prior Intravesical	Bladder Cancer Th	erapy		Yes No		
	y prior Intravesical Date //MM/YYYY)	Bladder Cancer Th			No	Indication	
	Date				No	Indication	
	Date				No	Indication	
	Date				No	Indication	
(DD/	Date /MM/YYYY)	Agent Type*			stillations		RBT Instillation
(DD/	Date /MM/YYYY)				No stillations	Indication Postoperative TUF	



Current Bladder Tumor Status

Protocol No.: SP	I-QAP-306	Site No.:		Patient No.:	
Is the current tu	ımor primary or re	current bladder	○ Primary		
			Recurrent cancer histor	t (please also complete Bladder y form)	
	Total I	Number of Recui	rences :		
Presentation :					
Hematuria	○ No ○Yes				
If Yes,	GrossMicroscop	pic			
Please provide th extravesical (uppo Check all that app	er tract) and meta		☐ CTIVP ☐ MRU ☐ CT ☐ MRI ☐ Ultrasound ☐ Retrograde Pr ☐ CXR ☐ Other, Specify	Date Date Date yelogram Date Date	
Current presumed	AUA risk catego	ory:			
	Low risk				
	OTTEN			ng or TURBT should not be enrolle Irrent over a year of last re	
	Intermediate ris	k			
	Solitary, Low	Grade Ta, <= 3 o	cm, Recurrent within	a year of last resection	
	Solitary, Low	Grade Ta, > 3 cr	n		
	Solitary, High	Grade Ta, <= 3	cm, Primary		
	O Multiple, all L	ow Grade Ta			

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(According to AUA Guidelines 2016)

SPECTRU PHARMACEUT Redefining Cancer	Vital Sign	s (Screening)
Protocol No.: SPI-	QAP-306 Site No.:	Patient No.:
☐ Not Done	If not done, please specify reason	
Date of Assessment	(DD/MMM/YYYY)	
Height	(cm)	Body Temperature (°C)
Body Weight	(kg)	Blood Pressure (mmHg) Systolic / Diastolic
		Heart Rate (beats/minute)



PHYSICAL EXAMINATION (Screening)

Protocol No.: SPI-QAP-306 Site No	.: Patient No.:
☐ Check if Physical Examination was not dor	ne.
If not done, please specify reason	
Date of Examination (DD/MMM/YYY)	Y)
Were there any clinically significant abnorma	al findings?
* (Please record all clinically abnormal find	lings on the General Medical/Surgical History page)

SPECTR PHARM. Redefining C	CEUTICALS			Complet	e Blood Cou	unt (S	Scr	eening	g)	Panel Collection dat	te	
Protocol No	o.: SPI-0	QAP-306 Site	No.:		Patient No.:						(DD/MM	M/YYYY)
☐ Not Done	e Pai	nel Lab ID	L f not dor	ne,please provide reaso	ın					Panel Time Drawı	n	
				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,							(00:00-	23:59)
Test Nar	ne:	Not Done		Result	:			Unit		Clinical Signif	icance	
WBC		Not Done	Result:				Unit:		○ Norma		NCS	○ cs
Hemoglobin		Not Done	Result:				Unit:		Norma		NCS	○ cs
Hematocrit		Not Done	Result:				Unit:		○ Norma	ı	NCS	○ cs
Platelets		Not Done	Result:				Unit:		Norma	ı) NCS	○ cs
	Wh	ere, NCS - Abnormal, N	ot Clin	ically Significant and	CS - Abnormal &	Clinica	illy S	Significa	nt			
V-1.2 25AUG2		e: At Screening visit, p	lease li	ist the Abnormal and	Clinically Signific	ant ab	nori	mality in	Medical	History form.		

SPECTRUM PHARMAGEUTICALS	TM	Blood Chem	istry (Screening	J)				
Protocol No.: SPI	-QAP-306 Site N	o.: Patie	nt No.:	nel Time Drav	wn	Panel Collection date	Panel La	ab de
☐ Not Done	If not done,please	e provide reason			(00:00-23:59	(DD/MMM/YYYY)	טו	
Test Name:	Not Done		Result		Unit	Clinical Sign	ificance	
	п						1	
Glucose	Not Done	Result:			Unit:	Normal	O NCS	○ cs
Blood Urea Nitrogen	Not Done	Result:			Unit:	Normal	○ NCS	○ cs
Creatinine	Not Done	Result:			Unit:	Normal	○ NCS	○ cs
Sodium	Not Done	Result:			Unit:	Normal	○ NCS	○ cs
Potassium	Not Done	Result:			Unit:	Normal	○ NCS	○ CS
Chloride	Not Done	Result:			Unit:	Normal	○ NCS	○ cs
Carbon Dioxide	Not Done	Result:			Unit:	Normal	○ NCS	○ cs
Albumin	Not Done	Result:			Unit:	Normal	○ NCS	○ cs
Alk Phosphatase	Not Done	Result:			Unit:	Normal	○ NCS	○ cs
AST	Not Done	Result:			Unit:	Normal	○ NCS	○ cs
ALT	Not Done	Result:			Unit:	Normal	○ NCS	○ cs
Where, N	CS - Abnormal, Not Cl	nically Significant and	l CS - Abnormal &Clir	ically Sig	nificant			
Note: At S	Screening visit, please	list the Abnormal and	Clinically Significant	abnorma	lity in Medic	al History form.		
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SPECTRUM PHARMACEUTICAL Redefining Cancer Can
Protocol No.: SPI-QA

Pregnancy Test (Screening)

Redefining Cancer Care	.
Protocol No.: SPI-QAP-306 Site No.:	Patient No.:
☐ Not Applicable	
Reason if Pregnancy Test Not Applicable:	
Patient is post-menopal and/or surgically non-re	usal (≥1 year since last menses) productive female.
Collection Date	
(DD/MMM/YYYY)	
RESULT: Negative	
O Positive*	
Note:- (* Pregnancies involving a study patient or a patient's partner, to treatment through 35 days after the last dose of study treatment Investigator has gained knowledge of the event via fax or e-mail outcome of the pregnancy will be requested by the Spectrum Ph	t, must be reported within 24 hours after the l. Follow-up information regarding the
All patients who become pregnant during participation in this st	tudy are to be withdrawn from the study.)

Protocol No.	: SPI-QAP-3	06	Site No.:		Pat	tient No.:	
	ot done, please son:	provide		Collectio	n Date (DD/MMM/Y)		Clinical Significance
Test			Result				
Glucose	○ Not Done	○ Nega	tive C'	Value*			CS NCS
Ketones	○ Not Done	○ Nega	tive O'	Value*			CS NCS
Specific Gravity	O Not Done						CS NCS
Blood	O Not Done	○ Nega	tive	Moderate Tr		;*	CS NCS
рН	O Not Done						CS NCS
Protein	O Not Done	○ Nega	tive	Value*	-		CS NCS
Nitrite	○ Not Done	○ Nega	tive	tive			CS NCS
Leukocytes	O Not Done	○ Nega	tive				CS NCS
Where, NCS	- Abnormal, 1	Not Clin	ically Significar	nt and CS - Abno	ormal &Clin	ically Signific	cant

Treatment(Visit 1 Day 1)



Vital Signs (Visit 1 Day 1)

Protocol No.: SPI-	QAP-306 Site No.:	Patient No.:				
☐ Not Dor	ne					
Date of Assessment						
	(DD/MMM/YYYY)					
Body						
Temperature	(oC)					
	(3)					
Blood Pressure	∍					
	(mmHg) Systolic / Diastolic					
Heart Rate						
(1	beats/minute)					

SPECTR PHARMAI	CEUTICALS		Complete Blood Count (Visit 1 Da	y 1) Panel Collection of	date	
Protocol No		QAP-306 Site	No.: Patient No.:			(DD/MMI	M/YYYY)
☐ Not Done	!	Pane	el Lab ID		Panel Time Dra		
_		Screening assessment v	vas done less than 72 hours ago If not done,please p	provide reason		(00:00-2	23:59)
Test Nan	ne:	Not Done	Result	Unit	Clinical Sign	nificance	
WBC		☐ Not Done	Result:	Unit:	Normal	○ NCS	○ cs
Hemoglobin		Not Done	Result:	Unit:	Normal	○ NCS	⊖ cs
Hematocrit		Not Done	Result:	Unit:	Normal	○ NCS	○ cs
Platelets		Not Done	Result:	Unit:	Normal	O NCS	○ cs
Wi	here, NC	S - Abnormal, Not Clini	ically Significant and CS - Abnormal &Clinically Sig	nificant			
			st the Abnormal and Clinically Significant abnormal he Abnormal and Clinically Significant abnormality				

SPECTRUM Blood Chemistry (Vist 1 Day 1)								
Protocol No.: SPI-	QAP-306 Site N	O.: Patient No.: Panel Time Dra	wn	Panel Collection date	Panel Lab			
☐ Not Done If not o	done,please provide rea	ason	(00:00-23:59	(DD/MMM/YYYY)	ID			
☐ Not Applicable as Screening assessment was done less than 72 hours ago								
Test Name:	Not Done	Result	Result Unit Clinical Significance					
Glucose	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
Blood Urea Nitrogen	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
Creatinine	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
Sodium	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
Potassium	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
Chloride	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
Carbon Dioxide	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
Albumin	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
Alk Phosphatase	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
AST	Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
ALT [Not Done	Result:	Unit:	Normal	○ NCS	○ cs		
Where, NO	CS - Abnormal, Not Cl	nically Significant and CS - Abnormal &Clinically Sig	nificant					
Note: At S	Screening visit, please	list the Abnormal and Clinically Significant abnorma	lity in Medic	al History form.				
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Urine Dipstick (Visit 1 Day 1) just Prior to instillation

Recemning Cancer Care						
Protocol No.:	SPI-QAP-30	O6 Site No.: Patient No.:				
☐ Not done	Collection Date	(DD/MMM/YYYY)				
If not done, please	If not done, please provide reason: Collection Time (00:00 to 23:59)					
Test		Result	1			
Appearance (Color)	○ Not Done	Colorless Pale Yellow Dark Yellow Amber Blue Green Pink Red Maroon				
Appearance (Clarity)	○ Not Done	Clear Chazy Cloudy Cturbid Milky Small clots Medium clots Clarge clots				
Glucose	○ Not Done	○ Negative ○ Value*	CS NCS			
Ketones	○ Not Done	○ Negative ○ Value*	CS NCS			
Specific Gravity	○ Not Done		CS NCS			
Blood	○ Not Done	Negative Trace Moderate Trace Value*	CS NCS			
рН	O Not Done		CS NCS			
Protein	O Not Done	○ Negative ○ Trace ○ Value*	CS NCS			
Nitrite	O Not Done	○ Negative ○ Positive	CS NCS			
Leukocytes	O Not Done	○ Negative ○ Value*	CS NCS			
Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal & Clinically Significant *Please enter value/grading per dipstick report/kit						

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Transurethral Resection of Bladder Tumor (Visit 1 Day 1)

Protocol No.: SPI-QAP-306	Site No.: Patient No.:				
Date of TURBT (DD/MMM/YYYY)					
TURBT Start Time (00:00 to 23:59)	Visualization				
TURBT Stop Time					
(00:00 to 23:59) Total Number of Lesions	Post resection Irrigation No irrigation Syringe Irrigation Continuous Bladder Irrigation				
Lesion Site # Location Code# Size(cm)					
1					
	OP Report uploaded to eCaselink: Yes				
2	○ No				
3	Comments :				
4					
5					
6	(Note:- All Histology specimens should be sent to local pathology laboratory, each				
7	lesion in separate specimen container identified by site & lesion number). (If sending multiple specimens from same lesion please mark consistently as A.				
8	Lesion 1, left wall papillary tumor: B. Lesion 1 left wall, base of tumor and so on.)				
A= Anterior Wall P= P	ateral Wall L=Left Lateral Wall				

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SPECTRUM PHARMACEUTICALS Redefining Cancer Care	NDOMIZATION (Visit 1 Day 1)
Protocol No.: SPI-QAP-306 Site No.:	Patient No.:
Will patient be Randomized?	☐ No ☐ Yes
If no, provide reason	
Randomization Date (DD/MMM/YYYY)	



Study Drug Instillation (Visit 1 Day 1)

Protocol No.: SPI-QAP-306	Site No.:		Patier	nt No.:		
Kit Niveshan and	i ana a di					
Kit Number ass	ignea:					
Was instillation done?	○Yes					
	O Not done due to s	significant bleeding (please record He	ematuria	on AE Page)	
	ONot done due to r	non-target populatior	1			
	○ Not done due to F	PUNLMP histology				
Not done due to bladder wall integrity/safety concern						
	○ Not done due to 0	Other reason, Specif	y			
Was visual assessment of uring	ne & urinalysis dip stri	ip test Ye	Any observ	ations?	_	
carried out right before drug ir		○ No	-			
		<u> </u>				
Was the bladder completely dra	ined prior to drug inst	illation ?	'es			
		\bigcirc	lo			
Instillation Date						
(DD/MMM/YY	11)					
Time Study Drug Instillation Bega	n:		provide the	OR	(Operation Room)	
	(00:00-23:59)		performed? Outp		(Recovery Room)	
Time Study Drug Drained from Bla	adder:	perform			tpatient Office	
, 0	(00:00-23:59	<u> </u>			er, Specify	
Was the start of instillation at	·		○Yes			
end of TURBT?	•	,	○ No			
If No, please give reason:			0110			
Volume of Instillate?		○ 50	mL			
		○ Oth	ner, Specify			
If Other than 50 ml give re						
If Other than 50 mL, give rea	ason. 					
Was the study drug retained in	n bladder		○Voo			
for 60 minutes (+/-5 minutes)			○ Yes ○ No			
If No, please give reason:			UNU			
, I						



Pathology (Visit 1 Day 1)

Protocol No.: SPI-QAP-306		Site No.:		Patient No.:					
☐ Not Done Please provide the location codes*		WHO 2004	Report Date (DD/MMM/YYYY) WHO 2004						
Lesion Site #	Location Code#	pT Staging*	Grade**	Muscular	is Propria Presence				
1									
				 ✓ Muscle not commented upon by pathologist ✓ Muscle Present ✓ Muscle Absent 					
2				Cannot be determined (explain)					
				Muscle not commented upon by pathologistMuscle Present					
3				Cannot be determined (explain)					
				Muscle Present Muscle Absent					
4 Cannot be determined (explain				•					
5				Muscle Present Muscle Absent Cannot be determined (explain)					
					nted upon by pathologist				
6				Muscle Present (Cannot be determine	Muscle Absent ned (explain)				
					nted upon by pathologist Muscle Absent				
7				Cannot be determine					
					nted upon by pathologist				
8				Muscle Present (Cannot be determine	Muscle Absent				
					nted upon by pathologist				
	G,Mitomyc	additional intravesicain) for bladder cance			report therapy on Concor	nitant Medication page)			

Report uploaded to eCaselink?	⊜Yes ⊝No
Comments:	
# Tumor Site: T= Trigone R= Right Lateral Wall L=Left Latera	al Wall
A= Anterior Wall P= Posterior Wall D= Dome O= Other, Specify N= Not Specified E * pT Stage Codes:	3= Bladder Neck
pTX: Primary tumor cannot be assessed pT0: No evidence of primary tumor pTa: Noninvasive papillary carcinoma pTis: Carcinoma in situ: "flat tumor" pT1: Tumor invades lamina propria (subepithelial cont pT2: Tumor invades muscularis propria (detrusor mus pT2a: Tumor invades superficial muscularis propria (in pT2b: Tumor invades deep muscularis propria (outer pT3: Tumor invades perivesical tissue pT3a: Microscopically (extravesicular mass)	ccle) nner half)

2004 WHO / ISUP Consensus Classification for Urothelial Lesions

pT4b: Extravesical tumor invades pelvic wall, or abdominal wall

pT4: Tumor invades any of the following: prostatic stroma, seminal vesicles, uterus, vagina, pelvic wall, abdominal wall pT4a: Extravesical tumor invades directly into prostatic stroma, uterus, or

Urothelial carcinoma in situ

Papillary urothelial carcinoma, low grade

Papillary urothelial carcinoma, high grade

Papillary urothelial neoplasm of low malignant potential

Urothelial papilloma

Inverted urothelial papilloma

Other



Risk Assessment based on pathology review (Visit 1 Day 1)

Protocol No.: SPI-QAP-306 Site No.:	nt No.:
Please choose based on the Highest Stage/Grade :	
<u>Target Population - Low Risk</u>	
PUNLMP*	0
Solitary, Low Grade Ta, <= 3cm, Primary or if Recurrent over a year of last resection	0
Target Population - Intermediate Risk	
Solitary, Low Grade Ta, <=3cm, Recurrent within a year of last rese	ection
Solitary, Low Grade Ta ,> 3cm	
Solitary, High Grade Ta, <= 3cm, Primary	
Multiple, all Low Grade Ta	0
Non-Target Population	
Solitary, High Grade Ta, >3cm or Recurrent	0
Multiple, High Grade Ta	0
Low Grade T1	0
High Grade T1	0
cis	О
T2 or above	0
With any variant histology, or any lymphovascular invasion, or any high-grade prostatic urethral involvement	0
No Malignant tumor present	C

Safety Follow Up/ Visit 2 Day 35



Vital Signs (Visit 2 Day 35)

Nederning Cancer	Care		
Protocol No.: SPI-	QAP-306 Site No.:	Patient No.:	
☐ Not Dor	ne		
Date of Assessment	(DD/MMM/YYYY)		
Body Temperature	(°C)		
Blood Pressure	(mmHg) Systolic / Diastolic		
Heart Rate (I	beats/minute)		



PHYSICAL EXAMINATION (Visit 2 Day 35)

Protocol No.: SPI-QAP-306 Site No.:	Patient No.:
☐ Check if Physical Examination was not done.	
If not done, please specify reason	
Date of Examination (DD/MMM/YYYY)	
Were there any clinically significant abnormal findings?	☐ No ☐ Yes*
* (Please record all clinically abnormal findings on th	e Adverse Events page.
SAE and AE Reporting Guidelines	
For all Consented patients during the screening pro- Only Serious Adverse Events related to study proced	
For patients who do not receive drug instillation at tie Only Serious Adverse Events related to study proced	
For all non-Target population patients, (received age All AEs and SAEs from the time of study drug admin recorded and followed until resolution.	• • • • • • • • • • • • • • • • • • • •
Visit. Only deaths and AEs related to study procedures wil	tudy drug administration until the 3-month Follow-up
Study. Adverse events will be followed until resolution or ba	nck to baseline.)

SPECTR PHARM. Redefining C	ACEUTICALS			Complete Blood Count	(Vis	it 2 Da	y 35) Panel Collection of	date	
Protocol No	o.: SPI-C	QAP-306 Site	No.:	Patient No.:				(DD/MM	M/YYYY)
☐ Not Done	e Par	nel Lab ID	ا f not do	ne,please provide reason			Panel Time Dra		
								(00:00-	23:59)
Test Nar	me:	Not Done		Result		Unit	Clinical Sign	nificance	
WBC		☐ Not Done	Result:		Unit:		Normal	○ NCS	○ cs
Hemoglobin		☐ Not Done	Result:		Unit:		Normal	○ NCS	○ cs
Hematocrit		Not Done	Result:		Unit:		Normal	○ NCS	○ cs
Platelets		Not Done	Result:		Unit:		Normal	○ NCS	○ cs
W	here, NC	S - Abnormal, Not Clin	ically S	ignificant and CS - Abnormal &Clinically Sig	gnific	ant			
				Abnormal and Clinically Significant abnormations and Clinically Significant abnormality					

SPECTRUM"		Blood Chemistry (Visit 2 Day 35)			
Protocol No.: SPI-	QAP-306 Site N	Io.: Patient No.: Panel Time Dra	wn	Panel Collection date	Panel Lab ID
☐ Not Done	If not done,please	e provide reason	(00:00-23:59	9) (DD/MMM/YYYY)	
Test Name:	Not Done	Result	Unit	Clinical Sign	ificance
Glucose	Not Done	Result:	Unit:	Normal	O NCS O CS
Blood Urea Nitrogen	Not Done	Result:	Unit:	Normal	O NCS OCS
Creatinine	Not Done	Result:	Unit:	Normal	O NCS O CS
Sodium	Not Done	Result:	Unit:	Normal	O NCS O CS
Potassium	Not Done	Result:	Unit:	CNormal	○ NCS ○ CS
Chloride	Not Done	Result:	Unit:	Normal	○ NCS ○ CS
Carbon Dioxide	Not Done	Result:	Unit:	Normal	○ NCS ○ CS
Albumin	Not Done	Result:	Unit:	Normal	O NCS O CS
Alk Phosphatase	Not Done	Result:	Unit:	Normal	O NCS O CS
AST	Not Done	Result:	Unit:	Normal	O NCS O CS
ALT [Not Done	Result:	Unit:	Normal	O NCS O CS
		inically Significant and CS - Abnormal &Clinically Sig			
Note: At S	dreening visit, please	list the Abnormal and Clinically Significant abnorma	nity in Medic	cal History form.	
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SPECT Redefin	TRUM HARMACEUTICALS ing Cancer Care	Urine Dipstick (Visit 2 Day 35)
Protocol No.	: SPI-QAP-30	06 Site No.: Patient
	ot done, please son:	provide Collection Date (DD/MMM/YYYY)
Test		Result
Glucose	○ Not Done	○ Negative ○ Value*
Ketones	○ Not Done	○ Negative ○ Value*
Specific Gravity	O Not Done	
Blood	ONot Done	Negative Trace Moderate Trace Value*
pН	O Not Done	
Protein	O Not Done	○ Negative ○ Trace ○ Value*
Nitrite	○ Not Done	○ Negative ○ Positive

○ Not Done ○ Negative ○ Value*_____

No.:

Clinical Significance

☐ CS ☐ NCS

☐ CS ☐ NCS

CS NCS

☐ CS ☐ NCS

CS NCS

☐ CS ☐ NCS

CS NCS

☐ CS ☐ NCS

■ Normal

□ Normal

☐ Normal

□ Normal

☐ Normal

■ Normal

☐ Normal

·			☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal & Clinically Significant

Leukocytes





Cystoscopy (Visit 3 Month 3)

Protocol No.: SI	PI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY) Were any le	esions seen?		☐ Yes	
		er of lesions		□ No	
	Were any other abnor	malities seer	n?	○ No ○ Yes	
	If Yes, explain:				
	OP Report uploaded t	o eCaselink?		○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 3 Month 3)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done		ot done, please cify reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology ma	arked as posit	ive *		
Were any enhanced imaging techniques source?	ues used to de		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY)			
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra
Any other t	findings			

SPECTRUM PHARMACEUTICALS Redefining Cancer Care Vital Signs (Visit 3 Month 3)							
tocol No.: SPI-C	QAP-306 Site No.:	Patient No.:					
☐ Not Done	If not done, please specify reas	son					
Date of Assessment	(DD/MMM/YYYY)						
		Body Temperature (°C)					
		Blood Pressure (mmHg) Systolic / Diastolic					
		Heart Rate (beats/minute)					



PHYSICAL EXAMINATION (Visit 3 Month 3)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:							
☐ Check if Physical Examination was not done.							
If not done, please specify reason							
Date of Examination (DD/MMM/YYYY)							
Were there any clinically significant abnormal findings? ☐ No ☐ Yes*							
* (Please record all clinically abnormal findings on the Adverse Events page.							
SAE and AE Reporting Guidelines							
For all Consented patients during the screening process and TURBT. Only Serious Adverse Events related to study procedures.							
For patients who do not receive drug instillation at time of Day 1 TURBT Only Serious Adverse Events related to study procedures, (screening and TURBT)							
For all non-Target population patients, (received agent and discontinued after final pathology) All AEs and SAEs from the time of study drug administration until Day 35 (±5 days) post-TURBT will be recorded and followed until resolution.							
For Target population patients continuing the trial All AEs and SAEs will be recorded from the time of study drug administration until the 3-month Follow-up Visit. Only deaths and AEs related to study procedures will be recorded from the 3 month visit until the End-of-							
Study. Adverse events will be followed until resolution or back to baseline.)							

SPECTR PHARMAC Redefining Ca	CEUTICALS		Complete Bl	ood Count (Visit	t 3 Month	3) Panel Collection of	date	
Protocol No	.: SPI-0	QAP-306 Site	No.:	Patient No.:			(DD/MMI	M/YYYY)
☐ Not Done	Par	nel Lab ID I	f not done,please provide reaso	n		Panel Time Dra	(00:00-2	23:59)
Test Nam	ne:	Not Done	Result	:	Unit	Clinical Sigr	nificance	
WBC		Not Done	Result:		Unit:	Normal	O NCS	○ cs
Hemoglobin		Not Done	Result:		Unit:	Normal	○ NCS	○ cs
Hematocrit		☐ Not Done	Result:		Unit:	Normal	○ NCS	⊖ cs
Platelets		☐ Not Done	Result:		Unit:	Normal	○ NCS	⊖ cs
Wh	here, NC	S - Abnormal, Not Clin	ically Significant and CS - Ab	normal &Clinically Sig	nificant			
			ist the Abnormal and Clinicall he Abnormal and Clinically Si					

SPECTRUM PHARMACEUTICALS		Blood Chemistry (Visit 3 Month 3)			
Protocol No.: SPI-	QAP-306 Site N	lo.: Patient No.: Panel Time Dra	wn	Panel Collection date	Panel Lab ID
☐ Not Done	If not done,please	e provide reason	(00:00-23:59	9) (DD/MMM/YYYY)	
Test Name:	Not Done	Result	Unit	Clinical Sign	ificance
Γ	Not Borns		1	l CNI	C NO. C 00
Glucose	Not Done	Result:	Unit:	Normal	O NCS O CS
Blood Urea Nitrogen	Not Done	Result:	Unit:	Normal	O NCS O CS
Creatinine	Not Done	Result:	Unit:	Normal	O NCS O CS
Sodium	Not Done	Result:	Unit:	Normal	O NCS
Potassium	Not Done	Result:	Unit:	Normal	○ NCS ○ CS
Chloride	Not Done	Result:	Unit:	Normal	O NCS O CS
Carbon Dioxide	Not Done	Result:	Unit:	Normal	O NCS O CS
Albumin	Not Done	Result:	Unit:	Normal	O NCS O CS
Alk Phosphatase	Not Done	Result:	Unit:	Normal	O NCS O CS
AST	Not Done	Result:	Unit:	Normal	O NCS O CS
ALT	Not Done	Result:	Unit:	Normal	O NCS O CS
Where, NC	S - Abnormal, Not Cl	inically Significant and CS - Abnormal &Clinically Sig	nificant		
Note: At S	creening visit, please	list the Abnormal and Clinically Significant abnorma	lity in Medic	cal History form.	
V-1.2 25AUG20177				1	

SPECTRUM PHARMACEUTICALS Redefining Cancer Care										
Protocol No.:	: SPI-QAP-30	06	S							
☐ Not done If no reas	ot done, please son:	provide								
Test										
Glucose	○ Not Done	○ Nega	tive							
Ketones	○ Not Done	○ Nega	tive							
Specific Gravity	O Not Done									

Urine Dipstick (Visit 3 Month 3)

Protocol No.:	SPI-QAP-30	06	Site No.:			Patien	t No.:	
☐ Not done If not reaso	done, please pon:	provide			Collectio	n Date (DD/MMM/YYYY)	_	Clinical Significance
Test			Result					
Glucose	O Not Done	○ Negati	ve	○ Valu	ıe*			CS NCS
Ketones	○ Not Done	○ Negati	ve	⊜ Valu	ıe*			CS NCS
Specific Gravity	O Not Done							CS NCS
Blood	○ Not Done	○ Negati			oderate OTra	ace		CS NCS
рН	○ Not Done							CS NCS
Protein	○ Not Done	○ Negati	ve	e ()Va	alue*			CS NCS
Nitrite	○ Not Done	○ Negati	ve OF	Positive				☐ CS ☐ NCS ☐ Normal
Leukocytes	○ Not Done	○ Negati	ve OValue	e*				☐ CS ☐ NCS ☐ Normal
Where, NCS -	Abnormal, N	Not Clinic	ally Signifi	cant ai	nd CS - Abno	ormal &Clinical	lly Signifi	 Scant

Visit 4 (Month 6)



Cystoscopy (Visit 4 Month 6)

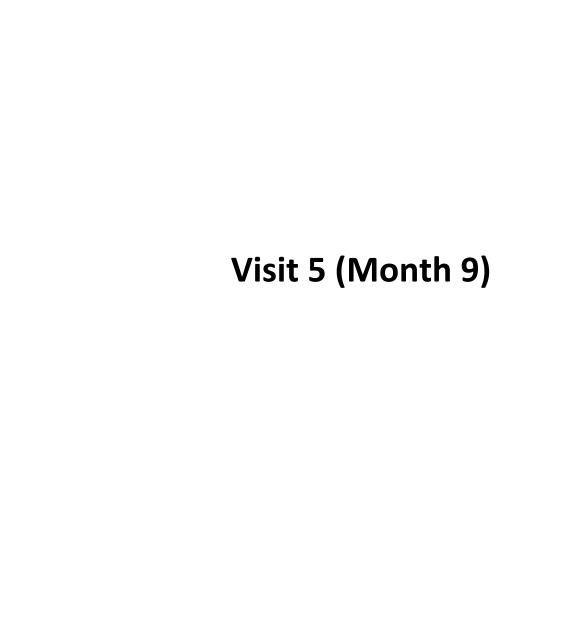
Protocol No.: S	PI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY Were any	() lesions seen?		☐ Yes ☐ No	
	Total num	ber of lesions	noted :		
	Were any other abno	ormalities seer	n?	○ No ○ Yes	
	If Yes, explain:				
	OP Report uploaded	I to eCaselink?	,	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 4 Month 6)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:				
☐ Mark if not done		ot done, please cify reason:					
Collection Date (DD/MMM/YYYY)							
Urine Cytology Results? Positive or suspicious for High Grade Malignancy * Negative, No evidence of Malignancy Other, Specify							
If Cystoscopy negative & Cytology m	arked as positi	ive *					
Were any enhanced imaging techniques source?	es used to de	<u> </u>	es o, Please specify reason_				
<u>If Yes</u>							
Collection Date (DD/MMM/YYYY)						
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	thra			
Any other f	indings						

Protocol N	o.: SPI-QAP-3	06	Site No.:		Patient No.:	
	not done, please eason:	provide		Collection	on Date (DD/MMM/YYYY)	Clinical Significand
Test			Result			
Glucose	○ Not Done	○ Negati	ve 🔷 🗀	/alue*		CS NCS
Blood	○ Not Done	○ Negativ	ve		race	CS NCS
Protein	○ Not Done	○ Negati	ve	Value*	_	CS NCS
Nitrite	○ Not Done	○ Negati	ve (Posit	iive		CS NCS
Leukocytes	○ Not Done	○ Negativ	ve			CS NCS
Where, NO	ES - Abnormal, 1	\ \Vot Clinic	eally Significan	t and CS - Abn	ormal &Clinically Signif	icant (
			, ~ g,			





Cystoscopy (Visit 5 Month 9)

Protocol No.: S	SPI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY) Were any le) esions seen?		☐ Yes	
	·			□ No	
	Total numb	per of lesions	noted :		
	Were any other abnor	rmalities seer	n?	○ No ○ Yes	
	If Yes, explain:	· · · · · · · · · · · · · · · · · · ·			
	OP Report uploaded	to eCaselink?	,	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 5 Month 9)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:				
☐ Mark if not done		ot done, please cify reason:					
Collection Date (DD/MMM/YYYY)							
Urine Cytology Results? Positive or suspicious for High Grade Malignancy * Negative, No evidence of Malignancy Other, Specify							
If Cystoscopy negative & Cytology m	arked as positi	ive *					
Were any enhanced imaging techniques source?	ues used to de		es o, Please specify reason_				
<u>If Yes</u>							
Collection Date (DD/MMM/YYYY)						
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra			
Any other t	findings						

Protocol N	o.: SPI-QAP-3	06	Site No.:		Pat	tient No.:	
	not done, please eason:	provide		Collection	n Date (DD/MMM/Y		Clinical Significanc
Test			Result				
Glucose	○ Not Done	○ Negative	e OV	/alue*			☐ CS ☐ NCS
	0.101.201.0	riogan					☐ Normal
Blood	○ Not Done	○ Negative	e	Moderate OTra)*	CS NCS
Protein	○ Not Done	○ Negative	e () Trace ()	Value*			CS NCS
Nitrite	○ Not Done	○ Negative	e (Positi	ve			CS NCS
Leukocytes	○ Not Done	○ Negative	e				☐ CS ☐ NCS ☐ Normal
Where, NC	CS - Abnormal, 1	Not Clinica	ally Significan	t and CS - Abno	rmal &Clin	ically Signific	cant

Visit 6 (Month 12)



Cystoscopy (Visit 6 Month 12)

Protocol No.: S	SPI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY	·)			
	Were any	lesions seen?		☐ Yes ☐ No	
	Total num	ber of lesions	noted :		
	Were any other abno	ormalities seer	n?	◯ No ◯ Yes	
	If Yes, explain:				
	OP Report uploaded	to eCaselink?	,	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 6 Month 12)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done		ot done, please cify reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology m	arked as positi	ive *		
Were any enhanced imaging techniques source?	ues used to de		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY)			
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra
Any other t	findings			

Protocol N	o.: SPI-QAP-3	Site No.:		Patient No.:	
	not done, please eason:	provide	Colle	ection Date(DD/MMM/YYYY)	Clinical Significance
Test		Result			
Glucose	○ Not Done	○ Negative	○ Value*	_	CS NCS
Blood	○ Not Done			Trace Value*lemolyzed	CS NCS
Protein	○ Not Done	○ Negative ○ Trac	e		CS NCS
Nitrite	○ Not Done	○ Negative	Positive		CS NCS
Leukocytes	○ Not Done	○ Negative ○ Valu	e*		CS NCS
Where. NO	CS - Abnormal, 1	Not Clinically Signif	icant and CS - A	bnormal &Clinically Signif	ïcant

Visit 7 (Month 15)



Cystoscopy (Visit 7 Month 15)

Protocol No.: S	SPI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY) Were any le) esions seen?		☐ Yes	
	·			□ No	
	Total numb	per of lesions	noted :		
	Were any other abnor	rmalities seer	n?	○ No ○ Yes	
	If Yes, explain:	· · · · · · · · · · · · · · · · · · ·			
	OP Report uploaded	to eCaselink?	,	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 7 Month 15)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done		ot done, please cify reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology m	arked as positi	ive *		
Were any enhanced imaging techniques source?	ues used to de		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY)			
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra
Any other t	findings			

Protocol N	o.: SPI-QAP-3	06	Site No.:		Patient No.:	
	not done, please eason:	provide		Collection	on Date (DD/MMM/YYYY)	Clinical Significand
Test			Result			
Glucose	○ Not Done	○ Negativ	/e ()	/alue*		CS NCS
Blood	○ Not Done	○ Negativ	/e Trace Non-Hemolyze		race	CS NCS
Protein	○ Not Done	○ Negativ	ve CTrace C	Value*	_	CS NCS
Nitrite	○ Not Done	○ Negativ	ve ⊜Posit	tive		CS NCS
Leukocytes	○ Not Done	○ Negativ	ve			CS NCS
Where, NO	ES - Abnormal, I	Vot Clinic	allv Significan	at and CS - Abno	ormal &Clinically Signif	icant
			y zigiiyii			

Visit 8 (Month 18)



Cystoscopy (Visit 8 Month 18)

Protocol No.: S	SPI-QAP-306	Site No.:	Patient No.:	
Exam Date	(DD/MMM/YYYY)			
	Were any lesi	ons seen?	☐ Yes ☐ No	
	Total number	of lesions noted :		
	Were any other abnorm	alities seen?	○ No ○ Yes	
	If Yes, explain:		 	
	OP Report uploaded to	eCaselink?	⊜ No ⊝ Yes	
	Comments:			



Urine Cytology (Visit 8 Month 18)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done		ot done, please cify reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology m	arked as positi	ive *		
Were any enhanced imaging techniques source?	ues used to de		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY)			
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra
Any other t	findings			

Protocol N	o.: SPI-QAP-30	06	Site No.:		Patient No.:	
	not done, please eason:	provide		Collection	on Date (DD/MMM/YYYY)	Clinical Significan
Test			Result			
Glucose	○ Not Done	○ Negativ	e OV	/alue*		CS NCS
Blood	○ Not Done	○ Negativ	e Trace Non-Hemolyzed		race OValue*	CS NCS
Protein	○ Not Done	○ Negativ	e	Value*	_	CS NCS
Nitrite	○ Not Done	○ Negativ	e (Positi	ve		CS NCS
Leukocytes	○ Not Done	○ Negativ	e			CS NCS
Where, NC	CS - Abnormal, N	Not Clinica	ally Significan	t and CS - Abn	ormal &Clinically Signific	cant
Where, NC	CS - Abnormal, I	\\ Not Clinica	ally Significan	t and CS - Abn	ormal &Clinically Signific	

Visit 9 (Month 21)



Cystoscopy (Visit 9 Month 21)

Protocol No.: S	SPI-QAP-306 Site No.:	Patient No.:
Exam Date	(DD/MMM/YYYY) Were any lesions seen?	☐ Yes
	There dilly residing seems	□ No
	Total number of lesions noted :	
	Were any other abnormalities seen?	○ No ○ Yes
	If Yes, explain:	
	OP Report uploaded to eCaselink?	○ No ○ Yes
	Comments:	



Urine Cytology (Visit 9 Month 21)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done		ot done, please cify reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology m	arked as positi	ive *		
Were any enhanced imaging techniques source?	ues used to de		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY)			
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra
Any other t	findings			

Protocol N	o.: SPI-QAP-3	06	Site No.:		Patient No.:	
	not done, please eason:	provide		Collection	on Date (DD/MMM/YYYY)	Clinical Significand
Test			Result			
Glucose	○ Not Done	○ Negati	ve 🔷	/alue*		CS NCS
Blood	○ Not Done	○ Negati	ve Trace Non-Hemolyze		race	CS NCS
Protein	○ Not Done	○ Negati	ve	Value*	-	CS NCS
Nitrite	○ Not Done	○ Negati	ve (Posit	tive		CS NCS
Leukocytes	○ Not Done	○ Negati	ve			CS NCS
Where, NO	ES - Abnormal, 1	\ \Vot Clinic	cally Significan	at and CS - Abno	ormal &Clinically Signif	ïcant
,	,		,g . y			

Visit 10 (Month 24)



Cystoscopy (Visit 10 Month 24)

Protocol No.: S	PI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY Were any	() lesions seen?		☐ Yes ☐ No	
	Total num	ber of lesions	noted :		
	Were any other abno	ormalities seer	n?	○ No ○ Yes	
	If Yes, explain:				
	OP Report uploaded	I to eCaselink?	,	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 10 Month 24)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:		
☐ Mark if not done		t done, please ify reason:			
Collection Date (DD/MMM/YYYY)					
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy		
If Cystoscopy negative & Cytology mo	arked as positiv	<u>ve *</u>			
Were any enhanced imaging techniqu source?	ere any enhanced imaging techniques used to determine Ores Oren No, Please specify reason				
<u>If Yes</u>					
Collection Date (DD/MMM/YYYY)					
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra	
Any other f	indings				

V-1.2 25AUG2017

Protocol No.: SPI-QAP-306 Si			ite No.: Patient No.:				
Not done If not done, please provide reason:			Collection Date (DD/MMM/YYYY)			Clinical Significand	
Test			Result				
Glucose	○ Not Done	○ Negative	\bigcirc	/alue*			CS NCS
Blood	○ Not Done	○ Negative	OTrace ON Non-Hemolyze	Moderate OT	race CValue	*	CS NCS
Protein	○ Not Done	○ Negative	○Trace ○	Value*	_		CS NCS
Nitrite	○ Not Done	○ Negative	○ Posit	ive			CS NCS
Leukocytes	○ Not Done	○ Negative	○ Value*				☐ CS ☐ NCS
Where, NC	CS - Abnormal, 1	Vot Clinical	ly Significan	t and CS - Abn	ormal &Clin	ically Signific	cant
,						, ,	

Visit 11 (Month 30)



Cystoscopy (Visit 11 Month 30)

Protocol No.: S	PI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY Were any le) esions seen?		☐ Yes	
				□ No	
	Total numb	per of lesions	noted :		
	Were any other abno	rmalities seer	n?	○ No ○ Yes	
	If Yes, explain:				
	OP Report uploaded	to eCaselink?		○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 11 Month 30)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:		
☐ Mark if not done		t done, please ify reason:			
Collection Date (DD/MMM/YYYY)					
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy		
If Cystoscopy negative & Cytology mo	arked as positiv	<u>ve *</u>			
Were any enhanced imaging techniqu source?	ere any enhanced imaging techniques used to determine Ores Oren No, Please specify reason				
<u>If Yes</u>					
Collection Date (DD/MMM/YYYY)					
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra	
Any other f	indings				

V-1.2 25AUG2017

Protocol N	o.: SPI-QAP-3	06 Site No.:	Patient No.:	
Not done If not done, please provide reason:		provide	Collection Date (DD/MMM/YYYY)	Clinical Significand
Test		Result		
Glucose	○ Not Done	○ Negative	/alue*	☐ CS ☐ NCS
				☐ Normal
Blood	○ Not Done	Negative Trace Non-Hemolyze	Moderate ⊝Trace ⊝Value* d Hemolyzed	CS NCS
Protein	○ Not Done	○ Negative ○ Trace ○) Value*	☐ CS ☐ NCS
Nitrite	○ Not Done	○ Negative ○ Posit	ive	☐ Normal ☐ CS ☐ NCS ☐ Normal
Leukocytes	○ Not Done	○ Negative ○ Value*		CS NCS
Where, NC	CS - Abnormal, 1	Not Clinically Significan	t and CS - Abnormal &Clinically Sign	ificant

Visit 12 (Month 36)



Cystoscopy (Visit 12 Month 36)

Protocol No.: S	SPI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY) Were any le) esions seen?		☐ Yes	
	·			□ No	
	Total numb	per of lesions	noted :		
	Were any other abnor	rmalities seer	n?	○ No ○ Yes	
	If Yes, explain:				
	OP Report uploaded	to eCaselink?	,	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 12 Month 36)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done		t done, please ify reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology mo	ırked as positiv	<u>ve *</u>		
Were any enhanced imaging techniqu source?	es used to de		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY)				
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra
Any other f	indings			

Protocol N	o.: SPI-QAP-3	06 S	ite No.:		Pat	tient No.:	
	not done, please eason:	provide		Collecti	on Date OD/MMM/Y		Clinical Significand
Test			Result				
Glucose	O Not Done	○ Negative	\bigcirc V	/alue*			CS NCS
Blood	○ Not Done	○ Negative	○ Trace ○ Non-Hemolyze	Moderate OT	race OValue	·*	CS NCS
Protein	○ Not Done	○ Negative	○Trace ○	Value*	_		CS NCS
Nitrite	○ Not Done	○ Negative	○ Posit	ive			CS NCS
Leukocytes	○ Not Done	○ Negative	○ Value*				☐ CS ☐ NCS ☐ Normal
Where, NO	CS - Abnormal, 1	⊥ Vot Clinical	ly Significan	t and CS - Abn	ormal &Clin	ically Signific	cant
,	,						

Visit 13 (Month 42)



Cystoscopy (Visit 13 Month 42)

Protocol No.: S	SPI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY) Were any le) esions seen?		☐ Yes	
	·			□ No	
	Total numb	per of lesions	noted :		
	Were any other abnor	rmalities seer	n?	○ No ○ Yes	
	If Yes, explain:				
	OP Report uploaded	to eCaselink?	,	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 13 Month 42)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done	If not do specify r	ne, please reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		○ Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology mo	arked as positive *			
Were any enhanced imaging techniques source?	es used to detern		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY))			
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	thra
Any other f	indings			

Protocol No	o.: SPI-QAP-3	06 S	ite No.:		Pat	ient No.:	
	not done, please eason:	provide		Collection	n Date (DD/MMM/Y)		Clinical Significand
Test			Result				
Glucose	○ Not Done	○ Negative	OV	/alue*			CS NCS
Blood	O Not Done	○ Negative	○ Trace ○ Non-Hemolyzed	Moderate Tra		*	CS NCS
Protein	O Not Done	Negative	○Trace ○	Value*			CS NCS
Nitrite	O Not Done	○ Negative	○ Positi	ive			CS NCS
_eukocytes	○ Not Done	○ Negative	⊜Value*				CS NCS
Where, NC	S - Abnormal, I	Not Clinicall	ly Significant	t and CS - Abno	rmal &Clin	ically Signific	cant

Visit 14 (Month 48)



Cystoscopy (Visit 14 Month 48)

Protocol No.: S	SPI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYY	Y) / lesions seen?		☐ Yes	
		nber of lesions		□ No	
	i otal nui	TIDEL OF TESTORIS	noted .		
	Were any other abr	normalities seer	1?	○ No ○ Yes	
	If Yes, explain:				
	OP Report uploade	d to eCaselink?	•	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 14 Month 48)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done		t done, please ify reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology mo	ırked as positiv	<u>ve *</u>		
Were any enhanced imaging techniqu source?	es used to de		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY)				
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra
Any other f	indings			

Protocol N	o.: SPI-QAP-3	06	Site No.:		Patient No.:	
	f not done, please eason:	provide		Collection	Date (DD/MMM/YYYY)	Clinical Significance
Test			Result			
Glucose	○ Not Done	○ Negativ	ve ()	/alue*		CS NCS
Blood	○ Not Done	○ Negativ	ve Trace (ace	CS NCS
Protein	○ Not Done	○ Negativ	ve CTrace (Value*		CS NCS
Nitrite	○ Not Done	○ Negativ	ve C Posi	tive		CS NCS
Leukocytes	○ Not Done	○ Negativ	ve			CS NCS
Where NO	CS - Abnormal 1	Vot Clinic	ally Significan	ot and CS - Ahno	rmal &Clinically Signific	cant
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	7101101 Huu, 1	voi Ciliic	any significan	i unu CS 110110	mui Cenneuny Signific	

Visit 15 (Month 54)



Cystoscopy (Visit 15 Month 54)

Protocol No.: S	SPI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY				
	Were any I	esions seen?		☐ Yes ☐ No	
	Total numl	per of lesions	noted :		
	Were any other abno	rmalities seer	n?	○ No ○ Yes	
	If Yes, explain:				
	OP Report uploaded	to eCaselink?	,	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 15 Month 54)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done		t done, please ify reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology mo	ırked as positiv	<u>ve *</u>		
Were any enhanced imaging techniqu source?	es used to de		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY)				
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra
Any other f	indings			

Protocol N	o.: SPI-QAP-3	06	Site No.:		Pat	ient No.:	
	not done, please eason:	provide		Collection	n Date		Clinical Significanc
Test			Result	_			
Glucose	○ Not Done	○ Negative	e OV	/alue*			☐ CS ☐ NCS
							Normal
Blood	○ Not Done	○ Negative	e Trace Non-Hemolyzed	Moderate CTra		*	CS NCS
Protein	○ Not Done	○ Negative	e () Trace ())Value*			CS NCS
Nitrite	○ Not Done	○ Negative	e (Positi	ive			CS NCS
Leukocytes	○ Not Done	○ Negative	e OValue*				☐ CS ☐ NCS ☐ Normal
Where. NO	C S - Abnormal, I	Not Clinica	lly Significant	t and CS - Abno	rmal &Clin	ically Signific	cant

Visit 16 (Month 60)



Cystoscopy (Visit 16 Month 60)

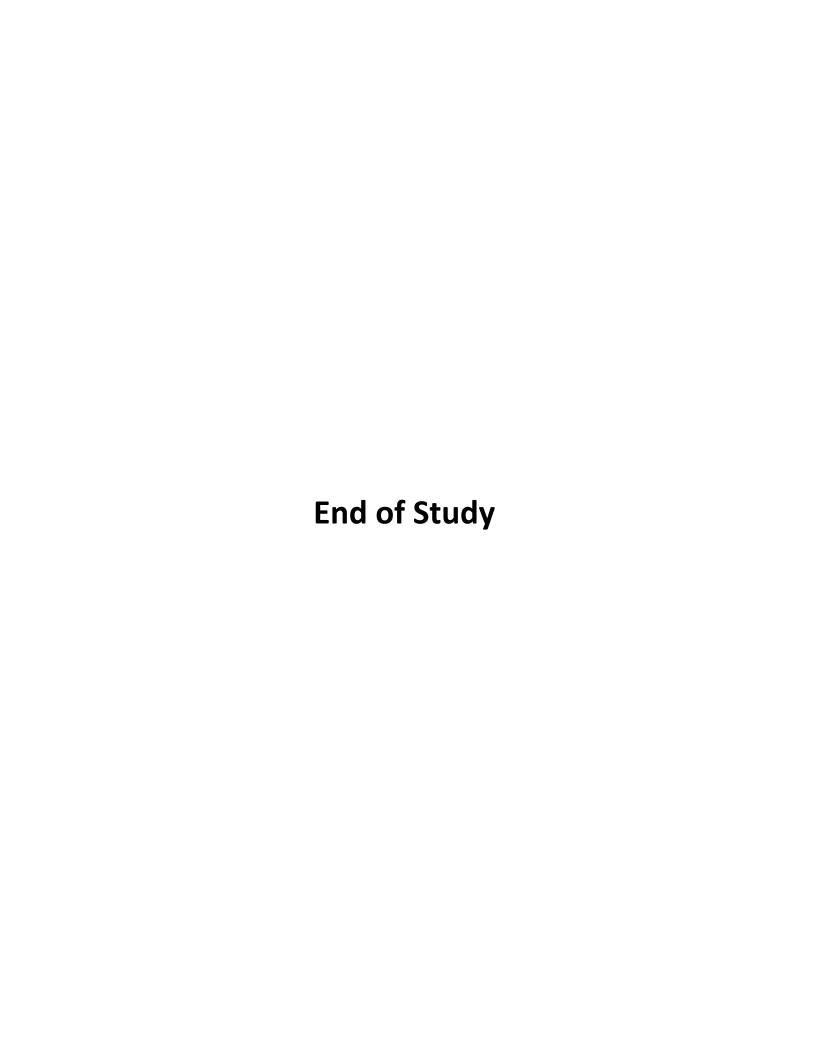
Protocol No.: S	SPI-QAP-306	Site No.:		Patient N	o.:
Exam Date	(DD/MMM/YYYY) Were any le	esions seen?		☐ Yes ☐ No	
	Total numb	er of lesions	noted :		
	Were any other abnor	malities seer	n?	○ No ○ Yes	
	If Yes, explain:				
	OP Report uploaded	o eCaselink?	,	○ No ○ Yes	
	Comments:				



Urine Cytology (Visit 16 Month 60)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:	
☐ Mark if not done		t done, please ify reason:		
Collection Date (DD/MMM/YYYY)				
Urine Cytology Results?		O Negative, No	uspicious for High Grade o evidence of Malignancy fy	
If Cystoscopy negative & Cytology mo	ırked as positiv	<u>ve *</u>		
Were any enhanced imaging techniqu source?	es used to de		es o, Please specify reason_	
<u>If Yes</u>				
Collection Date (DD/MMM/YYYY)				
Was the source determined by enhance techniques per Institute Standard of Car		⊜Yes, Sou	urce is Upper Tract or Ure urce is Bladder could not be determined	ethra
Any other f	indings			

Protocol N	o.: SPI-QAP-3	06	Site No.:		Patient No.:	
	not done, please eason:	provide		Collection	Date (DD/MMM/YYYY)	Clinical Signifi
Test			Result			
Glucose	○ Not Done	○ Negati	ve OV	/alue*		CS
Blood	○ Not Done	○ Negati	ve Trace Non-Hemolyze		rice (Value*	CS Normal
Protein	○ Not Done	○ Negati	ve	Value*		CS I
Nitrite	○ Not Done	○ Negati	ve	ive		CS I
Leukocytes	○ Not Done	○ Negati	ve			CS I
Where, NO	CS - Abnormal, 1	Not Clinic	ally Significan	t and CS - Abno	rmal &Clinically Sigi	nificant





End of Study

Protocol No.: SPI-QAP-30	Site No.:		Patient No.:	
Date patient completed/ withdrew from study:	(DD/MMM/YY	YY)		
Did patient complete protocol-s	pecified treatment and	d all follow-up visits ?		
☐ No ☐ Yes				
If No, discontinued due to (che	ck one box):			
○ It is determined by Day 1 path	ology review that the p	atient has histology ot	her than low- to intermediat	e- risk NMIBC
O Development of an adverse ev	ent (AE) (Please enter	in AE CRF)		
Withdrawal of consent				
Investigator decision, Specify_				
Sponsor decision				
The patient refuses further fol	ow-up study procedure	es, including cystoscop	у	
○ The patient is lost to follow-up	(missed at least two co	onsecutive follow-up cy	stoscopies)	
Patient has a cystectomy				
Patient has a histologically con	nfirmed recurrence			
O Death (please complete death	form)			
Pregnancy				
The study drug was not instilled	ed on Day 1, Specify rea	son	_	
Other, specify				

SPECTRUM PHARMACEUTICALS Redefining Cancer Care
Protocol No.: SPI-QA

Death

otocol No.: SPI-QAP-306	Site No.:	Patient No.:	
Date of Death (DD/MMM/YY			
Cause of Death:			
O Disease Progression			
○ Adverse Event* (<i>Please ent</i>	er in AE CRF)		
Other, specify:		 	-

* (Please record all clinically abnormal findings on the Adverse Events page. Only deaths and AEs related to study procedures will be recorded from the 3 month visit until the End-of-Study.)



PHARMACEUTICALS Redefining Cancer Care	Investigator Ve	erification	
Protocol No.: SPI-QAP-306	Site No.:	Patient No.:	
○ Yes ○ No			
I have reviewed laboratory and i CRFs.	imaging data as well as documentat	tion of data changes. I approve the cor	npleted
Principle Investigator's Signature	-e	Date: (DD/MMM/YYYY)	
Print Name:			

Adverse Events & Concomitant Medications



Adverse Events

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:				
☐ Check if No AEs occurred							
Row: Adverse Event Term*	:				SAE ⁵	☐ No ☐ Yes	
Otart Data:	Data	☐ ☐ Ong	oing SAE		○ Fatal		
	Date:		Categ	ory ⁵ :	○ Life-threatening		
(DD/MMM/YYYY)	(DD/MMM/YYYY)				○ Initial or pr	olonged Hospitalization	
					O Disability of	or Permanent Damage	
Dose Related Action(s) Taken:1	Severity ²	!			○ Congenita	l Anomaly/Birth Defect	
Doco Rolated Felicin(e) Falloni.	Coverny				Other Impo	ortant Medical Events	
Outcome: ³ Relationship to	Study Drug ⁴	Was Tre	eatment Given? ⁶	☐ No	☐ Yes	Are there additional Adverse Events:	☐ Yes
¹ Dose Related Action Taken Codes: ² Event Grade Codes CTCAE (4.03):		³ Outcome Codes:		⁴ Relationshi	p Codes:		
0 = Dose Not Changed 1 = Dose Reduced 2 = Drug Interrupted 3 = Drug Withdrawn 7 = Dose Delayed	1 = Mild 2 = Moderate 3 = Severe 4 = Life-threatening/Disabling 5 = Fatal		1 = Recovered/Resolve 2 =Recovered/ Resolve sequelae 3 = Not Resolved 4 = Fatal 5 = Unknown		0 = Not Relate 1 = Unlikely R 2 = Possibly F 3 = Probably F 4 = Definitely	elated Related Related	
⁵ SAEs (regardless of their relationship to study Pharmaceuticals, Inc.Primary Contact: Pharmaceuticals, I	macovigilance Department Fa	ax: +1 (949) 86	adverse event report (SAE 1-6599 E-mail: drugsafet	ER) faxed or y@sppirx.c	e-mailed within 2 om	4 hours of knowledge of the even	t to: Spectrum

(*SAE and AE Reporting Guidelines

For all Consented patients during the screening process and TURBT. Only Serious Adverse Events related to study procedures.

For patients who do not receive drug instillation at time of Day 1 TURBT Only Serious Adverse Events related to study procedures, (screening and TURBT)

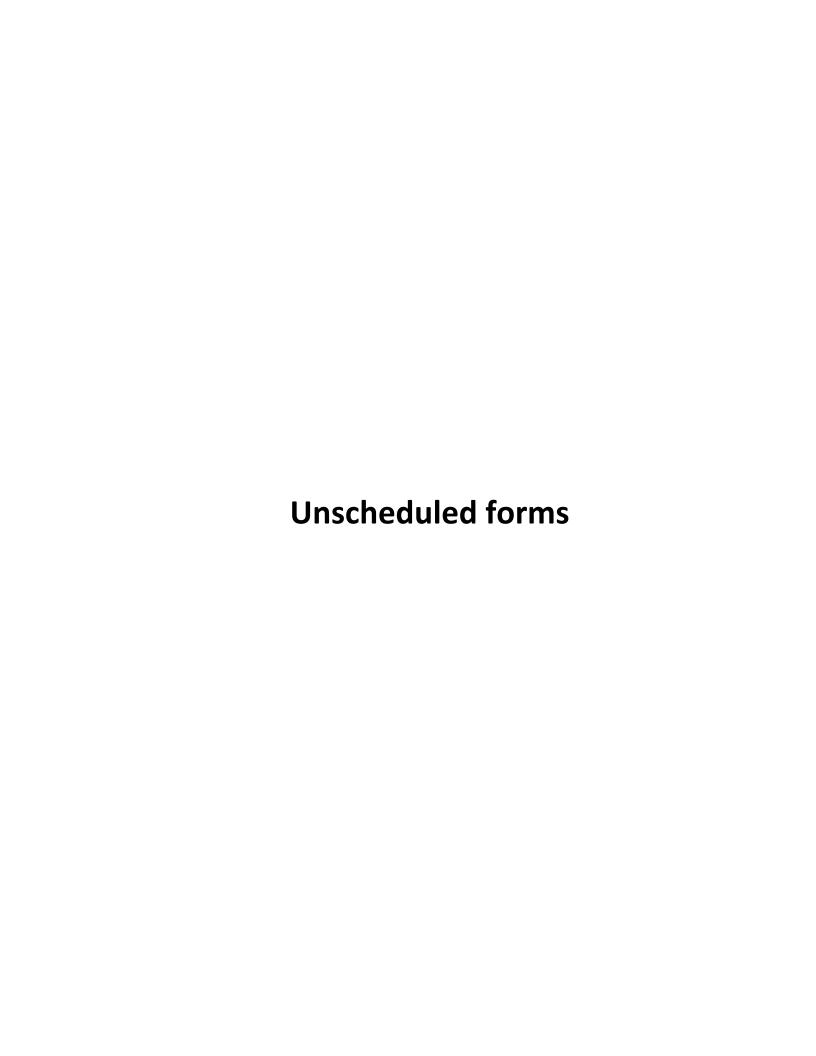
For all non-Target population patients, (received agent and discontinued after final pathology) All AEs and SAEs from the time of study drug administration until Day 35 (±5 days) post-TURBT will be recorded and followed until resolution.

For Target population patients continuing the trial All AEs and SAEs will be recorded from the time of study drug administration until the 3-month Follow-up Visit. Only deaths and AEs related to study procedures will be recorded from the 3 month visit until the End-of-Study. Adverse events will be followed until resolution or back to baseline.)

SPECTRUM PHARMACEUTICALS Redefining Cancer Care
Protocol No.: SPI
Check if No Medica
Row: Med

Concomitant Medications

Protocol No.: SPI-QAP-306 Site No.: Patient No.:
☐ Check if No Medications were given
Row: Medication: Dose Unit: Dosing Frequency
Prophylaxis
Route:
☐ Topical ☐ Nasal ☐ Intraocular ☐ OTHER: Specify:
Start Date: Stop Date: Continuing (DD/MMM/YYYY) (DD/MMM/YYYY)
Are there additional Concomitant Medications?



SPECTRUN PHARMACEUTIC Redefining Cancer C	vital Signs	(Unscheduled)
Protocol No.: SPI-C	Site No.:	Patient No.:
☐ Not Done	If not done, please specify reason	
Date of Assessment	(DD/MMM/YYYY)	
		Body Temperature (°C)
		Blood Pressure (mmHg) Systolic / Diastolic
		Heart Rate (beats/minute)



PHYSICAL EXAMINATION (Unscheduled)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:
☐ Check if Physical Examination was not done.
If not done, please specify reason
Date of Examination (DD/MMM/YYYY)
Were there any clinically significant abnormal findings? ☐ No ☐ Yes*
* (Please record all clinically abnormal findings on the Adverse Events page.
SAE and AE Reporting Guidelines
For all Consented patients during the screening process and TURBT. Only Serious Adverse Events related to study procedures.
For patients who do not receive drug instillation at time of Day 1 TURBT Only Serious Adverse Events related to study procedures, (screening and TURBT)
For all non-Target population patients, (received agent and discontinued after final pathology) All AEs and SAEs from the time of study drug administration until Day 35 (±5 days) post-TURBT will be recorded and followed until resolution.
For Target population patients continuing the trial All AEs and SAEs will be recorded from the time of study drug administration until the 3-month Follow-up Visit. Only deaths and AEs related to study procedures will be recorded from the 3 month visit until the End-of-
Study. Adverse events will be followed until resolution or back to baseline.)

SPECTRI PHARMACI Redefining Can	UM" EUTICALS Incer Care			Complete Blood Co	unt (Un	schedu	uled) Panel Coll	ection date	
Protocol No.: SPI-QAP-306 Site No.:				Patient No.:				(DD/N	1MM/YYYY)
□ Not Done	Pa	nel Lab ID	f not do	ne,please provide reason			Panel Ti	ime Drawn	20.00.50
								•	00-23:59)
Test Nam	e:	Not Done		Result		Unit	(where NCS-A	cal Significance Abnormal, Not C ignificant & I &Clinically Sig	linically
WBC		Not Done	Result:		Unit	::	Normal	○ NCS	○ cs
Hemoglobin		Not Done	Result:		Unit	::	Normal	○ NCS	○ cs
Hematocrit		Not Done	Result:		Unit	::	Normal	○ NCS	○ cs
Platelets		Not Done	Result:		Unit	::	Normal	○ NCS	○ cs
V-1.2 25AUG20)17								

SPECTRUN PHARMACEUTICAL	n's	BI	ood Chemistry (Unscheduled)					
Protocol No.: SP	ere.	lo.:	Patient No.: Panel Time Dr	awn	Panel Collection date	Panel La	ab di	
☐ Not Done	If not done,please	e provide	e reason	(00:00-2	(00:00-23:59) (DD/MMM/YYYY)			
Test Name:	Not Done		Result	Unit	Unit Clinical Significance			
Glucose	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
Blood Urea Nitrogen	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
Creatinine	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
Sodium	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
Potassium	Not Done	Result:		Unit:	Normal	○ NCS	○ CS	
Chloride	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
Carbon Dioxide	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
Albumin	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
Alk Phosphatase	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
AST	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
ALT	Not Done	Result:		Unit:	Normal	○ NCS	○ cs	
14/1	NOO Almania Nation	::	Cinnificant and CO. Alexander 1900's 11 O.					
			Significant and CS - Abnormal & Clinically Si Abnormal and Clinically Significant abnorm		adical History form			
Note: At	Sureening visit, please	nst uie	Abnormal and Chincally Significant abnorm	anty III IVIE	च्याज्या माठाण ५ १०॥॥.			
V-1.2 25AUG20177								



Cystoscopy (Unscheduled)

Protocol No.: S	SPI-QAP-306	Site No.:		Patient No.:	
Exam Date	(DD/MMM/YYYY)				
	Were any les	ions seen?	☐ Yes		
	Total number	r of lesions noted :			
	Were any other abnorm	nalities seen?		○ No ○ Yes	
	If Yes, explain:				
	OP Report uploaded to	eCaselink?		○ No ○ Yes	
	Comments:				_



Urine Cytology (Unscheduled)

Protocol No.: SPI-QAP-306	Site No.:		Patient No.:						
☐ Mark if not done		ot done, please cify reason:							
Collection Date (DD/MMM/YYYY)									
Urine Cytology Results?		Positive or suspicious for High Grade Malignancy *Negative, No evidence of MalignancyOther, Specify							
If Cystoscopy negative & Cytology m	If Cystoscopy negative & Cytology marked as positive *								
Were any enhanced imaging techniques used to determine Source? One No, Please specify reason									
<u>If Yes</u>									
Collection Date (DD/MMM/YYYY)								
Was the source determined by enhance techniques per Institute Standard of Ca		hra							
Any other	findings								

Protocol No.	: SPI-QAP-3	06	Site No.:		Pa	tient No.:		
Not done If not done, please provide reason:			Collection Date (DD/MMM/YYYY)				Clinical Significance	
Test			Result					
Glucose	○ Not Done	○ Nega	tive \(\)	/alue*			CS NCS	
Ketones	○ Not Done	O Negative O Value*					CS NCS	
Specific Gravity	O Not Done						CS NCS	
Blood	○ Not Done	○ Nega	tive Trace (Moderate Tra		e*	CS NCS	
рН	O Not Done						CS NCS	
Protein	O Not Done	○ Nega	tive	Value*			CS NCS	
Nitrite	○ Not Done	○ Nega	tive	tive			CS NCS	
Leukocytes	○ Not Done	○ Nega	tive				CS NCS	
Where, NCS	- Abnormal, I	Not Clin	ically Significan	at and CS - Abno	rmal &Clin	ically Signific	cant	



Transurethral Resection of Bladder Tumor (Unscheduled)

Protocol No.: SPI-QAP-306	Site No.: Patient No.:						
Date of TURBT (DD/MMM/YYYY)							
TURBT Start Time (00:00 to 23:59)	Visualization						
TURBT Stop Time							
(00:00 to 23:59) Total Number of Lesions	Post resection No irrigation Syringe Irrigation Continuous Bladder Irrigation Bladder Irrigation Syringe Irrigation Syringe Irrigation Continuous Bladder Irrigation Syringe Irrigation No irrigation Syringe Irrigation Continuous Bladder Irrigation Syringe Irrigation Continuous Bladder Irrigation Syringe Irrigation Continuous Bladder Irrigation Syringe Irrigation No irrigation Syringe Irrigation Continuous Bladder Irrigation Syringe Irrigation Continuous Syringe Irrigation Syringe Irrigation						
Lesion Site # Location Code# Size(cm)							
1	OP Report uploaded to eCaselink: Yes						
2	○ No						
3	Comments :						
4							
5							
6	(Note:- All Histology specimens should be sent to local pathology laboratory, each						
7	lesion in separate specimen container identified by site & lesion number). (If sending multiple specimens from same lesion please mark consistently as A.						
8	Lesion 1, left wall papillary tumor: B. Lesion 1 left wall, base of tumor and so on.)						
A= Anterior Wall P= P	ateral Wall L=Left Lateral Wall						



Pathology (Unscheduled)

Protocol No.: SPI-QAP-306			Site No.:				Patient No.:	
☐ Not Done Date of s Please provide the location codes*			f sample collect	cample collection (DD/MMM/YYYY) Report Date WHO 2004				(DD/MMM/YYYY)
Lesion Site #	i i				Muscular	is Prop	oria Presence	
1				Canr	not be determin	ned (ex	cle Absent plain) pon by pathologist	
2								
3				Canr	not be determin	ned (ex	cle Absent plain) pon by pathologist	
4				Canr	not be determir	ned (ex	cle Absent plain) pon by pathologist	
5				Canr	not be determin	ned (ex	cle Absent plain) pon by pathologist	
6				Canr	not be determir	ned (ex	cle Absent plain) pon by pathologist	
7				Canr	not be determir	ned (ex	cle Absent plain) pon by pathologist	
8				Canr	not be determin	ned (ex	cle Absent plain) pon by pathologist	
	G,Mitomyc	additional intravesic in) for bladder cance		⊜Y€ ⊝No	,	report	therapy on Concom	nitant Medication page)

Report uploaded to eCaselink?	⊜Yes ⊝No
Comments:	
# Tumor Site: T= Trigone R= Right Lateral Wall L=Left Latera	al Wall
A= Anterior Wall P= Posterior Wall D= Dome O= Other, Specify N= Not Specified E * pT Stage Codes:	3= Bladder Neck
pTX: Primary tumor cannot be assessed pT0: No evidence of primary tumor pTa: Noninvasive papillary carcinoma pTis: Carcinoma in situ: "flat tumor" pT1: Tumor invades lamina propria (subepithelial cont pT2: Tumor invades muscularis propria (detrusor mus pT2a: Tumor invades superficial muscularis propria (in pT2b: Tumor invades deep muscularis propria (outer pT3: Tumor invades perivesical tissue pT3a: Microscopically (extravesicular mass)	ccle) nner half)

2004 WHO / ISUP Consensus Classification for Urothelial Lesions

pT4b: Extravesical tumor invades pelvic wall, or abdominal wall

pT4: Tumor invades any of the following: prostatic stroma, seminal vesicles, uterus, vagina, pelvic wall, abdominal wall pT4a: Extravesical tumor invades directly into prostatic stroma, uterus, or

Urothelial carcinoma in situ

vagina

Papillary urothelial carcinoma, low grade

Papillary urothelial carcinoma, high grade

Papillary urothelial neoplasm of low malignant potential

Urothelial papilloma

Inverted urothelial papilloma

Other