

EXHIBIT A

ICH stability	Batch number 27001369			Stability Condition		Reason		Protocol number		Packaging		
Item 2001063	Pilot batch			25°C - 60 % RH		1 st batch		PS 212.070 Ed 03		Double LDPE bag inside a heat sealed foil pouch inside an HDPE drum		
Analysis	Specifications \ Time points	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₀	T ₃₆	T ₄₈	T ₆₀
Appearance	White to off-white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply	Comply	Comply	Comply	Comply		Comply	Comply	
XRPD	Corresponds to the reference (form A)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Comply*	Comply	Comply	
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	100.5	100.1	100.3	99.9	100.8	98.3	97.5		98.9	99.9	
Assay by UPLC	For information (%w/w as is)	100.4	100.1	100.2	99.9	100.8	98.3	97.5		98.9	99.9	
Individual impurities												
KPT-375	≤ 0,15 % w/w	ND	ND	ND	ND	0.07	ND	ND		ND	ND	
KPT-454	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND		ND	ND	
KPT-453	≤ 0.15 % w/w	ND	ND	ND	ND	< LOQ	ND	ND		ND	ND	
KPT-452	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND		ND	ND	
KPT-479	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
KPT-509	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
KPT-472	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
Any other individual impurity	≤ 0.10 % w/w	ND	ND	ND	ND	ND	ND	ND		< LOQ	ND	
Total impurity	≤ 1,5 % w/w	NQ	NQ	NQ	NQ	0.07	NQ	NQ		NQ	NQ	
Water content by KF	≤ 2,0 % w/w	0.02	0.07	0.06	0.03	0.00	0.05	0.03		< LOQ	< LOQ	
Residual KPT-459 by LC/MS	≤ 40 ppm	< 40	< 40	< 40	< 40	< 40	< 40	< 5		< 5	< 5	
Residual KPT-534 by LC/MS	≤ 40 ppm	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
Residual KPT-548 by LC/MS	≤ 40 ppm	N/a	N/a	N/a	N/a	N/a	N/a	6		6	5	
Microbial limit tests												
TAMC	≤ 1000 CFU/g	Comply				Comply		Comply		Comply	Comply	
TYMC	≤ 100 CFU/g	Comply				Comply		Comply		Comply	Comply	
Specified microorganism												
- <i>Staphylococcus aureus</i>	Absence	Comply				Comply		Comply		Comply	Comply	
- <i>Escherichia coli</i>	Absence	Comply				Comply		Comply		Comply	Comply	
- <i>Pseudomonas aeruginosa</i>	Absence	Comply				Comply		Comply		Comply	Comply	
- <i>Salmonella</i>	Absence	Comply				Comply		Comply		Comply	Comply	

ND: Not detected

NQ: Not Quantifiable

LOQ: Limit of quantification = 0,05 %

N/a: Not applicable

*Protocol revised to include XRPD at T30M

Exhibit A

ICH stability	Batch number 27001370			Stability Condition		Reason		Protocol number		Packaging		
Item 2001063	Pilot batch			25°C - 60 % RH		2nd batch		PS 212.070 Ed 03		Double LDPE bag inside a heat sealed foil pouch inside an HDPE drum		
Analysis	Specifications \ Time points	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₀	T ₃₆	T ₄₈	T ₆₀
Appearance	White to off-white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply	Comply	Comply	Comply	Comply		Comply	Comply	
XRPD	Corresponds to the reference (form A)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Complies*	Comply	Comply	
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	101.2	99.2	100.2	100.2	100.3	101.1	97.6		99.6	99.2	
Assay by UPLC	For information (%w/w as is)	101.2	99.2	100.2	100.1	100.3	101.0	97.6		99.6	99.2	
Individual impurities												
KPT-375	≤ 0,15 % w/w	ND	ND	ND	ND	< LOQ	ND	ND		ND	ND	
KPT-454	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND		ND	ND	
KPT-453	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND		ND	ND	
KPT-452	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND		ND	ND	
KPT-479	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
KPT-509	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
KPT-472	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
Any other individual impurity	≤ 0.10 % w/w	ND	ND	ND	ND	< LOQ	ND	ND		< LOQ	ND	
Total impurity	≤ 1,5 % w/w	NQ	NQ	NQ	NQ	NQ	NQ	NQ		NQ	NQ	
Water content by KF	≤ 2,0 % w/w	0.02	0.02	0.05	0.01	0.00	0.06	0.05		< LOQ	< LOQ	
Residual KPT-459 by LC/MS	≤ 40 ppm	< 40	< 40	< 40	< 40	< 40	< 40	ND		< 5	< 5	
Residual KPT-534 by LC/MS	≤ 40 ppm	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
Residual KPT-548 by LC/MS	≤ 40 ppm	N/a	N/a	N/a	N/a	N/a	N/a	ND		< 5	< 5	
Microbial limit tests												
- TAMC	≤ 1000 CFU/g	Comply				Comply		Comply		Comply	Comply	
- TYMC	≤ 100 CFU/g	Comply				Comply		Comply		Comply	Comply	
Specified microorganism												
- <i>Staphylococcus aureus</i>	Absence	Comply				Comply		Comply		Comply	Comply	
- <i>Escherichia coli</i>	Absence	Comply				Comply		Comply		Comply	Comply	
- <i>Pseudomonas aeruginosa</i>	Absence	Comply				Comply		Comply		Comply	Comply	
- <i>Salmonella</i>	Absence	Comply				Comply		Comply		Comply	Comply	

ND: Not detected

NQ: Not quantifiable

LOQ = Limit of quantification = 0,05%

N/a: Not applicable

*Protocol revised to include XRPD at T30M

Exhibit A

ICH stability	Batch number 27001373			Stability Condition		Reason		Protocol number			Packaging	
Item 2001063	Pilot batch			25°C - 60 % RH		3rd batch		PS 212.070 Ed 03			Double LDPE bag inside a heat sealed foil pouch inside an HDPE drum.	
Analysis	Specifications \ Time points	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₀	T ₃₆	T ₄₈	T ₆₀
Appearance	White to off-white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply	Comply	Comply	Comply	Comply		Comply	Comply	
XRPD	Corresponds to the reference (form A)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Complies*	Comply	Comply	
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	100.8	99.8	100.2	100.4	100.0	99.4	98.0		99.2	99.4	
Assay by UPLC	For information (%w/w as is)	100.7	99.8	100.2	100.3	100.0	99.3	98.0		99.2	99.4	
Individual impurities												
KPT-375	≤ 0,15 % w/w	ND	ND	ND	ND	0.09	ND	ND		ND	ND	
KPT-454	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND		ND	ND	
KPT-453	≤ 0.15 % w/w	ND	ND	ND	ND	< LOQ	ND	ND		ND	ND	
KPT-452	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND		ND	ND	
KPT-479	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
KPT-509	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
KPT-472	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
Any other individual impurity	≤ 0.10 % w/w	ND	ND	ND	ND	ND	ND	ND		< LOQ	ND	
Total impurity	≤ 1,5 % w/w	NQ	NQ	NQ	NQ	0.09	NQ	NQ		NQ	NQ	
Water content by KF	≤ 2,0 % w/w	0.03	0.01	0.04	0.01	0.01	0.05	0.07		< LOQ	< LOQ	
Residual KPT-459 by LC/MS	≤ 40 ppm	< 40	< 40	< 40	< 40	< 40	< 40	< 5		ND	ND	
Residual KPT-534 by LC/MS	≤ 40 ppm	N/a	N/a	N/a	N/a	N/a	N/a	ND		ND	ND	
Residual KPT-548 by LC/MS	≤ 40 ppm	N/a	N/a	N/a	N/a	N/a	N/a	< 5		< 5	< 5	
Microbial limit tests												
- TAMC	≤ 1000 CFU/g	Comply				Comply		Comply		Comply	Comply	
- TYMC	≤ 100 CFU/g	Comply				Comply		Comply		Comply	Comply	
Specified microorganism												
- <i>Staphylococcus aureus</i>	Absence	Comply				Comply		Comply		Comply	Comply	
- <i>Escherichia coli</i>	Absence	Comply				Comply		Comply		Comply	Comply	
- <i>Pseudomonas aeruginosa</i>	Absence	Comply				Comply		Comply		Comply	Comply	
- <i>Salmonella</i>	Absence	Comply				Comply		Comply		Comply	Comply	

ND: Not detected

NQ: Not quantifiable

LOQ: Limit of quantification = 0,05 %

N/a: Not applicable

*Protocol revised to include XRPD at T30M

Exhibit A

ICH stability	Batch number 27001383			Stability Condition		Reason		Protocol number		Packaging	
Item 2001083	Pilot batch			25°C - 60 % RH		4 th batch		PS 212.071 Ed 02		Double LDPE bag inside a heat sealed foil pouch inside an HDPE drum	
Analysis	Specifications \ Time points	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆	T ₄₈	T ₆₀
Appearance	White to off-white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	white powder	
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply	Comply	Comply	Comply	Comply	Comply	Comply	
XRPD	Corresponds to the reference (form A)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Comply	Comply	
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	98.9	99.1	100.1	98.4	99.9	99.1	98.0	98.7	99.9	
Assay by UPLC	For information (%w/w as is)	98.8	99.1	100.1	98.2	99.9	99.1	98.0	98.7	99.9	
Individual impurities											
KPT-375	≤ 0,15 % w/w	0.05	ND	ND	ND	ND	ND	ND	ND	ND	
KPT-454	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND	ND	ND	
KPT-453	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND	ND	ND	
KPT-452	≤ 0.15 % w/w	ND	ND	ND	ND	ND	ND	ND	ND	ND	
KPT-479	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND	ND	ND	
KPT-509	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND	ND	ND	
KPT-472	≤ 0.15 % w/w	N/a	N/a	N/a	N/a	N/a	N/a	ND	ND	ND	
Any other individual impurity	≤ 0.10 % w/w	ND	ND	ND	ND	ND	ND	ND	< LOQ	ND	
Total impurity	≤ 1,5 % w/w	0.05	NQ	NQ	NQ	NQ	NQ	NQ	NQ	NQ	
Water content by KF	≤ 2,0 % w/w	0.05	0.05	0.04	0.02	0.07	0.05	0.04	< LOQ	< LOQ	
Residual KPT-459 by LC/MS	≤ 40 ppm	< 40	< 40	< 40	< 40	< 40	< 40	< 5	ND	ND	
Residual KPT-534 by LC/MS	≤ 40 ppm	N/a	N/a	N/a	N/a	N/a	N/a	ND	ND	ND	
Residual KPT-548 by LC/MS	≤ 40 ppm	N/a	N/a	N/a	N/a	N/a	N/a	< 5	ND	ND	
Microbial limit tests											
- TAMC	≤ 1000 CFU/g	Comply				Comply		Comply	Comply	Comply	
- TYMC	≤ 100 CFU/g	Comply				Comply		Comply	Comply	Comply	
Specified microorganism											
- <i>Staphylococcus aureus</i>	Absence	Comply				Comply		Comply	Comply	Comply	
- <i>Escherichia coli</i>	Absence	Comply				Comply		Comply	Comply	Comply	
- <i>Pseudomonas aeruginosa</i>	Absence	Comply				Comply		Comply	Comply	Comply	
- <i>Salmonella</i>	Absence	Comply				Comply		Comply	Comply	Comply	

ND: Not detected

NQ: Not quantifiable

LOQ: Limit of quantification = 0,05 %

N/a: Not applicable