

EXHIBIT B

ICH stability	Batch number 27001369			Stability Condition				Protocol number		Packaging	
Item 2001063	Pilot batch			25°C - 60 % RH				PS 212.070 Ed 01		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							
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply							
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	100,5	100,1	100,3							
Assay by UPLC	For information (%w/w as is)	100,4	100,1	100,2							
Individual impurities											
KPT-375	≤ 1.5 % w/w	ND	ND	ND							
KPT-454	≤ 0.5 % w/w	ND	ND	ND							
KPT-453	≤ 0.5 % w/w	ND	ND	ND							
KPT-452	≤ 0.5 % w/w	ND	ND	ND							
Any other individual impurity	≤ 0.5 % w/w	ND	ND	ND							
Total impurity	≤ 2,0 % w/w	ND	ND	ND							
Water content by KF	≤ 2,0 % w/w	0,02	0,07	0,06							
Residual KPT-459 in KPT-330	≤ 40 ppm	< 40	< 40	< 40							
Microbial limit tests											
- TAMC	≤ 1000 CFU/g	Comply									
- TYMC	≤ 100 CFU/g	Comply									
Specified microorganism											
- <i>Staphylococcus aureus</i>	Absence	Comply									
- <i>Escherichia coli</i>	Absence	Comply									
- <i>Pseudomonas aeruginosa</i>	Absence	Comply									
- Salmonella	Absence	Comply									

ND: Not detected

Exhibit B

ICH stability	Batch number 27001369			Stability Condition				Protocol number		Packaging	
Item 2001083	Pilot batch			40°C - 75 % RH				PS 212.070 Ed 01		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							
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply							
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	100,5	100,8	100,4							
Assay by UPLC	For information (%w/w as is)	100,4	100,7	100,4							
Individual impurities											
KPT-375	≤ 1.5 % w/w	ND	ND	ND							
KPT-454	≤ 0.5 % w/w	ND	ND	ND							
KPT-453	≤ 0.5 % w/w	ND	ND	ND							
KPT-452	≤ 0.5 % w/w	ND	ND	ND							
Any other individual impurity	≤ 0.5 % w/w	ND	ND	ND							
Total impurity	≤ 2,0 % w/w	ND	ND	ND							
Water content by KF	≤ 2,0 % w/w	0,02	0,09	0,05							
Residual KPT-459 in KPT-330	≤ 40 ppm	< 40	< 40	< 40							
Microbial limit tests											
- TAMC	≤ 1000 CFU/g	Comply									
- TYMC	≤ 100 CFU/g	Comply									
Specified microorganism											
- <i>Staphylococcus aureus</i>	Absence	Comply									
- <i>Escherichia coli</i>	Absence	Comply									
- <i>Pseudomonas aeruginosa</i>	Absence	Comply									
- Salmonella	Absence	Comply									

ND: Not detected

Exhibit B

ICH stability	Batch number 27001370			Stability Condition				Protocol number		Packaging	
Item 2001063	Pilot batch			25°C - 60 % RH				PS 212.070 Ed 01		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							
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply							
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	101,2	99,2	100,2							
Assay by UPLC	For information (%w/w as is)	101,2	99,2	100,2							
Individual impurities											
KPT-375	≤ 1.5 % w/w	ND	ND	ND							
KPT-454	≤ 0.5 % w/w	ND	ND	ND							
KPT-453	≤ 0.5 % w/w	ND	ND	ND							
KPT-452	≤ 0.5 % w/w	ND	ND	ND							
Any other individual impurity	≤ 0.5 % w/w	ND	ND	ND							
Total impurity	≤ 2,0 % w/w	ND	ND	ND							
Water content by KF	≤ 2,0 % w/w	0,02	0,02	0,05							
Residual KPT-459 in KPT-330	≤ 40 ppm	< 40	< 40	< 40							
Microbial limit tests											
- TAMC	≤ 1000 CFU/g	Comply									
- TYMC	≤ 100 CFU/g	Comply									
Specified microorganism											
- <i>Staphylococcus aureus</i>	Absence	Comply									
- <i>Escherichia coli</i>	Absence	Comply									
- <i>Pseudomonas aeruginosa</i>	Absence	Comply									
- <i>Salmonella</i>	Absence	Comply									

ND: Not detected

Exhibit B

ICH stability	Batch number 27001370			Stability Condition				Protocol number		Packaging	
Item 2001083	Pilot batch			40°C - 75 % RH				PS 212.070 Ed 01		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							
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply							
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	101,2	100,0	100,5							
Assay by UPLC	For information (%w/w as is)	101,2	100,0	100,5							
Individual impurities											
KPT-375	≤ 1.5 % w/w	ND	ND	ND							
KPT-454	≤ 0.5 % w/w	ND	ND	ND							
KPT-453	≤ 0.5 % w/w	ND	ND	ND							
KPT-452	≤ 0.5 % w/w	ND	ND	ND							
Any other individual impurity	≤ 0.5 % w/w	ND	ND	ND							
Total impurity	≤ 2,0 % w/w	ND	ND	ND							
Water content by KF	≤ 2,0 % w/w	0,02	0,03	0,04							
Residual KPT-459 in KPT-330	≤ 40 ppm	< 40	< 40	< 40							
Microbial limit tests											
- TAMC	≤ 1000 CFU/g	Comply									
- TYMC	≤ 100 CFU/g	Comply									
Specified microorganism											
- <i>Staphylococcus aureus</i>	Absence	Comply									
- <i>Escherichia coli</i>	Absence	Comply									
- <i>Pseudomonas aeruginosa</i>	Absence	Comply									
- <i>Salmonella</i>	Absence	Comply									

ND: Not detected

Exhibit B

ICH stability	Batch number 27001373			Stability Condition				Protocol number		Packaging	
Item 2001063	Pilot batch			25°C - 60 % RH				PS 212.070 Ed 01		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							
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply							
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	100,8	99,8	100,2							
Assay by UPLC	For information (%w/w as is)	100,7	99,8	100,2							
Individual impurities											
KPT-375	≤ 1.5 % w/w	ND	ND	ND							
KPT-454	≤ 0.5 % w/w	ND	ND	ND							
KPT-453	≤ 0.5 % w/w	ND	ND	ND							
KPT-452	≤ 0.5 % w/w	ND	ND	ND							
Any other individual impurity	≤ 0.5 % w/w	ND	ND	ND							
Total impurity	≤ 2,0 % w/w	ND	ND	ND							
Water content by KF	≤ 2,0 % w/w	0,03	0,01	0,04							
Residual KPT-459 in KPT-330	≤ 40 ppm	< 40	< 40	< 40							
Microbial limit tests											
- TAMC	≤ 1000 CFU/g	Comply									
- TYMC	≤ 100 CFU/g	Comply									
Specified microorganism											
- <i>Staphylococcus aureus</i>	Absence	Comply									
- <i>Escherichia coli</i>	Absence	Comply									
- <i>Pseudomonas aeruginosa</i>	Absence	Comply									
- Salmonella	Absence	Comply									

ND: Not detected

Exhibit B

ICH stability	Batch number 27001373			Stability Condition				Protocol number		Packaging	
Item 2001083	Pilot batch			40°C - 75 % RH				PS 212.070 Ed 01		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							
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply							
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	100,8	100,4	100,2							
Assay by UPLC	For information (%w/w as is)	100,7	100,4	100,1							
Individual impurities											
KPT-375	≤ 1.5 % w/w	ND	ND	ND							
KPT-454	≤ 0.5 % w/w	ND	ND	ND							
KPT-453	≤ 0.5 % w/w	ND	ND	ND							
KPT-452	≤ 0.5 % w/w	ND	ND	ND							
Any other individual impurity	≤ 0.5 % w/w	ND	ND	ND							
Total impurity	≤ 2,0 % w/w	ND	ND	ND							
Water content by KF	≤ 2,0 % w/w	0,03	0,02	0,04							
Residual KPT-459 in KPT-330	≤ 40 ppm	< 40	< 40	< 40							
Microbial limit tests											
- TAMC	≤ 1000 CFU/g	Comply									
- TYMC	≤ 100 CFU/g	Comply									
Specified microorganism											
- <i>Staphylococcus aureus</i>	Absence	Comply									
- <i>Escherichia coli</i>	Absence	Comply									
- <i>Pseudomonas aeruginosa</i>	Absence	Comply									
- Salmonella	Absence	Comply									

ND: Not detected

Exhibit B

ICH stability	Batch number 27001383			Stability Condition				Protocol number		Packaging	
Item 2001083	Pilot batch			25°C - 60 % RH				PS 212.071 Ed 01		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							
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply							
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	98,9	99,1	100,1							
Assay by UPLC	For information (%w/w as is)	98,8	99,1	100,1							
Individual impurities											
KPT-375	≤ 1.5 % w/w	0,05	ND	ND							
KPT-454	≤ 0.5 % w/w	ND	ND	ND							
KPT-453	≤ 0.5 % w/w	ND	ND	ND							
KPT-452	≤ 0.5 % w/w	ND	ND	ND							
Any other individual impurity	≤ 0.5 % w/w	ND	ND	ND							
Total impurity	≤ 2,0 % w/w	0,05	ND	ND							
Water content by KF	≤ 2,0 % w/w	0,05	0,05	0,04							
Residual KPT-459 in KPT-330	≤ 40 ppm	< 40	< 40	< 40							
Microbial limit tests											
- TAMC	≤ 1000 CFU/g	Comply									
- TYMC	≤ 100 CFU/g	Comply									
Specified microorganism											
- <i>Staphylococcus aureus</i>	Absence	Comply									
- <i>Escherichia coli</i>	Absence	Comply									
- <i>Pseudomonas aeruginosa</i>	Absence	Comply									
- Salmonella	Absence	Comply									

ND: Not detected

Exhibit B

ICH stability	Batch number 27001383	Stability Condition		Protocol number	Packaging		
Item 2001083	Pilot batch						
		40°C - 75 % RH		PS 212.071 Ed 01	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
Appearance	White to off-white powder	white powder	white powder	White powder			
Identification by UPLC	Retention time same as reference standard's	Comply	Comply	Comply			
Assay by UPLC	97.0 – 102.0 % w/w anhydrous basis	98,9	98,9	100,4			
Assay by UPLC	For information (%w/w as is)	98,8	98,9	100,4			
Individual impurities							
KPT-375	≤ 1.5 % w/w	0,05	ND	ND			
KPT-454	≤ 0.5 % w/w	ND	ND	ND			
KPT-453	≤ 0.5 % w/w	ND	ND	ND			
KPT-452	≤ 0.5 % w/w	ND	ND	ND			
Any other individual impurity	≤ 0.5 % w/w	ND	ND	ND			
Total impurity	≤ 2,0 % w/w	0,05	ND	ND			
Water content by KF	≤ 2,0 % w/w	0,05	0,02	0,04			
Residual KPT-459 in KPT-330	≤ 40 ppm	< 40	< 40	< 40			
Microbial limit tests							
- TAMC	≤ 1000 CFU/g	Comply					
- TYMC	≤ 100 CFU/g	Comply					
Specified microorganism							
- <i>Staphylococcus aureus</i>	Absence	Comply					
- <i>Escherichia coli</i>	Absence	Comply					
- <i>Pseudomonas aeruginosa</i>	Absence	Comply					
- Salmonella	Absence	Comply					

ND: Not detected