

3.2.S.4.4. 팻치분석

Batch number		C552202010	C552202011	C552202012
Manufacturing date		2022.02.08	2022.02.09	2022.02.09
Batch quantity		400.84kg	400.84kg	400.84kg
Testing Item	Standad	Result	Result	Result
Description	White crystal or crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder
pH	6.0 ~ 7.0	6.3	6.3	6.3
Identifi cation	IR	should be consistent with the standard infrared spectrum	Consistent with standard infrared spectrum	Consistent with standard infrared spectrum
	Optical Rotation, $^{\circ}$	+26.5 ~ +29.0	28.0	28.3
Clarity of the solution	≤No. 1 Turbidity Standard	<No. 1 Turbidity Standard	<No. 1 Turbidity Standard	<No. 1 Turbidity Standard
color of solution	≤B9	<B9	<B9	<B9
Wate %	≤ 7.0	0.81	0.66	0.77

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Batch quantity		400.84kg	400.84kg	400.84kg
Residue on ignition	≤ 0.2	0.02	0.03	0.01
Chloride,ppm	≤ 300	< 300	< 300	< 300
Sulfate(ppm)	≤ 200	< 200	< 200	< 200
Ammonium ,ppm	≤ 400	< 400	< 400	< 400
Heavy metal,ppm	≤ 10	< 10	< 10	< 10
Iron, ppm	≤ 30	< 30	< 30	< 30
Other Amino Acids,%	Spots other than the main spots in the test solution are not larger than the spots obtained in the standard solution	Compliance	Compliance	Compliance
Residual solvent methanol ppm	≤3000	91	95	89
Assay, %	98.0 ~ 102.0	98.6	98.9	99.0

보완사유 : 신청 규격으로 제출한 시험항목 중 투명도 및 혼탁도와 착색시험, 아세트산수는 반응시험, 폴리브도포스포릭산 반응시험 미 실시 되었으며, 기준 및 시험방법 관련 각 항목 보완중임.

<보완> (3.2.S.4.4.) 타당하게 설정된 기준 및 시험방법에 따라 실시된 시험성적 자료 제출.