

CERTIFICATE OF ANALYSIS

SAM-e 400 mg tablets
10-count blisters (type BAN)

Batch Nr.: 0001900978

Manufacturing date: February 2020

Expiry date: February 2023

TESTS	SPECIFICATIONS	UM	RESULTS
Description	Cream oblong film-coated tablets	-	Complies
Description: blister	Complies	-	Complies
Blister: Dimensions	Complies	-	Complies
Printed text (black ink)	Complies	-	Complies
Batch variable printed data	Complies	-	Complies
Dimensions: width	8,80 - 9,20	mm	9,00
Dimensions: length	19,00 - 19,60	mm	19,20
Dimensions: thickness	7,5 - 8,3	mm	7,6
Uniformity of weight	Complies	-	Complies
SAM-e identification (HPLC)	Positive	-	Complies
SAM-e ion Assay (HPLC)	400 - 460	mg/g	425
Rel. sub. (HPLC): Adenine (ADN)	<= 3,0	%	0,9
Rel. sub. (HPLC): Methylthioade. (MTA)	<= 2,0	%	0,8
Water content (K.F.)	<= 3,0	%	< 2,5
Dissolution: after 2h in buffer stage	25 - 50	%	35
Dissolution: after 4h in buffer stage	50 - 85	%	76
Dissolution: after 7h in buffer stage	>= 75	%	92
S,S isomer (HPLC)	>= 65,0	%	70,4
Total aerobic count	<= 1000	CFU/g	< 1000
Total combined yeast & mold count	<= 100	CFU/g	< 100
E. Coli	Absent/10g	-	Complies
Salmonella Spp.	Absent/10g	-	Complies
S. aureus	Absent/10g	-	Complies