

# SAM-e 200 mg tablets type A, 10-count blisters

## CERTIFICATE OF ANALYSIS

Batch Number: 0001500202

Manufacturing date: January 2016

Expiry date: January 2019

TESTS	SPECIFICATIONS	RESULTS
<b>Blisters Specifications:</b>		
Description	Alu/Alu blisters containing 10 tablets	Complies
Dimensions	7.5 cmx 12.7 cm	Complies
Printed text ( black ink )	Corresponds to the customer's artwork	Complies
Batch variable printed data	Lot no. and Exp. date embossed on the longer side of the blister	Complies
<b>Tablets Specifications:</b>		
Description	Yellow, round film-coated tablets	Complies
Dimensions:		
- diameter	11.0 -11.4 mm	11.2 mm
- thickness	5.80 - 6.30 mm	6.00mm
Weight	585-680 mg	646 mg
SAM-e ion assay (HPLC)	200-230 mg/tablet	213 mg/tablet
Related substances (HPLC):		
- Adenine	≤ 2.0 %	0.5 %
- Methylthioadenosine (MTA)	≤ 3.0 %	0.5 %
Water content (K.F.)	≤ 3.0 %	2.2 %
Disintegration:		
- gastric fluid pH 1.2	Intact after 60 minutes	Complies
- intestinal fluid pH 6.8	Complete disintegration in 60 minutes	Complies
S,S isomer (HPLC)	≥ 65.0% at release	73.4 %
Microbial limits:		
- Total aerobic microbial count	≤ 10 <sup>3</sup> CFU / g	< 10 CFU/g
- Total combined yeast & mold count	≤ 10 <sup>2</sup> CFU / g	< 10 CFU/g
- E.coli	Absent / 10 g	Absent / 10 g
- Salmonella Sp.	Absent / 10 g	Absent / 10 g
- S.aureus	Absent / 10 g	Absent / 10 g

Date: August 01, 2016

Approved by:

Corporate QA