

Certificate of Analysis

Product name

CAL-fas Bottle - wo. values for OEM i.B.

Material No.

04629710211

Lot No.

59526721

Date of Manufacturing

2024-01-12

Expiry Date

2026-07

Parameter	Result	Unit
Tested acc. to specifications edition	31	
Appearance	corresponds	
Appearance, sol. after reconstitution	corresponds	
pH(25 deg.C)	7,0	
Turbidity(A 546)	0,380	
Residual moisture	0,9	%
Bioburden	< 3	CFU/bt
Single donor testing	corresponds	
HBsAg	non reactive	
anti-HIV1+2	negative	
anti-HCV	negative	
HCV NAT	non reactive	

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Maharashtra 401208

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HEMEDIAMED LLP

2nd Floor, 4, 1981, Anjikath Lane, near
Vallathol Junction Vazhakala, Thrikkakara,
Edappally, Ernakulam, Kakkanad, Kerala 682021
MOB: +91 7395966499

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Parameter	Result	Unit
HIV-1 NAT	non reactive	
BILT_Homogeneity	1,0	%
ALT (IFCC w. Pyp.)_Homogeneity	1,0	%
AST (IFCC with Pyp.)_Homogeneity	0,8	%
ALP (IFCC, liquid)_Homogeneity	0,9	%
Glucose (HK)_Homogeneity	0,7	%
ACP	27	u/l
ACP after 4h/25°C	98	%
ACP after 24h/4°C	99	%
ACP after 14d/-20°C	100	%
ACP-NPP	7,8	u/l

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Parameter	Result	Unit
Albumin BCG plus	37,3	g/l
ALP (IFCC, liquid)	284	u/l
ALP (IFCC liquid) 8h/25°C	102	%
ALP (IFCC liquid) after 28d/-20°C	101	%
ALT (IFCC w. Pyp.)	92	u/l
ALT (IFCC w. Pyp.) 8h/25°C	101	%
AMY (IFCC liquid)	183	u/l
AMY (IFCC liquid) after 8h/25°C	101	%
AMY-P (liquid)	167	u/l
AST (IFCC with Pyp.)	97	u/l
AST (IFCC w. Pyp.) 8h/25°C	102	%
BIL-D Diazo gen. 2	46,9	μmol/l

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Parameter	Result	Unit
BIL-D Diazo gen. 2 after 3H/25°C	99	%
BIL-D Diazo gen. 2 after 8h/4°C	99	%
Bil-D Diazo gen. 2 after 14d/-20°C	99	%
Bilirubin(DPD)	67,9	μmol/l
BIL-T (DPD) 6h/25°C	102	%
Bil-T (DPD), after 24h/4°C	101	%
BIL-T (DPD) gen. 3 after 14d/-20°C	101	%
BUN (Urease UV)	16,7	mmol/l
CALCIUM gen.2	2,8	mmol/l
CHE Gen.2 butyryl.	4960	u/l
CHE Gen.2 butyryl. after 8h/25°C	102	%

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Parameter	Result	Unit
Cholesterol	4,09	mmol/l
CK (IFCC liquid)	362	u/l
CK (IFCC liquid) 8h/25°C	102	%
CREA-plus	333	μmol/l
Crea (plus) after 8h/25°C	102	%
Iron	36,8	μmol/l
g-GT (Szasz, liquid)	90	u/l
g-GT (Szasz liquid) after 8h/25°C	101	%
GIDH(opt.)	24	u/l
Glucose (HK)	10,74	mmol/l
Glucose (HK), after 8h/25°C	102	%
HBDH	267	u/l

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Parameter	Result	Unit
L-Lactate(enzym.)	3,40	mmol/l
LDH (IFCC, liquid)	248	u/l
LDH (IFCC liquid) 8h/25°C	101	%
LITHIUM (COLORIMETRIC)	1,43	mmol/l
Lipase	103	u/l
Lipase after 8h/25°C	103	%
MAGNESIUM gen.2	1,12	mmol/l
Phosphor (UV)	1,7	mmol/l
Salicylat	10	mg/dl
Triglycerides	1,62	mmol/l
Protein (biuret)	49,5	g/l

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Parameter	Result	Unit
UA	360	$\mu\text{mol/l}$
UREA (Urease UV)	16,7	mmol/l

This lot meets our specification

Disposition by

Sarah Goller-Stingaciu

This certificate is a computer printout and has therefore not been signed by hand.

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