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GURVEY&BERRY

Ingredients for wellness, nutrition, beauty and more.

BAJAJ HEALTHCARE LTD. [UNIT-II]

6 th Floor, Bhoomi Velocity Infotech Park, ICICI Bank
Road No.23 Wagle Industrial Estate, Thane(W)-400604
Tel : +91 22 66177400/66177499 Website : www.bajajhealth.com

POST GOTHADA VADODARA

CERTIFICATE OF ANALYSIS

Product	: L-Choline Bitartrate USP (Coated)	A.R. No.	: FM/LCBC/0014/16-17
Batch No.	: LCBC - 00140816	Batch Size	: 500 kg
Mfg. Date	: AUG-2016	Sample Size	: 100 g
Exp. Date	: JUL-2021	Sampled on	: 13/08/2016

TEST	LIMITS	RESULT
Description	White hygroscopic crystalline powder.	White crystalline powder odourless, hygroscopic.
*Solubility	Freely soluble in water, slightly soluble in ethanol, insoluble in ether in Chloroform & in benzene.	Complies
*Identification		
A) By IR Spectrum	IR spectrum of the sample should be concordant with that of reference spectrum.	Complies
B) By Chemical	A white precipitate is formed.	Complies
pH (1 in 10)	Between 3.0 and 4.0.	3.35
Water	NMT 0.5 %	0.30 %
*Residue on ignition	NMT 0.1 %	0.03 %
*Arsenic	NMT 2 ppm	Passes
*Lead	NMT 0.3 ppm	Passes
* Heavy metals	NMT 10 ppm	Passes
*Specific Rotation	Between +17.5°and+18.5°	+18.18°
*Limit of total amines	NMT 10 ppm	Passes
*Chromatographic Purity:	To comply USP	Complies
Assay after coating	NLT 98.0 % of $C_5H_{15}NO_7$ on anhydrous basis.	98.8 %
*Residual Solvent:		
a) 1,4 Dioxane	NMT 10 ppm	Complies
b) Methanol	NMT 3000 ppm	Complies
c) Isopropyl alcohol	NMT 5000 ppm	Complies
Particle Size	100 % passing through 20 mesh	Complies

Conclusion: The sample Complies / ~~Does not comply~~ with the standard of quality as per USP 38.

*** Test carried out prior to Coating.**

Sign			
Name	Pankaj Sukla	Girish Patel	Awadhoot Gadwalkar
Designation	QC Executive	QC Executive	GM-Quality
	Prepared By	Checked By	Approved by

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BAJAJ HEALTH CARE LTD. POST GOTHADA VADODARA

CERTIFICATE OF ANALYSIS

Product	: L-Choline Bitartrate USP (Coated)	A.R. No.	: FM/LCBC/00300317
Batch No.	: LCBC - 00300317 ✓	Batch Size	: 500 kg
Mfg. Date	: MAR-2017	Sample Size	: 100 g
Exp. Date	: FEB - 2022 ✓	Sampled on	: 17/03/2017

TEST	LIMITS	RESULT
Description	White hygroscopic crystalline powder.	White crystalline powder odourless, hygroscopic.
*Solubility	Freely soluble in water, slightly soluble in ethanol, insoluble in ether in Chloroform & in benzene.	Complies
*Identification		
A) By IR Spectrum	IR spectrum of the sample should be concordant with that of reference spectrum.	Complies
B) By Chemical	A white precipitate is formed.	Complies
pH (1 in 10)	Between 3.0 and 4.0.	3.43
Water	NMT 0.5 %	0.38 %
*Residue on ignition	NMT 0.1 %	0.04 %
*Arsenic	NMT 2 ppm	Passes
*Lead	NMT 0.3 ppm	Passes
* Heavy metals	NMT 10 ppm	Passes
*Specific Rotation	Between +17.5°and+18.5°	+18.01°
*Limit of total amines	NMT 10 ppm	Passes
*Chromatographic Purity:	To comply USP	Complies
Assay after coating	NLT 98.0 % of $C_5H_{14}NO_7$ on anhydrous basis.	99.3 %
*Residual Solvent:		
a) 1,4 Dioxane	NMT 10 ppm	Complies
b) Methanol	NMT 3000 ppm	Complies
c) Isopropyl alcohol	NMT 5000 ppm	Complies
Particle Size	100 % passing through 20 mesh	Complies

Conclusion: The sample Complies / ~~Does not comply~~ with the standard of quality as per USP 38.

*** Test carried out prior to Coating.**

Sign			
Name	Aakash Shah	Pankaj Shukla	Awadhoot Gadwalkar
Designation	QC Assistant	QC Executive	GM-Quality
	Prepared By	Checked By	Approved by

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