



DRUGS AND CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Works : 333/1, G.I.D.C. Industrial Estate Phase - 2,
Chitra, Bhavnagar - 364 004. Gujarat (INDIA). | Ph. : +91-278-2446342 / 2447013 / 2445588

Registered Office : 815, Nilamber Triumph,
Gotri-Vasna Road, Vadodara - 390 007. Gujarat (INDIA). | Ph. : +91-265-2991021 / 2991022

THE DRUGS & COSMETICS ACT 1940 AND RULES THEREUNDER CERTIFICATE OF ANALYSIS
APPROVED TESTING LABORATORY BY FDCA-GANDHINAGAR

Email : sales@pardrugs.com | qc@pardrugs.com

www.pardrugs.com

QUALITY ASSURANCE DEPARTMENT

Material Name: Dried Aluminum Hydroxide Gel USP					Page 1 of 1
Batch No.	ALH/24/0239			Qty. Sampled	100 gm
Batch Qty.	2000 kg	Mfg. Date	July-2024	Exp. Date	June-2029
Released date	15/07/2024				

Reference: USP - 40 + In-house			CAS No.	21645-51-2
Mol. Formula			Mol. Weight	78.00 gm/mol
Sr. #	Test	Result	Specification	
1	Description*	Pass	White or almost white, amorphous powder.	
2	Solubility	Pass	Practically insoluble in water. It dissolves in dilute mineral acids & in solution of alkali hydroxides.	
3	Identification	Pass	(A)By Infrared Spectrophotometer (B)It gives reaction of Aluminium	
4	Acid neutralizing capacity	34.09 mEq	Not less than 25 mEq per gm	
5	pH (1 in 25) *	9.78	Not more than 10	
6	Chloride	Complies	Not more than 0.85 %	
7	Sulfate	Complies	Not more than 0.6 %	
8	Arsenic	Complies	Not more than 8 ppm	
9	Assay*	79.44 %	Not less than 76.5 % of Al(OH) ₃	

Additional Test :

10	Total Aerobic Microbial Count	Complies	NMT 1000 cfu/gm (As per BP-2013)
11	Total Yeast & Mold Count	Complies	NMT 100 cfu/gm (As per BP-2013)
12	Bacteria Gram Negative	Pass	Negative (As per BP-2013)
13	E. coli	Pass	Negative (As per USP-32)
14	Total Aerobic Microbial Count	Complies	100 cfu/ml (As per USP-32)
15	Bulk Density (Tapped)	0.4166 gm/ml	Between 0.3 to 0.6 gm/ml
16	Average Particle Size D(0.9)	37.873 um	Between 30.0 um to 52.0 um

* Re-testing parameter.

OPINION: The above sample **Complies** / **Does not comply** to the prescribed standard of quality in respect of the above tests as per USP + In-house specification.

Remarks: Heavy Grade

Protocol No. #	Page #	Test performed (Sr. #)	Analyzed by	Date
N. A.	1	1 to 9 & 15		10/07/2024
N. A.	1	10 to 14		15/07/2024
N. A.	1	16		10/07/2024

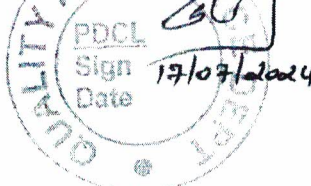
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Checked by:

Date: 17/07/2024

Approved by:

Date:



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