Pacé
Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title	:	Certificate of Analysis Finished Product

Product Name	**CLARICAN 500MG** Injection	**A.R. No.**	NB/FP/23/338
Generic Name	Clarithromycin for Infusion BP 500mg	**Sampled qty.**	45 vials
Batch No.	N23320A	**Sampled by**	Vineet
Batch Size	2000 Vials	**Sampled on**	23/12/2023
Mfg. Date	11/2023	**Date of Testing**	23/12/2023
Exp. Date	10/2025	**Date of Conditionally Release**	05/01/2024

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification	The absorption spectrum of the test preparation should exhibits maxima at same wavelength with that obtained with similar preparation of Clarithromycin working standard.	Complies
3.	Uniformity of Weight	Average weight ±10%	-3.26% & +4.74%
4.	Average weight	Informative.	865.12 mg
5.	Clarity & Colour of solution	A solution is not more opalescent than refrence suspension II, And not more intensely coloured than reference solution Y_7.	Complies
6.	Related Substance	The area of any secondary peak is not greater than twice the area of the principle peak in the Chromatogram obtained with solution (3) (1%) not more than for such peaks have an greater than 0.8 times the area of the principle peak in the chromatogram obtained with solution (3) (0.4%) the sum of the area of all the secondary peaks is not greater than 7 times the area of the principle peak in the chromatogram obtained with solution (3) (3.5%) Disregard any peak with an area less than 0.2 times the area of the principle peak in the chromatogram obtained with solution (3) (0.1%) Disregard any peaks eluting before Impurity I and after Impurity H.	Complies
7.	pH	4.0 to 6.0	4.29
8.	Water	NMT-3.0% w/w	1.65% w/w

Pacé
Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P

Title	:	Certificate of Analysis Finished Product

Product Name	**CLARICAN 500MG** Injection	**A.R. No.**	NB/FP/23/338
Generic Name	Clarithromycin for Infusion BP 500mg	**Sampled qty.**	45 vials
Batch No.	N23320A	**Sampled by**	Vineet
Batch Size	2000 Vials	**Sampled on**	23/12/2023
Mfg. Date	11/2023	**Date of Testing**	23/12/2023
Exp. Date	10/2025	**Date of Conditionally Release**	05/01/2024

9.	Particulate matter		
	a.)Visible particulate matter (b.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm	Should Free from any type of visual particles NMT-6000/vial NMT-600/vial	Complies 3211/vial 2/vial
10.	Sterility	No microbial growth should be observed.	Under process
11.	Bacterial Endotoxins	NMT- 0.20 EU/mg of Clarithromycin.	Less than 0.20 EU/mg of Clarithromycin.
12.	Assay: Each glass vial Contains :		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Clarithromycin (Sterile) IP Lyophilized	500 mg	495.84 mg	99.17%	95.0% to 105.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ ~~is not of the~~ standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ ~~not complies~~ as per ~~IP/BP/USP/IHS~~.

Analysis by	Checked by	Approved by

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager