

**DERREN HEALTHCARE PVT. LTD.**

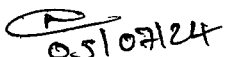
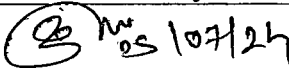

Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India  
Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi,  
Ahmedabad-382 213, Gujarat (India)

**CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)**

<b>Name of Product</b>	Dicyclomine hydrochloride 10 mg/ml with Diclofenac sodium 25 mg/ml injection(Diclocan Spas)		
<b>Batch No.</b>	CF24001	<b>A.R. No.</b>	FP/24/0049
<b>Mfg. Date</b>	06/24	<b>Exp. Date</b>	05/26
<b>Sampled Qty.</b>	71 Nos.	<b>Date of Analysis</b>	17/06/24
<b>Batch Size</b>	125 Ltr.	<b>Date of Release</b>	05/07/24
<b>Container Type</b>	Amber Glass Ampoule	<b>Fill volume</b>	2.2 ml
<b>Mfg. Lic. No.</b>	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, colourless liquid free from visible particles and fibers.	Clear, colourless liquid free from visible particles and fibers.
2	Extractable volume	2.2 ml	NLT 2.0 ml
3	pH	6.65	5.5 to 8.5
4	Bacterial endotoxin	Less than 4.66EU/mg	NMT 4.66EU/mg
5	<b>Particulate matter</b>		
5.1	By Visual Inspection	The solution is free from particles of the foreign matter that is observed on visual inspection method.	The solution should be free from particles of the foreign matter that can be observed on visual inspection method.
5.2	By Light Obscuration Method	$\geq 10$ microns= 238.13/Container $\geq 25$ Microns= 18.40/Container	Sub visible particle by LPC $\geq 10$ microns=NMT 6000/Container $\geq 25$ Microns=NMT 600/Container
6	Sterility test	Sterile	Should be sterile
7	<b>Assay</b>		
7.1	Assay Each ml contains: Dicyclomine Hydrochloride 10 mg/ml	99.80%	93.0 %to 107.0%
7.2	Assay Diclofenac Sodium 25 mg/ml	98.84%	95.0 % to 105.0 %

Conclusion: The above sample complies as per In-House specification. ✓  
In the opinion of the undersigned the sample referred to above is of **standard** / ~~not of standard~~ quality as defined in the act and the rules made there under for the reasons given above.

Prepared By  05/07/24 QC Executive	Checked By  05/07/24 QC Sr. Executive	Approved By  QA MANAGER AHMEDABAD
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