
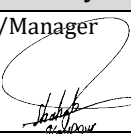
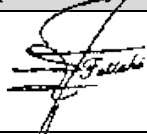
	Name of Document: Specification of Finished Product for Medrolin® (Methylprednisolone Sodium Succinate) 500 mg			
	Doc Code: QA-DC/SP.FP-009	Issue Date: 2016/01/12	Revision Date: 2024/02/19	Revision No.: 07
		Review Date: 2027/02/19	Validity period: 3 years	Page No.: 1 of 1

Specification of Finished Product

Name of Product: Medrolin® (Methylprednisolone Sodium Succinate) 500 mg	Storage Condition(s): Store below 25°C and protect form light
Dosage Form: Freeze-dried powder for injection	Maximum period of storage before expiry: 2 years
Batch Size: 39,000 vials (13000+26000)	Reference to master formula doc. code: RD-GN/MF-011
Code No.: 7511111017	Reference to sampling doc. code: QC-GN/SO-021
Primary Packaging Details: Container: Type I Glass, 15 R vial, Colorless Closure: Lyo Rubber Stopper 20 mm Flip-off Cap: 20 mm, Light gray	Reference to analysis doc. code: QC-PC/WI-175 and QC-MB/WI-077
	Description of the Packaging: Each carton contains 100 boxes of one vial.

Row	Tests	Limits	Reference
1	Appearance	White or almost white lyophilized powder	In-house
2	After Reconstitution ¹ A) pH (50 mg/mL) B) Clarity of solution C) Colour of Solution	7.0-8.0 Clear Colorless to pale yellow	USP 2024 <791> In-house In-house
3	Reconstitution Time	≤ 2 min	In-house
4	Identification - IR	Complies with the reference	USP 2024
5	Free methylprednisolone	NMT 6.6%	USP 2024
6	Loss on drying (at 105°C for 3 h)	NMT 2.0%	USP 2024 <731>
7	Assay	90.0% – 110.0%	USP 2024 <621>
8	Uniformity of Dosage Units	L1 (10 Units): AV ≤ 15.0 L2 (30 Units): Meets <u>both</u> of the following: a) AV ≤ 15.0 b) All units are within 75.0% to 125.0% of the Reference Value	USP 2024 <905>
9	Packaging Integrity (absence of leakage)	No leakage should be observed	USP 2024 <1207>
10	Sub-visible Particulate Matter (Method I) ≥ 10µm ≥ 25µm	≤ 6000 per container ≤ 600 per container	USP 2024 <788>
11	Bacterial Endotoxin	NMT 0.17 EU/mg of methylprednisolone	USP 2024 <85>
12	Sterility	Must be Sterile	USP 2024 <71>

¹ When reconstituted with 10 mL water for injection.

Title	Prepared by	Checked by	Approved by
Job Title	QA Expert	QC Supervisor/Manager	QA Manager
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