

**AARTI INDUSTRIES LIMITED**

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## CERTIFICATE OF ANALYSIS DESONIDE USP

Format No. : QA/FM-235/00

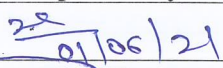
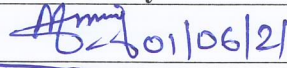
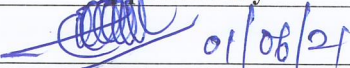
Batch No. : DS-20001(JM-01)-001	Date of Mfg. : MAR-2020
AR. No. : FG/0150/20	Retest Date : FEB-2024
Batch Qty. : 21.00 Kg	Date of Release : 09/04/20

Sr. No.	TESTS	RESULTS	SPECIFICATION
1.	Description	White powder	White powder or crystals.
2.	Solubility	Complies	Soluble in chloroform, sparingly soluble in ethanol and in acetone, practically insoluble in water.
3.	Identification A) By IR spectrum B) By HPLC	Complies Complies	The infrared spectrum of test sample should be concordant with similar preparation of that of Desonide WS. The retention time of the major peak in the chromatogram of the test preparation corresponds to that of the standard preparation, as obtained in the test of assay.
4.	Loss on drying (At 105°C ± 2°C for 3 hours)	0.19%	Not more than 0.5% w/w.
5.	Specific optical rotation	106.07°	Between +104.0° and +110° at 25°C (on dried basis)
6.	Residual on ignition	0.06 %	Not more than 0.10 % w/w.
7.	Organic impurities (By HPLC)	Below disregard limit Not Detected 0.04% Below disregard limit 0.04% Not Detected Not Detected Not Detected Below disregard limit 0.11% 0.05% 0.25%	16α-Hydroxyprednisolone <sup>a</sup> : Not more than 0.15% Prednisolone <sup>b</sup> : Not more than 0.15% Desonide glyoxal <sup>c</sup> : Not more than 0.50% Deoxyprednisolone-16-ene <sup>d</sup> : Not more than 0.50% Sum of desonide glyoxal and deoxyprednisolone-16-ene : Not more than 0.50% Dihydrodesonide <sup>e</sup> : Not more than 0.50% Epoxydesonide <sup>f</sup> : Not more than 0.50% Sum of dihydrodesonide and epoxydesonide : Not more than 0.50% Bromodesonide <sup>g</sup> : Not more than 0.15% Acetylidesonide <sup>h</sup> : Not more than 0.15% Any other impurity : Not more than 0.10% Total impurities : Not more than 1.0%
8.	Assay (By HPLC)	99.56 %	Not less than 98 % and Not more than 102 % w/w ( On dried basis)
9.	Residual solvent (By HSGC)	8 ppm 205 ppm 334 ppm Not Detected	Methanol : Not more than 3000 ppm Acetone : Not more than 5000 ppm Dichloromethane : Not more than 600 ppm Di-Isopropyl ether : Not more than 5000 ppm

**Additional Test**

1.	Particle Size	3.77 μm	D(90) < 10 μm
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Remark: The material complies as per USP-41 and above specification.

Prepared By  01/06/21	Checked By  01/06/21	Approved By  01/06/21
Executive Designee Quality Assurance	Manager Designee Quality Assurance	Head Quality Assurance/ Quality Control Designee

**HEAD OFFICE :**

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