



CERTIFICATE of ANALYSIS

BECLOMETASONE DIPROPIONATE USP35, Ph. Eur. 7.6, MICRONIZED

BATCH N.: C0783/1 12020

MAN. DATE: Jan/13

RE-TEST DATE: Jan/18

DESCRIPTION: White or almost white odorless powder. Very slightly soluble in water, very soluble in chloroform, freely soluble in acetone and in alcohol.

TEST	SPECIFICATIONS	RESULTS
1. Description	White or almost white crystalline powder	Complies
2. Solubility in acetone	Freely soluble	Complies
3. Identification	IR Chlorides According to reference standard Positive	Concordant Positive
4. Specific optical rotation	+ 88° a + 94° (c=1, dioxane, 25 °C) + 108° a + 115° (c=1, ethanol, 20 °C)	+ 89° + 109°
5. Loss on drying	≤ 0.5 %	0.2 %
6. Residue on ignition	≤ 0.1 %	< 0.1%
7. Related substances	Imp. H ≤ 0.15 % Imp. A ≤ 0.2 % Imp. B ≤ 0.5 % Imp. C ≤ 0.15 % Imp. D ≤ 0.2 % Imp. M ≤ 0.5 % Imp. N ≤ 0.2 % Imp. L ≤ 0.6 % Imp. F ≤ 0.5 % Unspecified ≤ 0.10 % Total ≤ 1.5 %	< 0.05 % < 0.05 % < 0.05 % < 0.05 % < 0.05 % < 0.05 % < 0.05 % < 0.05 % < 0.05 % 0.09 % 0.17 %
8. HPLC assay (dried basis)	97.0 - 103.0 % (USP)	99.9 %
9. HPLC assay (dried basis)	96.0 - 102.0% (Ph. Eur.)	99.7 %
10. Residual solvents	Methylene chloride < 600 ppm Isopropyl ether < 5000 ppm Ethyl acetate < 5000 ppm Tetrahydrofuran < 720 ppm	58 ppm < LOD* 459 ppm < LOD*
11. Particle size	100 % ≤ 15 µm 98 % ≤ 10 µm 90 % ≤ 5 µm	10 µm 6 µm 3 µm

* LOD: limit of detection

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