Crystal pharma

CERTIFICATE of ANALYSIS

BECLOMETASONE DIPROPIONATE USP35, Ph. Eur. 7.6, MICRONIZED

BATCH N.: C0783/1 12021 **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	According to reference standard	Concordant
Chlorides	Positive	Positive
4. Specific optical rotation	+ 88º a + 94º (c=1, dioxane, 25 ºC) + 108º a + 115º (c=1, ethanol, 20 ºC)	+ 90º + 110º
5. Loss on drying	≤ 0.5 %	0.4 %
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 %	0.06 % 0.07 % < 0.05 % < 0.05 % < 0.05 % < 0.05 % < 0.05 % < 0.05 % < 0.05 % 0.09 % 0.22 %
8. HPLC assay (dried basis)	97.0 - 103.0 % (USP)	99.4 %
9. HPLC assay (dried basis)	96.0 - 102.0% (Ph. Eur.)	98.6 %
10. Residual solvents	Methylene chloride < 600 ppm Isopropyl ether < 5000 ppm Ethyl acetate < 5000 ppm Tetrahydrofuran < 720 ppm	58 ppm < LOD* 306 ppm < LOD*
11. Particle size	100 % ≤ 15 µm 98 % ≤ 10 µm 90 % ≤ 5 µm	10 µm 6 µm 3 µm

* LOD: limit of detection

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
13E02-B06
Director Técnico

24/04/13
Quality Assurance Department